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RESEARCH ARTICLE

REVISED 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 [version 2; peer review: 2 approved]

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Abstract

Background: Several smoke-free tobacco and/or nicotine-containing products (TNP) have emerged in recent years to support tobacco harm reduction strategies and reduce individual health risks and population harm relative to continued cigarette smoking. This paper describes the nationwide prevalence and patterns of TNP use in Japan following the commercialization of one such smoke-free TNP, the heated tobacco product *IQOS*® (Philip Morris International).
Methods: We analyzed the first annual data (2016–2017) of two repeated cross-sectional surveys conducted in a representative sample of the Japanese general adult (≥20 years of age) population (N = 4,878) and a sample of adult *IQOS* users (N = 2,000). We assessed the prevalence of current TNP use according to type of product (cigarettes, *IQOS*, e-cigarettes, and other TNPs) in the general population and patterns of TNP use in the *IQOS* user sample.
Results: The prevalence of current use across all TNP in the sampled general population was 18.5% (95% confidence interval 17.2–19.5%), with 17.5% (16.4–18.6%) for cigarette smoking and 1.8% (1.4–2.2%) for *IQOS* use. Regarding the distribution of patterns of use in the *IQOS* user survey, the majority (63.4% [61.2–65.6%]) were exclusive users of *IQOS*, followed by 20.6% (18.7–22.5%) of individuals who reported dual use of *IQOS* and cigarettes.
Conclusions: In Japan, cigarette smoking remains the most prevalent way of consuming TNP; however, *IQOS* is being adopted by a growing number of adult Japanese smokers. These findings serve as baseline data for monitoring trends over time in the use and adoption of potential smoke-free TNP in Japan.

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version 2 (revision) 21 Mar 2022	✔ view	✔ view
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Any reports and responses or comments on the article can be found at the end of the article.

Keywords

Japan, smoking, heat-not-burn, heated tobacco product, IQOS, cross-sectional survey

REVISED Amendments from Version 1

Abstract
Minor grammatical update and addition of text to specify age range of sampled general population.

Introduction
Last sentence of introduction reworded slightly and moved further up in the introduction for clarity.
Text added "sample of current TNP users in the survey" to provide further context for cited Adamson *et al* study.
Addition of text to specify age range of sampled general population.

Methods
Text added to clarify the surveys were conducted "in both general population and IQOS user sample".
Text added to clarify the four waves of survey fieldwork.
Text added to specify members of the "IQOS owner database who agreed to be contacted for research purposes" were those contacted and invited for participation in the IQOS user survey.
Text added in analytical methods to clarify "Average daily consumption of TNP (mean consumption per day) refers to average number of units/times of product use per day on days used in the past 30 days".

Results
New footnote added to Table 1 to specify "N=550 individuals in IQOS user sample reported 'Don't know/Not applicable' for Occupation category". This information previously within the table was removed and replaced by the footnote.
"Other*" text and footnote in Table 2 changed to clearly specify this refers to "Other products*".
Addition of Table 3 and corresponding text to show distributions of patterns of use among current TNP users in the general population sample.
Previous Table 3 is now Table 4 and additional column added to show "mean number of days used in past 30 days".

Discussion
New texts and citation to expand on discussions related to comparisons with findings from other surveys, observed patterns of multiple product use, and limitations in study design and sampling.

Any further responses from the reviewers can be found at the end of the article

Introduction

Tobacco harm reduction aims to complement tobacco control efforts and reduce population harm by switching smokers to less-harmful smoke-free tobacco and/or nicotine-containing products (TNP). A key part of tobacco harm reduction is also to prevent initiation or re-initiation of TNP use by never and former users, respectively.[1–3] Unlike cigarettes, which burn tobacco and produce a complex mixture of harmful and potentially harmful constituents (HPHC) as a result of combustion, *IQOS*®—a smoke-free TNP developed by Philip Morris International (PMI)[4]—heats tobacco to temperatures below the level of combustion, producing an aerosol with markedly reduced levels of HPHCs. The aerosol generated from *IQOS* has, on average, 90–95% lower levels of HPHCs than cigarette smoke but provides comparable nicotine uptake and delivery.[5] Consequently, smokers switching completely to *IQOS* are exposed to much lower levels of HPHCs than those who continue smoking cigarettes.[6,7]

Since its launch in 2014 in Japan, *IQOS* has become available in 63 markets around the world, and approximately 14 million adult smokers have already switched to *IQOS* use.[4] The expansion in *IQOS* availability raises the need for monitoring its use by the population with the aim of informing public health advocates about its prevalence and use patterns, which will further enable regulators to ascertain its role in harm reduction as a substitute for cigarettes.[8,9] Only a few national surveillance surveys, including the DEBRA study in Germany[10] and the Japan National Health and Nutrition Survey,[11] have been updated to report the prevalence of use of heated tobacco products, such as *IQOS,* and the adoption of these products by smokers.

Tabuchi *et al.* pioneered an attempt to describe the prevalence of smoke-free TNP use in Japan by using the *Japan "Society and New Tobacco" Internet Survey* (JASTIS),[12] a longitudinal study of 8,240 individuals from 2015 to 2017. At baseline, 48% of JASTIS participants reported awareness of existence of these products, and 1.3% reported current use (use in the last 30 days) of e-cigarettes and heated tobacco products, with the current use of *IQOS* increasing from 0.3% in 2015 to 3.6% in 2017.[13,14] A recent pilot cross-sectional survey of 4,154 TNP consumers in Tokyo, Osaka, and Sendai also shed light on TNP usage following the introduction of heated tobacco products in Japan.[15] In contrast to the JASTIS survey, this study defined current use as ever use and consumption of at least 100 cigarettes or equivalent of other TNP rather than use in the last 30 days. The authors reported usage of heated tobacco products (IQOS, glo, and Ploom) by 5% of the participants, 67% of whom were IQOS users. In the sample of current TNP users in the survey, 16% reported exclusive use of heated tobacco products and 11% reported dual use with cigarettes. While these studies provided some insight into the use of *IQOS* and other TNP, they were not based on a representative sample of the Japanese general adult

population or they were focused on specific regions, which limited the possibility of obtaining an accurate and unbiased estimation of the nationwide prevalence of TNP use in Japan.[16–18]

This paper, therefore, reports the results of a population-based survey (2016-2017) on TNP use in Japan since the launch of *IQOS*. The main goal of this survey was to determine the nationwide prevalence of *IQOS* use in Japan following its introduction in the Japanese market. A second survey of individuals who were purchasers of *IQOS* was also conducted with the aim of describing the use patterns of *IQOS*, alone or in combination with other TNP. From a tobacco harm reduction perspective, in addition to assessing prevalence, it is also important to understand whether smoke-free TNP are being used alone or in combination with other TNP, especially combustible TNP such as cigarettes, and if those who had never used any TNP are now using these products to initiate TNP use. Considering that *IQOS* was fairly new in the Japanese TNP marketplace when the study was initiated, its prevalence of use was expected to be low, as illustrated by previous surveys;[13,15] likewise, the sample size of *IQOS* users to be recruited for the survey was also expected to be low. Obtaining a sufficient sample size for reliable estimation of the combined use of products and use patterns would have been prohibitively expensive in a nationwide population-based survey. Moreover, surveying the general adult population alone might only reflect a partial story of use at a pivotal time marking early adoption of the product. This might not always be the most practical means of gathering detailed information on product use and use patterns displayed by legal age (≥20 years of age) users who started using the product soon after it was available and before the majority of other smokers in the general population switched (i.e., "early adopters").[19]

Methods
Study design and setting
Cross-sectional surveys in both general population and *IQOS* user sample were initiated in a representative sample of the Japanese general adult population and in a sample of adult *IQOS* users in Japan in December 2016. Since then, these surveys were repeated annually over a period of three years. Each annual sampling of the surveys consisted of four approximately equal-sized waves of participants spaced throughout the year(s) to account for potential seasonal differences. The current paper analyzed the data from the first year of the surveys, which comprised four waves of fieldwork (i.e., Wave 1 in December 2016 and Waves 2, 3, and 4 in March, May, and July 2017, respectively). The fieldwork was coordinated and run by third-party suppliers (Ipsos Mori UK Ltd./Ipsos Japan).

Participants
Sampling: general population survey

The general adult population sample was obtained by means of a multi-purpose survey (Omnibus). The Omnibus is a syndicated survey with multiple participating organizations and companies and is divided into different sections; therefore, the topics covered might change from wave to wave. The Omnibus was based on a three-stage stratified proportional sampling strategy that included the whole country. At the first stage, sampling points (from the census units) were allocated among the 12 Japanese administrative regions on the basis of their share of the population. A total of 157 sampling points were selected for an initial sample selection of 4,000 addresses. The second stage involved the use of an electronic residential map for identifying households within each sampling point, followed by random selection of about 40 households within the sampling points. The third stage sampled respondents within the selected households. Respondents were visited and approached by interviewers who confirmed and recorded consent of the individuals to take part in the study. Participants had to meet the inclusion criteria of the study: be legally authorized to buy tobacco products in Japan (i.e., ≥20 years of age); be current residents of Japan; be able to read, write, and understand Japanese; and be willing to participate in the study. Within each sampling point, broad quotas on age and sex were set to ensure representativeness of the Japanese population (e.g. a minimum target of having at least 1 male aged 20-29 years from a sampling point).

For the purpose of the present study, the "Tobacco Use Prevalence" paper questionnaire was developed for this study similarly to several existing tobacco and/or nicotine product use questions in the literature[12] to capture information about product use and was a stand-alone section handed to the participants for self-completion. The interviewer was available in case of queries and to check the section for completeness. The mode of administration for other questionnaires in the Omnibus is generally through face-to-face interview with a paper questionnaire that is read by the interviewer. Each participant was given a coupon for 500 JPY (approximately 5 USD) for completing all of the questionnaires in the Omnibus.

Sampling: IQOS user survey

Upon purchasing an *IQOS* device, consumers are offered the opportunity to register in the PMI Japan *IQOS* owner database, and, while doing so, participants can also agree to be contacted in the future for research purposes. As communicated by the Philip Morris Japan IQOS consumer database team, as of July 2017, 350,000 adult *IQOS* owners

were registered in the PMI Japan *IQOS* owner database, which represented a coverage of approximately 45% of *IQOS* owners at the time (Philip Morris Japan Limited, written communication, February 2019).

Members of the PMI Japan *IQOS* owner database who agreed to be contacted for research purposes were selected randomly, contacted by email and invited for participation in each wave, taking into account the demographic distribution of the database (on the basis of age group and sex). Once the target sample size was reached within a wave, the survey was closed, and the respondents could not be sampled in a subsequent wave. The inclusion criteria were the same as those for the general adult population sample, with the addition that the adult participant had to have been a current daily or non-daily *IQOS* user in the past 30 days and consumed more than 100 *HeatSticks* (tobacco-containing sticks to be used with *IQOS*) in his/her lifetime. The *IQOS* users sample also completed the same "Tobacco Use Prevalence" questionnaire as the general population but as an online web survey.

Ethical conduct of the study

Prior to the start of the study, the study protocol and associated documents were reviewed and approved by the Hakata Clinic Institutional Review Board (Reference: P1-PMX-01-JP). In the general population survey, in line with the Omnibus processes, consent for participation in the general population Omnibus was given orally and recorded in a form by the interviewer; before answering the questions in the survey, the participants received an information sheet with background information on the research and were free to decline participation. For the *IQOS* user survey, electronic informed consent was obtained from all participants before they completed the survey online (i.e., participants had to indicate with a Yes/No response that they had read and understood the information about the study and agreed to participate in the survey). Overall, the study was performed in accordance with ethical principles that have their origin in the Declaration of Helsinki[20] and were consistent with Good Epidemiological Practice.[21,22]

Study size
General population survey

The target sample size for each year was set at 5,000 participants. This number sufficed to estimate sampling error with a 95% confidence interval (CI) and precision of ±0.275 percent units given a population prevalence of *IQOS* use considered to be around 1%.[23] To achieve this sample size, four waves of 1,250 adult participants were sampled.

IQOS user survey

The target sample size for each year was set at 2,000 participants. This number sufficed to estimate with a 95% CI and a precision of ±2.19 percent units given a population percentage of *IQOS* use in combination with other TNP considered to be around 50%.[23] Each annual survey sample of *IQOS* users consisted of four waves, with the aim of recruiting 500 adult participants per wave.

Analytical methods
Analyses were conducted using the SAS v9.4 software (SAS Inc., USA). Data were analyzed and summarized descriptively for Year 1 (combination of waves 1–4), and the prevalence of current use according to the type of product (cigarettes, *IQOS*, e-cigarettes, or other TNPs [including smokeless tobacco (chewing tobacco, snus, or snuff), smokeless tobacco pipe, cigars/pipes/kiseru/shisha, Ploom (tobacco vaporizer), and nicotine replacement therapy]) was calculated in the general population survey. Current use was defined as use of the product at the time of the survey and prior use of the product (daily or non-daily) in the past 30 days. Dual use was defined as current use of two types of TNP, and poly use was defined as current use of three or more types of TNP. Average daily consumption of TNP (mean consumption per day) refers to average number of units/times of product use per day on days used in the past 30 days. For participant characteristics, the summary statistics for continuous data included mean and standard deviation (SD). For categorical data, frequency and percentage were calculated. For all point estimates, 95% CI are reported. The prevalence of current use in the general adult population sample was also stratified and presented by age, sex, education level, and occupation status. The distribution of exclusive, dual, and poly use (patterns of use) and average daily consumption of TNP was determined among all current adult users in the *IQOS* user survey. An assessment of those who initiated TNP use when they started using *IQOS* in the 12 months prior to the survey was also carried out in both surveys.

For the general adult population survey, prevalence estimates were also standardized to the demographic structure (age and sex) of the Japanese population on the basis of the latest official Japanese census statistics.[24,25] However, there were no major differences between the standardized (by age and sex) and unstandardized prevalence estimates because of quota application at the sampling stage; therefore, the unstandardized estimates are presented here.
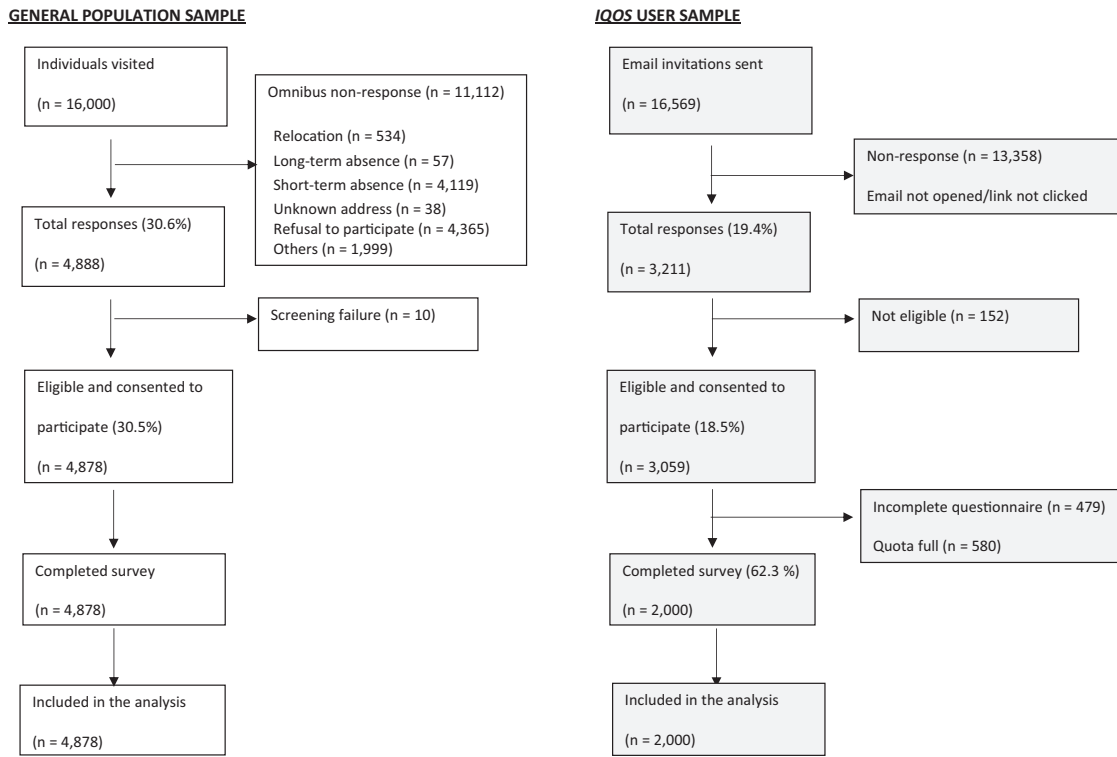
GENERAL POPULATION SAMPLE

Individuals visited
(n = 16,000)

Omnibus non-response (n = 11,112)
Relocation (n = 534)
Long-term absence (n = 57)
Short-term absence (n = 4,119)
Unknown address (n = 38)
Refusal to participate (n = 4,365)
Others (n = 1,999)

Total responses (30.6%)
(n = 4,888)

Screening failure (n = 10)

Eligible and consented to
participate (30.5%)
(n = 4,878)

Completed survey
(n = 4,878)

Included in the analysis
(n = 4,878)

IQOS USER SAMPLE

Email invitations sent
(n = 16,569)

Non-response (n = 13,358)
Email not opened/link not clicked

Total responses (19.4%)
(n = 3,211)

Not eligible (n = 152)

Eligible and consented to
participate (18.5%)
(n = 3,059)

Incomplete questionnaire (n = 479)
Quota full (n = 580)

Completed survey (62.3 %)
(n = 2,000)

Included in the analysis
(n = 2,000)

Figure 1. Flow diagram of study sample composition and response rate.

Results
Sample characteristics
General population survey

For the Omnibus, a response rate of 30% was achieved in the first year of the survey. This equates to 4,878 participants from a starting sample of 16,000 individuals. See Figure 1 for a breakdown of the participation rate. Table 1 presents the characteristics of the sample, as well as the Japanese population based on the most recent census data at the time of the survey. The demographic breakdown is, overall, comparable to that of the Japanese population. The age of the participants ranged from 20 to 97 years, with a mean ($\pm$SD) age of 53.7 ($\pm$17.92) years. While 48.1% of the participants were male, 51.9% were female. The highest level of education completed was high school in 49.1% of the sample and college or university education in 40.6%. The most common occupations were housewife (24.8%), manual employee (21.8%), and clerical employee (19.0%); and 17.1% of the participants were retired/unemployed.

IQOS user survey

Overall, 16,569 email invitations were sent out in four waves in the first year of the survey; 3,211 individuals clicked on the survey link, representing a response rate of 19.4%. Within the four waves of the first year, 2,000 individuals completed the survey, representing a completion rate of 62.3%. See Figure 1 for a breakdown of the participation rate. Table 1 shows the characteristics of the *IQOS* user sample. The mean ($\pm$SD) age of the participants was 38.50 ($\pm$9.73) years. While 81.6% of the participants were male, 18.4% were female. The highest level of education completed was college or university education in 56.8% of the sample and high school in 36.3%. The participants were most commonly engaged in managing professions (20.7%) and self-employed/small private business (16.5%).

Prevalence of TNP use in the general population survey
The overall prevalence (and 95% CI) of current use of any TNP was 18.5% (17.2–19.5%). As detailed in Table 2, the prevalence of current cigarette smoking was 17.5% (16.4–18.6%), while the prevalence of current *IQOS* use was 1.8% (1.4–2.2%; n = 86). The prevalence of current e-cigarette and other TNPs use were 0.7% (0.5–1.0%) and 1.8% (1.4–2.2%), respectively. Among the current TNP users (n = 887), 96.1% (94.5–97.3%) were cigarette smokers, 9.7% (7.8–11.9%) were *IQOS* users, and 3.9% (2.7–5.5%) were e-cigarettes users. In the general population sample, 1.3%

Table 1. Sample characteristics of each survey and the distribution of the Japanese general population.

	Japanese population[1]	General population survey (n = 4,878)		IQOS user survey (n = 2,000)	
	%	n	% [95% CI]	n	% [95% CI]
Sex					
Male	48.3	2,345	48.1 [46.6–49.5]	1,632	81.6 [79.8–83.3]
Female	51.7	2,533	51.9 [50.5–53.4]	368	18.4 [16.7–20.2]
Age (mean) [SD]			*53.75 [17.91]*		*38.50 [9.73]*
Age groups (years)					
20–29	12.0	528	10.8 [9.9–11. 8]	420	21.0 [19.2–22.9]
30–39	15.1	723	14.8 [13.8–15.9]	736	36.8 [34.6–39.0]
40–49	17.8	873	17.9 [16.8–19.1]	568	28.4 [26.4–30.5]
50+	55.2	2,754	56.5 [55.0–57.9]	276	13.8 [12.3–15.4]
Education level					
Junior high school	8.6	454	9.3 [8.5–10.2]	124	6.2 [5.1–7.4]
High school	40.1	2,395	49.1 [47.6–50.6]	726	36.3 [34.1–38.5]
College/University	41.8	1,980	40.6 [39.2–42.0]	1,135	56.8 [54.5–59.0]
Don't know/Not applicable	9.5	49	1.0 [0.7–1.4]	15	0.8 [0.4–1.3]
Occupation[4]					
Farming/Agriculture/Fishery		80	1.6 [1.3–2.1]	8	0.4 [0.1–0.8]
Self-employed/Small private business	12.1[2]	538	11.0 [10.1–12.0]	329	16.5 [14.8–18.2]
Clerical employee		927	19.0 [17.9–20.2]	284	14.2 [12.6–15.9]
Manual employee		1,063	21.8 [20.6–23.0]	268	13.4 [11.9–15.0]
Managing profession	46.9[3]	118	2.4 [2.0–2.9]	414	20.7 [18.9–22.6]
Housewife	19.9	1,211	24.8 [23.6–26.1]	84	4.2 [3.3–5.2]
Student	2.0	106	2.2 [1.7–2.7]	37	1.9 [1.3–2.6]
Retired/Unemployed	19.1	835	17.1 [16.0–18.3]	26	1.3 [0.8–1.9]

Data (n = 4,878) are % or n (%) and 95% confidence intervals (CI).
[1]Source: Statistics Bureau of Japan (2015) Source on Education: Statistics Bureau of Japan (2010) Source on Occupation: Public Opinion Survey on the Life of the People (23 June - 10 July 2016).
[2]Self-employed individuals and those working in farming and agriculture.
[3]Individuals in professional employment.
[4]N=550 individuals in IQOS user sample reported 'Don't know/Not applicable' for Occupation category.

(0.9–1.7%; n = 62) of individuals (i.e., 60% of all *IQOS* users) had started using *IQOS* within the past 12 months prior to the survey, and 96.8% (88.8–99.7%; N = 60) of these individuals had used other TNP prior to using *IQOS*.

The prevalence (and 95% CI) of cigarette smoking was 27.9% (26.1–29.9%) in men and 7.8% (6.8–9.0%) in women. For *IQOS* use, the prevalence in men and women were 3.0% (2.3–3.8%) and 0.6% (0.3–1.1%), respectively. The prevalence of cigarette smoking was the highest in the 40–49 age group, followed by the 30–39 years age group, and lowest in the 50+ age group (13.4% [12.1–14.8%]). The prevalence of *IQOS*, e-cigarette, and other TNPs use was similarly distributed across all age groups but tended to be lower in the 50+ age group.

Cigarette smoking was most prevalent in participants who had completed high school-level education (19.6% [95% CI: 18.0–21.3%]). In contrast, *IQOS* use was most prevalent among those who had completed college/university-level education (1.9% [1.3–2.6%]), followed by those who had completed high school-level education [1.8% (1.3–2.5%)]. The prevalence (and 95% CI) of cigarette smoking and *IQOS* use were also the highest among individuals in a managing profession (32.2% [23.8–41.5%] and 4.3% [1.4–9.7%], respectively).

Table 2. Prevalence of TNP use in the general population survey (overall and stratified by sample characteristics).

Characteristics	Prevalence n (%) [95% CI]			
	Cigarettes	IQOS	E-cigarettes	Other products*
Overall	852 (17.5) [16.4–18.6]	86 (1.8) [1.4–2.2]	35 (0.7) [0.5–1.0]	86 (1.8) [1.4–2.2]
Sex				
Male	654 (27.9) [26.1–29.9]	70 (3.0) [2.3–3.8]	25 (1.1) [0.6–1.6]	66 (2.8) [2.1–3.6]
Female	198 (7.8) [6.8–9.0]	16 (0.6) [0.3–1.1]	10 (0.4) [0.1–0.8]	20 (0.8) [0.4–1.3]
Age group (years)				
20–29	98 (18.6) [15.3–22.2]	20 (3.8) [2.3–5.8]	9 (1.7) [0.7–3.3]	7 (1.3) [0.5–2.8]
30–39	172 (23.9) [20.7–27.2]	23 (3.2) [2.0–4.8]	6 (0.8) [0.3–1.9]	18 (2.5) [1.4–4.0]
40–49	214 (24.5) [21.7–27.6]	25 (2.9) [1.8–4.3]	9 (1.0) [0.4–2.0]	26 (3.0) [1.9–4.4]
50+	368 (13.4) [12.1–14.8]	18 (0.7) [0.3–1.1]	11 (0.4) [0.2–0.8]	35 (1.3) [0.8–1.8]
Education level				
Junior high school	79 (17.4) [14.0–21.3]	5 (1.1) [0.3–2.6]	5 (1.1) [0.3–2.6]	9 (2.0) [0.9–3.8]
High school	469 (19.6) [18.0–21.3]	44 (1.8) [1.3–2.5]	18 (0.8) [0.4–1.2]	44 (1.8) [1.3–2.5]
College/University	299 (15.1) [13.5–16.8]	37 (1.9) [1.3–2.6]	12 (0.6) [0.3–1.1]	32 (1.6) [1.1–2.3]
Don't Know/Not applicable	5 (10.2) [3.3–22.3]	0	0	1 (2.0) [0.0–10.9]
Occupation				
Farming/Agriculture/Fishery	9 (11.5) [5.4–20.8]	1 (1.3) [0.0–6.8]	0	0
Self-employed/Small private business	156 (29.1) [25.2–33.2]	15 (2.8) [1.5–4.6]	7 (1.3) [0.5–2.7]	17 (3.2) [1.8–5.1]
Clerical employee	140 (15.1) [12.8–17.6]	29 (3.1) [2.1–4.5]	7 (0.8) [0.3–1.6]	14 (1.5) [0.8–2.6]
Manual employee	312 (29.4) [26.6–32.3]	31 (2.9) [2.0–4.2]	16 (1.5) [0.8–2.5]	33 (3.1) [2.1–4.4]
Managing profession	38 (32.2) [23.8–41.5]	5 (4.3) [1.4–9.7]	0	4 (3.4) [0.9–8.5]
Housewife	58 (4.8) [3.6–6.2]	4 (0.3) [0.0–0.9]	4 (0.3) [0.0–0.9]	6 (0.5) [0.1–1.1]
Student	16 (15.1) [8.8–23.4]	0	1 (0.9) [0.0–5.2]	0
Retired/Unemployed	123 (14.7) [12.3–17.4]	1 (0.1) [0.0–0.7]	0	12 (1.4) [0.7–2.5]

Data (n = 4,878) are n (%) and 95% confidence intervals (CI). Cigarettes: Manufactured and roll-your-own cigarettes; *IQOS*: *IQOS* with *HeatSticks*; TNP: tobacco and nicotine-containing products.
*Other products: including smokeless tobacco (chewing tobacco, snus, or snuff), smokeless tobacco pipe, cigars/pipes/kiseru/shisha, Ploom (tobacco vaporizer), and nicotine replacement therapy.

Distribution of use patterns among current TNP users in the general population and *IQOS* user survey

The patterns of current exclusive, dual, and poly product use among current TNP users in the general population survey are presented in Table 3. Of those participants for whom patterns could be defined (n=876), the majority 80.5% [95% CI: 77.6–83.1%] were only smoking cigarettes, whereas 2.5% [1.5–3.8%] were only using *IQOS*. The most common dual use patterns were cigarettes combined with other products (excluding *IQOS* and e-cigarettes) (7.3% [5.6–9.3%]), cigarettes and *IQOS* (4.6% [3.2–6.2%]), and cigarettes and e-cigarettes (1.5% [0.7–2.6%]). For poly-use (i.e., use of three or more products), the most common combination was cigarettes, *IQOS*, and e-cigarettes in 1.1% [0.5–2.1%] of current TNP users.

The patterns of current exclusive, dual, and poly product use in the *IQOS* user sample are presented in Table 4. Of the participants in the *IQOS* user survey, 74.8% had started using the product within the 12 months prior to the survey, and 98% of these *IQOS* users had been using other TNP prior to using *IQOS*. Of those participants for whom patterns could be defined, 63.4% [61.2–65.6%] were exclusive users of *IQOS*. The most common dual use pattern was *IQOS* combined with cigarettes (20.6% [18.7–22.5%]), and, among poly users, the most common combination was *IQOS*, cigarettes, and other TNPs (7.3% [6.1–8.6%]). On average, exclusive *IQOS* users used the product 29.6 [29.4–29.8] days out of the past 30 days and on days used, the average daily consumption of *IQOS HeatSticks* was greater among exclusive *IQOS* users

Table 3. Distribution of patterns of use among current TNP users (n=876) in the general population survey.

	Number (n)	Percentage [95% CI]
Exclusive users		
Cigarettes	705	80.5 [77.6–83.1]
IQOS	22	2.5 [1.5–3.8]
E-cigarettes	3	0.3 [0.0–1.0]
Dual users		
Cigarettes + *IQOS*	40	4.6 [3.2–6.2]
Cigarettes + e-cigarette	13	1.5 [0.7–2.6]
IQOS + e-cigarette	5	0.6 [0.1–1.4]
Cigarettes + other product*	64	7.3 [5.6–9.3]
IQOS + other product*	4	0.5 [0.1–1.2]
E–cigarette + other product*	1	0.1 [0.0–0.7]
Poly users		
Cigarettes + *IQOS* + e-cigarette	10	1.1 [0.5–2.1]
Cigarettes + other products*	2	0.2 [0.0–0.9]
Cigarettes + *IQOS* + other products*	4	0.5 [0.1–1.2]
Cigarettes + e-cigarette + other products*	3	0.3 [0.0–1.0]

Cigarettes: combustible cigarettes including Manufactured and roll-your-own cigarettes.
*Other product(s): including smokeless tobacco (chewing tobacco, snus, or snuff), smokeless tobacco pipe, cigars/pipes/kiseru/shisha, Ploom (tobacco vaporizer), and nicotine replacement therapy.
Exclusive users: current use of only one type of TNP; Dual users: current use of two types of TNP; Poly users: Current use of three or more types of TNP.

(16.8 *HeatSticks*) than among dual and poly users, who used 13.8 and 12.8 *HeatSticks*, respectively. The average daily consumption of cigarettes was 11.0 among dual cigarette and *IQOS* users and 12.8 among poly users.

Discussion

Three years after the launch of *IQOS* in Japan in 2014, the prevalence of current *IQOS* use in 2017 was 1.8% in the general population survey. The prevalence of cigarette smoking in the present study (17.5%) is in line with the reported prevalence of 18.2% in the Japan National Health and Nutrition Survey in 2015.[11,26] However, at the time of this study, this national survey did not report the prevalence of use of other smoke-free TNP, such as *IQOS* and only in 2018 did this national survey report a 5.1% prevalence of heated tobacco products in general. Adamson *et al.*[15] also reported a 5% prevalence of heated tobacco product use in their regional cross-sectional study, which is higher than the prevalence observed in the present study. However, they also included other heated tobacco products (glo and Ploom TECH) in their prevalence count, and alike the Japan National Health and Nutrition Survey, their data were collected in 2018, a year after the present study. Additional data, from the 2018 ITC Japan nationally representative web survey of 4684 participants by Sutanto *et al.*,[27] similarly show low prevalence (2.7%) of current heated tobacco product use, and even lower prevalence (0.9%) of exclusive heated tobacco product use with most users also smoking cigarettes. It is feasible that there had been an increase in the use of these products by 2018. The increasing use of heated tobacco products was reported by Tabuchi *et al.*,[13] who reported that the prevalence of current use of *IQOS* increased from 0.3% in 2015 to 0.6% in 2016 and up to 3.6% in 2017. Like Adamson *et al.,* these authors also reported a higher prevalence than that in the present study; however, their online non-representative survey included mostly a younger sample from the Japanese adult population. For instance, in their sample, 64.3% of the participants were below 50 years of age, while only 43.5% of the general population sample in the present study were below 50 years of age (similar to the reported 2015 census data of 44.8%).[25] Adamson *et al.* similarly oversampled participants in the younger 20-24 year age group. Nonetheless, the samples from these studies are more reflective of our *IQOS* user survey sample, which was also younger, on average. Together, these findings seem to support the fact that, similar to cigarette smoking, *IQOS* use tends to be more prevalent among men and middle-aged adults. However, unlike cigarette smoking, which is most prevalent among individuals with lower educational attainment,[28] *IQOS* use was more prevalent among individuals with higher educational attainment and in white-collar professions. These characteristics also tend to typify early adopters of a new product or technology such as *IQOS* and could change as more smokers in the population adopt *IQOS*.

Table 4. Distribution of patterns of use and consumption in the IQOS user survey.

Patterns of use	Number (n)	Percentage [95% CI]	Mean number of days used in past 30 days [95% CI]		Mean consumption per day [95% CI]	
			Cigarettes	IQOS (HeatSticks)	Cigarettes	IQOS (HeatSticks)
Exclusive users						
IQOS	1,234	63.4 [61.2–65.6]		29.6 [29.4–29.8]		16.8 [16.3–17.3]
Dual users						
IQOS–CC	400	20.6 [18.7–22.5]	23.8 [22.8–24.9]	28.1 [27.5–28.6]	11.0 [10.1–12.0]	13.8 [12.9–14.6]
IQOS–E-cigarettes	34	1.7 [1.2–2.5]	-	29.2 [27.5–30.9]		16.7 [14.1–19.3]
IQOS–other products[1]	96	4.9 [4.0–6.0]	-	29.4 [28.8–30.0]		17.9 [16.2–19.5]
Poly users	182		24.7 [23.0–26.3]	27.2 [26.3–28.1]	14.3 [12.8–15.9]	14.1 [12.9–15.4]
IQOS–CC–other products[1]	142	7.3 [6.1–8.6]			12.8 [11.1–14.5]	12.8 [11.3–14.2]
IQOS–other products[1] (poly use without cigarettes)	40	2.1 [1.4–2.8]				14.6 [12.2–17.0]

[1]Other products: including smokeless tobacco (chewing tobacco, snus, or snuff), smokeless tobacco pipe, cigars/pipes/kiseru/shisha, Ploom (tobacco vaporizer), and nicotine replacement therapy; CC: Manufactured and roll-your-own cigarettes.

Notably, our findings show low initiation of TNP use with *IQOS*; the majority of *IQOS* users in both the general adult population (96.8%) and *IQOS* user (98%) surveys had been using other TNP prior to using *IQOS*. This supports the findings of other studies,[13,14,29,30] as well as the overall goal of tobacco harm reduction, that the majority of current *IQOS* users are the intended users for such potential reduced-risk products[2] (i.e., adult cigarette smokers switching to the product instead of continuing smoking and low initiation and re-initiation of TNPs by never users or former users, respectively).

The results of the present surveys indicate a rapid expansion of *IQOS* in the Japanese market in 2017; 60% of *IQOS* users in the general adult population and 74.8% of participants in the *IQOS* user survey had started using the product within the 12 months prior to the survey. Hence, it is conceivable that, for early adopters of the products, complete displacement of cigarettes might take time, and, for some smokers, a period of dual use may be expected prior to exclusive *IQOS* use.[31,32] In this regard, the present results showed that 36.6% of participants in the *IQOS* user sample survey used the product in combination with other TNP, whereby 20.6% reported dual use with cigarettes. Patterns of dual and poly product use were also observed in the general population sample. Subsequent repeated cross-sectional data are needed to closely monitor the trends in multiple product use as *IQOS* use increases within a population and its implications for tobacco harm reduction.

Some limitations of the present study should be considered. First, the study relied only on self-reported product use. Previous studies have shown that the reliability of self-reported smoking in adults is generally high, suggesting that self-reported data provide reasonably valid estimates of cigarette smoking in the population.[33,34] However, the reliability of self-reported assessments has not yet been investigated and confirmed for smoke-free TNPs to the same extent and might warrant further investigation. Second, compared with other nationwide Japanese population surveys[11] that achieved response rates of 50–60%, the Omnibus had a relatively low response rate (30.5%). Overall, while the response rates to population surveys in Japan have been on the decline in recent years, this decline might also be influenced by the sampling methods employed.[35] Other surveys[36] tend to employ multimodal household, mail, telephone, and web-based methods for recruitment and data collection to improve response rates, whereas the Omnibus solely used a door-to-door household approach. However, the added value of an Omnibus survey is that it covers a range of topics and not only tobacco use behavior, which encourages people's willingness to participate in the survey. Moreover, the current survey also provided the respondents with a self-administration option for added privacy. Subsequently, a particular non-response bias toward the items of the current survey was not evident; only 10 of the 4,888 eligible participants from the Omnibus did not consent to completing the specific "Tobacco Use Prevalence" questionnaire. Nevertheless, the overall low response (19.4%) and completion (62.3%) rates for the web survey in the *IQOS* user sample could perhaps have been improved through multi-modal methodological changes in survey distribution, use of follow-up reminders, or greater incentives for participating in the web survey. Third, *IQOS* was newly introduced on the market at the time of the survey and the decision to adopt an innovation such as switching from cigarette smoking to sustained exclusive use of products such as *IQOS* is a dynamic process, with interactions among individual, situational, and contextual factors as well as attributes of the innovation itself.[19] Therefore, the present study can only provide some insight into some characteristics of the early adopters (e.g., demographic information such as age, sex, education, and career status). The longer the product is on the market, further investigations on what contributes to the *IQOS* adoption process will also need to consider the intrinsic and extrinsic attributes of the product itself (e.g., its relative advantage and compatibility within the adult population), the impact of tobacco regulatory policies, including on minors and youths, and other behavioral and environmental factors especially as more individuals adopt the use of *IQOS*. Lastly, the findings from the *IQOS* user sample are from a consumer panel which may not be representative of all *IQOS* users since the panelists are self-selected and incentivized to participate in follow-up surveys. Nevertheless, a substantial portion of estimated number of *IQOS* users in Japan are registered in this database and hence it provides access to a large number of *IQOS* users and more accurate picture of the use patterns of *IQOS* users which would not be possible with the sampling strategy of the general population given the low prevalence of *IQOS* use in the general population at the time of the survey. Future surveys should consider larger sample sizes in the general population surveys to allow for precise estimation of *IQOS* use patterns with other TNPs.

The main strength of the study lies in its design: annual repeated collection of data by using the same sampling framework and methods—namely face-to-face interviews of a national representative sample of participants coupled with a web survey of a large *IQOS* user sample—for gaining complimentary insights into a sizeable number of early adopters of the product. With additional waves and annual data, the present survey will continue to provide insights into the trends in prevalence and adoption of *IQOS* use in the Japanese adult population.

Conclusion

As of 2017, cigarette smoking remains the most prevalent way of consuming TNP in Japan; however, alternatives such as *IQOS* are already being adopted by a large number of adult Japanese smokers, with low initiation among TNP never users

and low re-initiation by former TNP users. This suggests the potential of smoke-free TNP as a harm-reduction alternative for replacing cigarettes. The present results complement those of previous surveys on the prevalence and use patterns of different TNP and serve as baseline data for monitoring early uptake and population trends over time in the use of potential smoke-free TNP in Japan.

Data availability

Underlying data
INTERVALS: YEAR 1 DATA (SAS DATASETS, CC-BY), https://doi.org/10.26126/intervals.vb4omj.[37]

This project contains the following underlying data:

- Three SAS datafiles in the Clinical Data Interchange Standards Consortium (CDISC) Analysis Data Model (ADaM) structure (www.cdisc.org/standards).

  - The ADSL (adsl.sas7bdat) is the Subject Level Analysis Dataset and contains the main information on participants identifier, demographics, and tobacco and/or nicotine product use groups and patterns to facilitate analysis and interpretation of analysis.

  - ADQS (adqs.sas7bdat) is the Questionnaire Analysis Dataset and contains specific information on the study survey, i.e. all questions and items answered by participants in the survey.

  - ADEX (adex.sas7bdat) is the Exposure Analysis Dataset and contains specific information on the tobacco and/nicotine product use exposure, i.e. all questions and items answered by participants in the survey related to their product use.

  - The ADAM specification and metadata file (ADaM_PMX01JP_AnY1_DBconv.xlsx) contains the dataset and variable labels and definitions, code lists to decode the variables names, terms and values, and the methods and computational algorithms to derive the analytical datasets.

Extended data
INTERVALS: YEAR 1 DATA (SAS DATASETS, CC-BY), https://doi.org/10.26126/intervals.vb4omj.[37]

This project contains the following extended data:

- "Tobacco Use Prevalence" questionnaire (Year 1 Tobacco Use Prevalence Questionnaire_eng_jp.pdf) is the questionnaire administered in the general population and IQOS user survey (Japanese and English version).

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Open Peer Review

Current Peer Review Status: ✓ ✓

Version 2

Reviewer Report 04 May 2022

https://doi.org/10.5256/f1000research.122553.r128142

✓ **Kenneth Michael Cummings** 🆔

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I appreciate the authors response to prior comments.

The addition of Table 3 to the paper is important and the findings despite small numbers should highlighted in the abstract. The predominate pattern of use of IQOS in the community sample was dual/poly use with cigarettes (59/85 = 69%). That is important to acknowledge, even with the caveat of low user numbers in absolute terms. Since this paper is now recast as a baseline upon with to compare the growth of IQOS and other heat tobacco products in Japan it is important to establish the low prevalence/high dual use pattern shown initially.

One other suggestion is to report the number of exclusive other product users in table 3. I would also provide a breakdown of other products used since a number of products are listed in the footnote, but given the descriptive nature of the study actually reporting the products reported would be helpful, especially since non-IQOS heat tobacco products were included in the other category.

Competing Interests: I'm a paid expert witness in litigation against cigarette manufacturers primarily talking to juries about the evidence from previously secret internal industry documents illustrating how cigarette companies conceal information about the addictiveness and harms of conventional cigarettes, and the impact of concealment on smoking related behaviors (i.e., uptake, quitting attempts, maintenance of cessation).

Reviewer Expertise: I'm interested in products and policies that will accelerate a decline in smoking related diseases. I've spent 40 years doing research on the harms of tobacco, smoking prevention and cessation. I have also followed closely the history of tobacco product innovations such as filters, low tar/light cigarettes and their failure to reduce the harms caused by cigarettes.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 26 April 2022

https://doi.org/10.5256/f1000research.122553.r128143

✔️

Lai Wei 🆔

Center for Research & Technology, Altria Client Services LLC, Richmond, VA, USA

The authors have addressed all my comments. The additions of Table 3 (pattern of use from the general population survey) and Table 4 (with added cigarette use frequency and consumption) provide valuable insights to further understand IQOS use behavior in Japan.

I have a few minor suggestions:

1. In the abstract (first sentence) and introduction (first paragraph), the term 'TNP' was introduced as 'smoke-free tobacco and/or nicotine-containing products'. The reviewer believes the term 'TNP' is referring to 'Tobacco and/or Nicotine Products' in some of the content. Examples include "assessed the prevalence of current TNP use according to type of product (cigarettes, IQOS, e-cigarettes, and other TNPs)", "The prevalence of current use across all TNP in the sampled general population was 18.5%, with 17.5% for cigarette smoking and 1.8% for IQOS use", etc. The reviewer suggests clarifying this 'TNP' term, going through the article to examine each use case of 'TNP'.

2. In discussion of Table 4 results, the reviewer suggests reiterating the sampling differences between the general population survey and the IQOS user survey. The participants in the IQOS user survey must have been consumed more than 100 HeatSticks in his/her lifetime. This inclusion criteria excluded IQOS experimental users from the IQOS user survey, which lead to the differences in the proportions of exclusive and dual/poly use when making comparisons between the two surveys. If data exists, it would add value to report the proportion of having consumed more than 100 HeatSticks in his/her lifetime among current IQOS users.

3. In Table 4, cigarette consumption measures for poly users should be moved down to the row 'IQOS-CC-other products'. And for consistency, a dash '-' sign should be added in places where cigarette consumption measures are not applicable.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Statistics, Epidemiology, Population Modeling and Tobacco Survey Research.

I confirm that I have read this submission and believe that I have an appropriate level of

expertise to confirm that it is of an acceptable scientific standard.

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Version 1

Reviewer Report 09 November 2021

https://doi.org/10.5256/f1000research.55681.r98493

✖ **Kenneth Michael Cummings** 🆔

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This is an interesting paper authored by Philip Morris scientists. The paper presents descriptive data on the prevalence of heat tobacco product use among adults from the 2016 and 2017 online Omnibus cross-sectional surveys which are designed to be representative the adult population in Japan. Analyses are based on 4,878 survey responders out of 16,000 households approached to participate. It appears the authors have combined results from the 2016 and 2017 Omnibus surveys which is unfortunate, since it prevents readers from seeing trends in the use of heated tobacco products overtime, as well as changes in cigarette smoking (potential displacement of cigarette use). A third survey conducted in 2018 is mentioned in the paper, but is not included in the analysis. It should be. The study also presents data on 2000 person customer IQOS user survey. Unfortunately, the source of this survey is not well described in the paper. The findings from the Omnibus surveys show that the predominate tobacco product consumed ay adults is cigarettes at 17.5% vs 4.0% for heated tobacco products and e-cigarettes combined. However, these prevalence figures (derived) from table 2 are likely inflated since it is likely that there is dual use across the product categories listed in the table. Unfortunately, the authors do not talk about dual use from their population based omnibus surveys, but instead report on dual use from their non-presentative consumer tracking study were dual use is likely to be lower due to self section and incentives to participate in the consumer use follow-up surveys. I have two strong recommendations to the authors.

First, they should report their population survey data separate from their consumer use surveys. Reader can get easily confused when these results based on very different groups are presented in the same paper.

Second, the most relevant findings for estimating smoking harm reduction are the findings from the population based surveys. The authors should present data separately for each survey year. Showing data for 2016 separately from 2017 and 2018 (and perhaps more recent surveys) would allow the reader to see trends in the use of heated tobacco products and different brands of products. Also, the authors should report on exclusive and dual use of products. I would suspect that many of those experimenting with heated tobacco products might dual use different brands.

One of the main limitation of the paper as presented was the failure to present detailed data on dual, patterns of use, and duration of use of different tobacco products. The low number of heated tobacco users in each survey year is likely a reason for not sharing such details, but they should be available to readers with appropriate caveats about sample size. Also, the sample size problem is a fixable since Philip Morris could could implement a larger survey in each year so that they can effectively estimate low level use of IQOS and other heated tobacco products. The Omnibus survey results as presented are helpful as a preliminary level to assess prevalence so that a larger study could be undertaken to look a dual use, patterns of use, and duration of use of heated tobacco products. Also, a larger study would allow the authors to estimate more precisely the uptake and continued regular use of heated tobacco products by non-smokers. The current study showed low current use of heated tobacco products (<2%, and ~10% of overall nicotine/tobacco use). On a positive note, among those reporting starting the use of a heated tobacco product in the past 12 months, only 2 out of 62 (~3%) reported themselves to be non-smokers. However, this study was restricted to adults aged 21 and older so it is unclear from this study whether heated tobacco products are gaining attention among teenagers and young adults, similar to what has been observed for e-cigarettes in some countries. This is a limitation that needs to be highlighted in the discussion also the authors should comment on other data sources to estimate use of heated tobacco use by minors, since that is a area of public health concern, which can not be ignored.

I would encourage PMI to make their deidentified data from these surveys available online for other researchers to interrogate. Similar data sets available from other countries should also be make available. I would encourage other manufacturers to do the same since the data on prevalence of use, dual use and patterns of use are essential elements to modeling the potential longer term impact of heated tobacco products on population health.

The authors should also comment on the overall low use of IQOS in their study (1.8% prevalence overall). Other heat tobacco products introduced into Japan after IQOS had the same prevalence rate of 1.8% which was surprising since IQOS was introduced earlier than the competitor products. ENDS products which are banned for sale in Japan had a lower prevalence of 0.7%, which makes sense. It would be useful for the authors to include a table comparing the prevalence rates from this study to those from other published source. It was hard to follow the comparisons form the text. Other population studies in Japan have found high rates of dual use of cigarettes and heat tobacco products (see, for example, an article I was involved with: Sutanto E, *et al.* 2019[1]); it would be useful (essential) for the authors to report dual use data from their population surveys versus those from other surveys in Japan. Dual vs exclusive use of IQOS will be one of the key metrics researchers will be interested in evaluating.

References
1. Sutanto E, Miller C, Smith D, O'Connor R, et al.: Prevalence, Use Behaviors, and Preferences among Users of Heated Tobacco Products: Findings from the 2018 ITC Japan Survey. *International Journal of Environmental Research and Public Health*. 2019; **16** (23). Publisher Full Text

Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and is the work technically sound?

Partly

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
No

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: I'm a paid expert witness in litigation against cigarette manufacturers primarily talking to juries about the evidence from previously secret internal industry documents illustrating how cigarette companies conceal information about the addictiveness and harms of conventional cigarettes, and the impact of concealment on smoking related behaviors (i.e., uptake, quitting attempts, maintenance of cessation).

Reviewer Expertise: I'm interested in products and policies that will accelerate a decline in smoking related diseases. I've spent 40 years doing research on the harms of tobacco, smoking prevention and cessation. I have also followed closely the history of tobacco product innovations such as filters, low tar/light cigarettes and their failure to reduce the harms caused by cigarettes.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Author Response 16 Mar 2022
Esther Afolalu, PMI R&D, Philip Morris Products S.A, Neuchâtel, Switzerland

This is an interesting paper authored by Philip Morris scientists. The paper presents descriptive data on the prevalence of heat tobacco product use among adults from the 2016 and 2017 online Omnibus cross-sectional surveys which are designed to be representative the adult population in Japan. Analyses are based on 4,878 survey responders out of 16,000 households approached to participate. It appears the authors have combined results from the 2016 and 2017 Omnibus surveys which is unfortunate, since it prevents readers from seeing trends in the use of heated tobacco products overtime, as well as changes in cigarette smoking (potential displacement of cigarette use). A third survey conducted in 2018 is mentioned in the paper, but is not included in the analysis. It should be.

Thanks for this observation. The annual survey/annual sampling of the surveys do not correspond to a calendar year but rather consisted of four approximately equal-sized waves of participants spaced throughout the year to account for potential seasonal differences. The data presented in the paper are from repeated cross-sectional surveys

conducted in 2016 (wave 1 in December) and 2017 (waves 2, 3, and 4 in March, May, and July respectively). The Study design and Settings in Methods section are made clearer to reflect this. Another paper is in preparation to show the trends for subsequent years (Year 2 (2017-2018) and Year 3 (2018-2019) (see further below).

The study also presents data on 2000 person customer IQOS user survey. Unfortunately, the source of this survey is not well described in the paper.

Upon purchasing an IQOS device, consumers are offered the opportunity to register in the PMI Japan IQOS owner database, and, while doing so, participants can also agree to be contacted in the future for research purposes. It was described in the section "Sampling: IQOS user survey" that these participants were members of the PMI Japan IQOS owner database who agreed to be contacted for research purposes and were selected randomly and contacted by email and invited for participation in each wave of the survey.

The findings from the Omnibus surveys show that the predominate tobacco product consumed ay adults is cigarettes at 17.5% vs 4.0% for heated tobacco products and e-cigarettes combined. However, these prevalence figures (derived) from table 2 are likely inflated since it is likely that there is dual use across the product categories listed in the table. Unfortunately, the authors do not talk about dual use from their population based omnibus surveys, but instead report on dual use from their non-presentative consumer tracking study were dual use is likely to be lower due to self section and incentives to participate in the consumer use follow-up surveys. I have two strong recommendations to the authors.

First, they should report their population survey data separate from their consumer use surveys. Reader can get easily confused when these results based on very different groups are presented in the same paper.

Thank you for these suggestions.

We have now added an additional Table (Table 3) to show distributions of patterns of TNP use among current TNP users in the general population sample. However, as the results show, the prevalence of IQOS use in general population was expected and indeed seen to be quite low (N=85) which limits the extent to gather interpretable and detailed information on specific product use patterns such as dual/poly use. This is why we supplement this information with information in Table 4 on patterns of use of IQOS users from the consumer survey, and report this in the same paper to provide two complementary views.

Related to the comments that the data on dual use from the consumer panel is not representative because the panelists are self-selected and have incentives to participate in follow-up surveys, we acknowledge this limitation and have expanded on this in the Discussion section. Indeed, IQOS users are invited to join the IQOS owner database and receive incentives for completing the surveys. However, a substantial portion of estimated number of IQOS users in Japan are registered in this database and hence it provides access to a larger number of IQOS users and more precise and accurate picture of the use

patterns of IQOS users which would not be possible with the sampling strategy of the general population given the rather low prevalence of IQOS use in the general population at the time of the survey. Participants from the database were randomly invited to participate in the survey based a quota that reflects the gender and age distribution of the population of users.

Second, the most relevant findings for estimating smoking harm reduction are the findings from the population based surveys. The authors should present data separately for each survey year. Showing data for 2016 separately from 2017 and 2018 (and perhaps more recent surveys) would allow the reader to see trends in the use of heated tobacco products and different brands of products.

Also, the authors should report on exclusive and dual use of products. I would suspect that many of those experimenting with heated tobacco products might dual use different brands. One of the main limitation of the paper as presented was the failure to present detailed data on dual, patterns of use, and duration of use of different tobacco products. The low number of heated tobacco users in each survey year is likely a reason for not sharing such details, but they should be available to readers with appropriate caveats about sample size.

This paper reflects the first year of this survey (Year 1 (2016-2017)) as an initial presentation of the data, another paper is in preparation to show the trends for subsequent years (Year 2 (2017-2018) and Year 3 (2018-2019)).

As explained above, we have now added an additional Table (Table 3) to show distributions of patterns of TNP use among current TNP users in the general population sample with the caveat about sample size and low prevalence of IQOS use in the general population at the time of the Year 1 survey.

Also, the sample size problem is a fixable since Philip Morris could could implement a larger survey in each year so that they can effectively estimate low level use of IQOS and other heated tobacco products. The Omnibus survey results as presented are helpful as a preliminary level to assess prevalence so that a larger study could be undertaken to look a dual use, patterns of use, and duration of use of heated tobacco products. Also, a larger study would allow the authors to estimate more precisely the uptake and continued regular use of heated tobacco products by non-smokers.

Thank you for this key suggestion, this has been considered for ongoing and future surveys and this point mentioned as part of limitations in the Discussion section.

The current study showed low current use of heated tobacco products (<2%, and ~10% of overall nicotine/tobacco use). On a positive note, among those reporting starting the use of a heated tobacco product in the past 12 months, only 2 out of 62 (~3%) reported themselves to be non-smokers. However, this study was restricted to adults aged 21 and older so it is unclear from this study whether heated tobacco products are gaining attention among teenagers and young adults, similar to what has been observed for e-cigarettes in some countries. This is a limitation that needs to be highlighted in the discussion also the authors

should comment on other data sources to estimate use of heated tobacco use by minors, since that is a area of public health concern, which can not be ignored.

Thank you for this suggestion. As this study was conducted in Japan, the lower age limit was 20 years old which represent the legal age to be authorized to buy tobacco products in Japan, and not 21 years old as stated. Additionally, we did not conduct the study in underage populations, hence it is beyond the scope of this paper to compare data sources on use by minors, however, we have included in the Discussion this should be a focus of further studies.

I would encourage PMI to make their deidentified data from these surveys available online for other researchers to interrogate. Similar data sets available from other countries should also be make available. I would encourage other manufacturers to do the same since the data on prevalence of use, dual use and patterns of use are essential elements to modeling the potential longer term impact of heated tobacco products on population health.

The deidentified Year 1 data reported in this paper is made publicly available, the link is in the data availability section of the manuscript https://doi.org/10.26126/intervals.vb4omj alongside high-level study description: https://www.intervals.science/studies/#/htp-use-prevalence-use-patterns-japan. As data from other years are published, the data will also be made publicly available.

The authors should also comment on the overall low use of IQOS in their study (1.8% prevalence overall). Other heat tobacco products introduced into Japan after IQOS had the same prevalence rate of 1.8% which was surprising since IQOS was introduced earlier than the competitor products. ENDS products which are banned for sale in Japan had a lower prevalence of 0.7%, which makes sense. It would be useful for the authors to include a table comparing the prevalence rates from this study to those from other published source. It was hard to follow the comparisons form the text.

The low IQOS use prevalence reflects the period of the current survey (December 2016 – July 2017), which is soon after the national introduction of IQOS in Japan. We presented comparisons with similar surveys in the text and not a table in order to provide sufficient context and ensure there is no misunderstanding in the interpretation of the findings given the considerable differences with the other surveys such as differences in sampling strategies, use of a non-representative general population sample, reporting of heated tobacco products in general and not IQOS specifically, and surveys conducted later than the time period reported in current paper, etc...

Other population studies in Japan have found high rates of dual use of cigarettes and heat tobacco products (see, for example, an article I was involved with: Sutanto E, *et al.* 2019[1]); it would be useful (essential) for the authors to report dual use data from their population surveys versus those from other surveys in Japan. Dual vs exclusive use of IQOS will be one of the key metrics researchers will be interested in evaluating.

In addition to the comparisons with other surveys described above, we have also now referred in the discussion to the Sutanto et al 2019 paper. As explained above, we have also

now added an additional Table (Table 3) to show distributions of patterns of TNP use among current users in the general population sample with the caveat about sample size and low prevalence of IQOS use in the general population at the time of the Year 1 survey.

Competing Interests: No competing interests were disclosed.

Reviewer Report 13 July 2021

https://doi.org/10.5256/f1000research.55681.r88350

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Lai Wei 🆔

Center for Research & Technology, Altria Client Services LLC, Richmond, VA, USA

The authors presented the prevalence and patterns of tobacco and/or nicotine-containing products (TNP) usage based on first annual (2016-2017) data of two cross-sectional surveys in Japan. The survey methodology and sampling methods were clearly described. The analysis results provided insights of the early adoption and market expansion of IQOS in Japan. The reviewer has listed the comments for each section below. The reviewer has the suggestions to add analysis results regarding exclusive, dual and poly use patterns from both surveys (i.e. general population survey and IQOS user survey) and the cigarette and IQOS use patterns (e.g. daily use, number of days used) for exclusive and dual/poly users.

Abstract
- The authors described that the analysis is based on 'general adult population' (and also mentioned 'legal age' in the Introduction section) while the analysis results were presented for 20 years of age or older. The authors should specify the age range of the baseline population upfront in the abstract as well as in the introduction or study design section as the 'adult age' or 'legal age' may differ by countries.

Introduction
- The authors stated 'In the full sample, 16% reported exclusive use of heated tobacco products and 11% reported dual use with cigarettes', following the mention of 5% heated tobacco product prevalence from the recent pilot cross-sectional survey of 4,154 TNP consumers. The authors need to clarify the 'full sample' that can calculate the 16% and 11%.

- The authors need to add the time frame (e.g. 2016-2017) of 'results of a population-based survey on TNP' in the first sentence of the last paragraph.

- The sentences following 'From a tobacco harm reduction perspective' explained the need to conduct the other cross-sectional survey based on IQOS purchasers. The reviewer suggests the author to add a sentence before 'From a tobacco harm reduction perspective' to introduce second cross-sectional survey instead of mentioning it at the end of the

paragraph with 'For these reasons'.

Methods

Study Design and Setting

○ The authors stated, 'The current paper analyzed the data from the first year of the surveys, which comprised four waves of fieldwork.' The author needs to clarify if this sentence and the following sentence are for both cross-sectional surveys. For example, the reviewer would like to know if the two cross-sectional surveys are conducted at the same time period (i.e. 'in December 2016 and March, May, and July 2017').

Participants

○ In the IQOS User Survey section, the authors should mention it was the 'Members of the PMI Japan IQOS Owner database *who agreed to be contacted for research purposes*' that were 'selected randomly and contacted by email.'

Study Size

○ The reviewer suggests changing the sentence with 'This number sufficed…' to 'This number sufficed to estimate a 95% confidence interval (CI) with a margin of error of ±0.275 percent given a population prevalence of IQOS use considered to be around 1%'. This suggestion also applies to the sentence in the IQOS User Survey.

Analytical Methods

○ Clarifications are needed for the 'average daily consumption of TNP'. There are two typical ways to report on average daily consumption: average usage per day *on days used* or usage per day *on 30-day average* (which is usage per day on days used*number of days used/30).

Results

Sample Characteristics

○ In Table 1, the authors reported 27.5% don't know/not applicable for the occupation distribution in the IQOS user survey. This 'Don't know/Not applicable' level was not included in the Japanese population column nor the 'General population survey' column. The reviewer suggests either to exclude this level for IQOS user survey or include this level for the general population survey to make occupation distributions comparable.

Prevalence of TNP Use in the general population survey

○ Given the TNP usage information is available, the reviewer suggests the authors to also report on exclusive, dual and poly use patterns among current IQOS users in the general population survey and compare the results with the use pattern from the IQOS user survey.

○ The word 'at least' should be removed from the sentence that 'Cigarette smoking was most prevalent in participants who had completed at least high school-level education….'

Distribution of use patterns among TNP users in the IQOS user survey

○ The reviewer suggests adding the proportion of daily versus non-daily users, and average number of days used IQOS or cigarettes from the IQOS user survey. These would provide additional context when evaluating the use consumption of IQOS or cigarettes for dual and poly users. The reviewer believes the mean consumption per day is average use consumption <u>on days used</u> so the number of days used cigarette and IQOS would be extremely helpful to understand the dual and poly use behavior.

Discussions

○ The reviewer suggests changing 'could change as the majority of smokers in the population adopt the product' to 'could change as more smokers in the population adopt the product'.

○ The reviewer suggests changing 'low initiation and re-initiation of TNPs by non-users or former users, respectively' to 'low initiation and re-initiation of TNPs by *never users* or former

users, respectively' to align with language used in later paragraphs regarding never and former users.

○ The reviewer suggests revising end of the sentence '...as more individuals adopt the use of IQOS the longer it is on the market.'

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Statistics, Epidemiology, Population Modeling and Tobacco Survey Research.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 16 Mar 2022
Esther Afolalu, PMI R&D, Philip Morris Products S.A, Neuchâtel, Switzerland

The authors presented the prevalence and patterns of tobacco and/or nicotine-containing products (TNP) usage based on first annual (2016-2017) data of two cross-sectional surveys in Japan. The survey methodology and sampling methods were clearly described. The analysis results provided insights of the early adoption and market expansion of IQOS in Japan. The reviewer has listed the comments for each section below. The reviewer has the suggestions to add analysis results regarding exclusive, dual and poly use patterns from both surveys (i.e. general population survey and IQOS user survey) and the cigarette and IQOS use patterns (e.g. daily use, number of days used) for exclusive and dual/poly users.

Abstract
○ The authors described that the analysis is based on 'general adult population' (and

also mentioned 'legal age' in the Introduction section) while the analysis results were presented for 20 years of age or older. The authors should specify the age range of the baseline population upfront in the abstract as well as in the introduction or study design section as the 'adult age' or 'legal age' may differ by countries.

Thanks for the observation, this is now clarified in the abstract.

Introduction
- The authors stated 'In the full sample, 16% reported exclusive use of heated tobacco products and 11% reported dual use with cigarettes', following the mention of 5% heated tobacco product prevalence from the recent pilot cross-sectional survey of 4,154 TNP consumers. The authors need to clarify the 'full sample' that can calculate the 16% and 11%

Thank you, now clarified that this sample refers to the sample of current tobacco users in the survey.

- The authors need to add the time frame (e.g. 2016-2017) of 'results of a population-based survey on TNP' in the first sentence of the last paragraph.

The time frame 2016-2017 now added for clarification.

- The sentences following 'From a tobacco harm reduction perspective' explained the need to conduct the other cross-sectional survey based on IQOS purchasers. The reviewer suggests the author to add a sentence before 'From a tobacco harm reduction perspective' to introduce second cross-sectional survey instead of mentioning it at the end of the paragraph with 'For these reasons'.

Thank you, this is now updated.

Methods
Study Design and Setting
- The authors stated, 'The current paper analyzed the data from the first year of the surveys, which comprised four waves of fieldwork.' The author needs to clarify if this sentence and the following sentence are for both cross-sectional surveys. For example, the reviewer would like to know if the two cross-sectional surveys are conducted at the same time period (i.e. 'in December 2016 and March, May, and July 2017').

Now clarified in 'Study design and Setting' section that the timeframe of the fieldwork applied to both the general population and IQOS user sample surveys.

Participants
- In the IQOS User Survey section, the authors should mention it was the 'Members of the PMI Japan IQOS Owner database *who agreed to be contacted for research purposes*' that were 'selected randomly and contacted by email.'

Thank you for this observation, this is now added for clarification.

Study Size
- The reviewer suggests changing the sentence with 'This number sufficed...' to 'This number sufficed to estimate a 95% confidence interval (CI) with a margin of error of ±0.275 percent given a population prevalence of IQOS use considered to be around 1%'. This suggestion also applies to the sentence in the IQOS User Survey.

Thank you for noting this omission, this is now updated.

Analytical Methods
- ○ Clarifications are needed for the 'average daily consumption of TNP'. There are two typical ways to report on average daily consumption: average usage per day *on days used* or usage per day *on 30-day average* (which is usage per day on days used*number of days used/30).

Now specified that Average daily consumption of TNP (mean consumption per day) refers to average number of units/times of product use per day on days used in the past 30 days.

Results

Sample Characteristics
- ○ In Table 1, the authors reported 27.5% don't know/not applicable for the occupation distribution in the IQOS user survey. This 'Don't know/Not applicable' level was not included in the Japanese population column nor the 'General population survey' column. The reviewer suggests either to exclude this level for IQOS user survey or include this level for the general population survey to make occupation distributions comparable.

Thank you, we agree this can be excluded from IQOS survey. We also added a footnote to Table 2 for further clarification.

Prevalence of TNP Use in the general population survey
- ○ Given the TNP usage information is available, the reviewer suggests the authors to also report on exclusive, dual and poly use patterns among current IQOS users in the general population survey and compare the results with the use pattern from the IQOS user survey.

Thanks for this suggestion, we have now added an additional Table (Table 3) to show distributions of patterns of TNP use among current TNP users in the general population sample and added a note on this comparison in the discussion.
- ○ The word 'at least' should be removed from the sentence that 'Cigarette smoking was most prevalent in participants who had completed at least high school-level education....'

The word 'at least' now removed for clarity.

Distribution of use patterns among TNP users in the IQOS user survey
- ○ The reviewer suggests adding the proportion of daily versus non-daily users, and average number of days used IQOS or cigarettes from the IQOS user survey. These would provide additional context when evaluating the use consumption of IQOS or cigarettes for dual and poly users. The reviewer believes the mean consumption per day is average use consumption <u>on days used</u> so the number of days used cigarette and IQOS would be extremely helpful to understand the dual and poly use behavior.

Thank you for the suggestion, we have now clarified that mean consumption per day refers to average number of units/times of product use per day on days used in the past 30 days. We have also added a column to show the average number of days used in past 30 days.

Discussions
- ○ The reviewer suggests changing 'could change as the majority of smokers in the population adopt the product' to 'could change as more smokers in the population

adopt the product'.

This text is now updated.

- ○ The reviewer suggests changing 'low initiation and re-initiation of TNPs by non-users or former users, respectively' to 'low initiation and re-initiation of TNPs by *never users* or former users, respectively' to align with language used in later paragraphs regarding never and former users.

Thank you, this text is now updated.

- ○ The reviewer suggests revising end of the sentence '…as more individuals adopt the use of IQOS the longer it is on the market.'

This sentence has now been rephrased.

Competing Interests: No competing interests were disclosed.

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