

Cross-sectional Survey to Assess Tobacco and Nicotine Product Use since the Introduction of Tobacco Heating Products in Japan: Wave 1

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Objective: In this study, we obtained key population-level data on use patterns and behavior relating to tobacco and nicotine products in Japan. **Methods:** We performed a nationwide cross-sectional survey of the general population in Japan in 2019 to assess use patterns after the introduction of tobacco heating products (THPs). Eligible participants were Japanese residents, aged 20 years or older who consented to complete the survey. Individuals living in institutions were excluded. A 3-stage probability sampling method was applied that was geographically stratified by street blocks proportionate to population density. Respondents self-reported patterns of product use and reasons for THP use. **Results:** Complete responses were available from 5306 individuals, of whom 933.5 (17.6%) were current users, 984.2 (18.5%) were former users, and 3388.4 (63.9%) were never users of tobacco products (weighted respondent totals). Cigarettes were used by 14.6% of current tobacco product users and THPs by 5.3%. Cigarettes and THPs were used exclusively by 64.5% and 12.2%, respectively, and both were used by 12.7%. The most common reasons reported for THP use were perceived reduction in harm to self and others compared to cigarettes. **Conclusions:** Whereas the prevalence of cigarette use in Japan is decreasing, THPs seem to be increasingly used as long-term alternatives to cigarette smoking.

Key words: tobacco use; nicotine; tobacco heating products; cigarettes; switching; behavior; use patterns

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During the past few decades, the global smoking landscape has changed substantially. Regulations restricting smoking have been introduced in many countries, with efforts made to reduce tobacco consumption and prevent initiation of use. Meanwhile, alternative tobacco and nicotine products have entered the market that aim to reduce overall exposure to harmful toxicants and reduce the risk associated with cigarette smoking.^{1,2}

To evaluate the modified-risk potential of a new product, a variety of studies are recommended to compare its effects with continued smoking, as well as the implications of its market introduction.³ To demonstrate benefits at the population level, data supporting the post-market evaluation of behavior

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and use patterns of these products are essential. A holistic approach is needed that considers current, former, and never users.

Tobacco heating products (THPs) heat tobacco sticks enough to release aerosol containing nicotine, glycerol, and some volatile tobacco flavor compounds without combustion. Therefore, the formation of many of the toxicants generated in cigarette smoke is prevented or substantially reduced.⁴⁻¹⁰ Japan, the first country where THPs were successfully introduced in 2014, has shown high levels of acceptance for this product category.^{11,12} THPs accounted for 23% of the Japanese tobacco market in 2018.¹³ Therefore, Japan is a preferred location for investigating the impact of THP introduction at a population level.

A pilot cross-sectional survey was conducted in 2018 across 3 areas of Japan (Tokyo, Osaka, and Sendai) to assess tobacco and nicotine product use after the introduction of THPs.¹¹ Following successful completion of the pilot study, a nationwide multi-wave survey was initiated.¹⁴ Here we report the results of wave 1.

METHODS

Study Design and Population

The wave 1 survey was performed between February 23 and April 7, 2019. The eligible study population was comprised of current residents of Japan living in a private household, aged 20 years (legal smoking age) or older, who could speak and read Japanese, and were willing to participate after study information was provided. People in institutionalised populations were excluded (eg, prisons, military bases, mental facilities, and homes for the aged).

This study was conducted in accordance with the latest version of the Declaration of Helsinki, Good Epidemiological Practice, the JMRA Marketing Research Guideline and the Personal Information Protection Guideline (which also complies with the ICC/ESOMAR codes of conduct), as well as any relevant local laws and regulations. Approval was obtained from the independent ethics committee at Kitamachi Clinic, Tokyo, Japan.

Sampling Design and Procedures

A geographically stratified 3-stage probability

sampling method was applied to select potential participants. Japan is classified into 9 regions containing 47 prefectures that are further separated into municipalities. Urbanization is stratified by 4 degrees – major cities, large cities, medium cities, and small towns – based on population data recorded by the residential registration program. The primary sampling units (PSUs) in this survey were street blocks selected by stratified random sampling. We randomly selected 500 PSUs that were proportionate in size to population density. Within each PSU, households were numbered in ascending order, using the Zenrin residential map database (Zenrin Co Ltd, Kitakyushu, Fukuoka, Japan). A starting number was chosen randomly from which 50 households separated by regular numeric intervals subsequently were selected. If there were not enough households in the selected PSU, households from the next street block listed on the residential map database in a neighboring PSU of the same municipality were added.

If an interviewer could not complete 10 interviews within the 50 listed households, he or she visited the next household based on the regular numeric interval until 10 interviews were completed. Within each household, one respondent was selected by the next birthday method.¹⁵ To control for inclusion of participants in multiple waves, different PSUs were used in the pilot study and each wave of the survey.

Based on previous experience and results from the pilot study, it was expected that the age groups 20-24 years and 25-29 years would be under-represented in the samples.¹¹ Therefore, we oversampled for these age groups by adding a quota to each assigned PSU. Once the target sample of 10 interviews was reached, the interviewer selected further households using the same method as for the main sample until the quota was met. Questionnaires from oversampling were specifically marked to differentiate them from the main sample to allow application of different weighting factors based on selection probability before they were merged into the final sample.

Study Instrument

Participants completed a self-administered paper-and-pencil questionnaire that was provided with instructions for completion. The questionnaire was

Table 1
A Summary of Relevant Changes to Questionnaire from Pilot Wave to Wave 1,
Concerning Tobacco Use Behavior

No.	Change Description
1	The questions regarding smoking/using 1–2 years ago and the amount of use up until 12 months ago were removed and the graphic visualization of the time periods were removed. Based on that, the order of questions was changed, and some questions were rephrased to be more specific
2	Preferred flavor for THP was specified as ‘Menthol flavor’, ‘Non-menthol flavor’, and ‘No flavor’
3	The addition of product name HEETS together with HeatSticks and NEOs together with NeoSticks, as they are sold in parallel
4	The sections on ‘Pipe and Kiseru’ and ‘Cigars and Cigarillos’ were deleted and summarized in the section on ‘Other Tobacco Products’
5	The section ‘Other tobacco heating products’ was added to account for THPs that entered the market after the questionnaire was finalized

adapted, as necessary, based on the results of the pilot study to cover topics that evolved during the study run time and which were found to be essential for tobacco use behavior (Table 1).¹¹

Survey Distribution and Data Collection

Interviewers visited target households and posted a card explaining the purpose of the study, a request to participate, and contact information. They returned on a different day to make first personal contact. Once the selected respondent in the household had been identified and consented to hear about the study, the interviewer explained the purpose of the study, provided a participant information letter, and answered questions, if necessary. If the respondent agreed to participate in the study, the interviewer provided the questionnaire and requested completion. By completing the questionnaire, the participant implicitly gave consent to participate.

The interviewer checked the returned data for completeness and correctness, and if necessary, asked the participant to clarify any unclear information and/or complete missing parts of the questionnaire. Completed questionnaires were returned in person or securely posted to the fieldwork provider for data entry. For completion of the questionnaire, each participant received a cash voucher for JPY1000 (approximately 10 US dollars).

Measures

Full details on the measures used in this study

were published as part of the protocol in 2019.¹⁴ All measures outlined had been used successfully in the 2018 pilot survey and were deemed appropriate for the first nationwide wave.¹¹

Intention to quit the use of cigarettes and THPs among current users was measured using the contemplation ladder, where 0 indicates no thought of quitting and 10 indicates taking action to quit.¹⁶ Reasons for THP use were assessed using tools available in published literature.¹⁷ The Heaviness of Smoking Index was used to estimate self-reported dependency on nicotine.¹⁸ Changes in tobacco use among the categories never users, current users, and former users were compared with self-reported status 12 months before the survey.

Data Analysis

All analyses were descriptive and were performed using appropriate epidemiological methods. The statistical evaluation was performed by using the software package SAS release 9.4 or higher (SAS Institute Inc., Cary, NC). Raw data were converted by the Clinical Data Interchange Standards Consortium Study Data Tabulation Model and processed into analysis datasets according to CDISC Analysis Data Model specifications, using Implementation Guide final version 1.1 and document final version 2.1 (CDISC, Austin, TX).

Weightings were applied to adjust for probabilities of selection of a respondent and non-response, with adjustments made according to known characteristics of the population.¹⁴

Table 2
Study Population Characteristics by Tobacco Use Status

Parameter	Total (N = 5306.1)	Never user (N = 3388.4)	Current user (N = 933.5)	Former user (N = 984.2)
Sex				
Male	2561.8 (48.3%)	1090.7 (32.2%)	704.9 (75.5%)	766.2 (77.9%)
Female	2744.3 (51.7%)	2297.8 (67.8%)	228.6 (24.5%)	217.9 (22.1%)
Age (years)				
Mean (SE)	53.5 (0.32)	53.4 (0.41)	48.2 (0.58)	58.8 (0.58)
Median	52.9	52.9	46.3	59.4
Minimum	20	20	20	20
Maximum	96	96	91	95
Highest level of education				
Junior high school	517.9 (9.8%)	312.4 (9.2%)	103.3 (11.1%)	102.2 (10.4%)
High school	2175.3 (41.0%)	1291.2 (38.1%)	467.1 (50.0%)	417.1 (42.4%)
Professional training college	642.3 (12.1%)	421.4 (12.4%)	106.1 (11.4%)	114.8 (11.7%)
Junior college	441.2 (8.3%)	361.8 (10.7%)	32.9 (3.5%)	46.5 (4.7%)
College, university, or graduate course	1379.7 (26.0%)	894.2 (26.4%)	200.9 (21.5%)	284.7 (28.9%)
Prefer not to answer	146.3 (2.8%)	104.0 (3.1%)	23.3 (2.5%)	19.0 (1.9%)
Missing	3.4 (0.1%)	3.4 (0.1%)	0.0 (0.0%)	0.0 (0.0%)
Employment status				
Person working in agriculture, forestry, or fisheries	69.1 (1.3%)	42.9 (1.3%)	9.4 (1.0%)	16.8 (1.7%)
Self-employed, family business, or professional	496.1 (9.3%)	249.3 (7.4%)	105.9 (11.3%)	140.9 (14.3%)
Regular employee	1725.8 (32.5%)	920.7 (27.2%)	461.3 (49.4%)	343.8 (34.9%)
Non-regular employee (part-timer)	871.2 (16.4%)	621.8 (18.3%)	141.7 (15.2%)	107.8 (11.0%)
Unemployed	329.5 (6.2%)	192.9 (5.7%)	49.1 (5.3%)	87.5 (8.9%)
Student	127.8 (2.4%)	112.7 (3.3%)	12.3 (1.3%)	2.8 (0.3%)
Full-time homemaker	809.5 (15.3%)	700.6 (20.7%)	46.9 (5.0%)	62.0 (6.3%)
Pensioner	745.0 (14.0%)	463.3 (13.7%)	73.4 (7.9%)	208.4 (21.2%)
Prefer not to answer	131.6 (2.5%)	83.8 (2.5%)	33.6 (3.6%)	14.1 (1.4%)
Missing	0.5 (0.0%)	0.5 (0.0%)	0.0 (0.0%)	0.0 (0.0%)

(continued on next page)

RESULTS

Population Characteristics

From the 24,071 listed households visited, 3914 (16%) interviews were completed successfully. Out of the remaining failed interviews, 12,381 (51% of all households visited) households could not be reached, 7642 (32%) refused to complete, and 134 (1%) returned an incomplete questionnaire. In cases where the number of completed interviews from the listed households was insufficient, the inter-

viewers visited unlisted households, with the same approach as for the listed sample, until reaching the required number of completions. From the 16,096 unlisted households visited, 1125 interviews (7%) were completed. The overall number of interviews completed includes 2 booster samples, both of 154 participants, in the 20-24-year-old and 25-29-year-old age groups.

Two participants with insufficient information to classify current tobacco use were excluded from

Table 2 (continued)
Study Population Characteristics by Tobacco Use Status

Parameter	Total (N = 5306.1)	Never user (N = 3388.4)	Current user (N = 933.5)	Former user (N = 984.2)
Marital status				
Never married	894.5 (16.9%)	651.2 (19.2%)	179.6 (19.2%)	63.7 (6.5%)
Married	3749.5 (70.7%)	2294.8 (67.7%)	633.4 (67.9%)	821.3 (83.4%)
Cohabiting	15.7 (0.3%)	5.5 (0.2%)	8.6 (0.9%)	1.6 (0.2%)
Widowed	369.5 (7.0%)	287.6 (8.5%)	25.5 (2.7%)	56.5 (5.7%)
Divorced	189.9 (3.6%)	86.8 (2.6%)	70.0 (7.5%)	33.0 (3.4%)
Prefer not to answer	87.0 (1.6%)	62.6 (1.8%)	16.4 (1.8%)	8.1 (0.8%)
Missing	0.0 (0.0%)	0.0 (0.0%)	0.0 (0.0%)	0.0 (0.0%)
Annual household income (JPY)				
< 3 million	1006.8 (19.0%)	666.8 (19.7%)	157.3 (16.9%)	182.6 (18.6%)
3 million to < 5 million	1234.1 (23.3%)	715.4 (21.1%)	272.4 (29.2%)	246.2 (25.0%)
5 million to < 10 million	1235.1 (23.3%)	725.3 (21.4%)	247.7 (26.5%)	262.1 (26.6%)
≥ 10 million yen	302.5 (5.7%)	191.7 (5.7%)	51.9 (5.6%)	59.0 (6.0%)
No income	49.5 (0.9%)	34.7 (1.0%)	7.7 (0.8%)	7.1 (0.7%)
Unknown	575.7 (10.8%)	451.4 (13.3%)	66.6 (7.1%)	57.7 (5.9%)
Preferred not to answer	899.8 (17.0%)	600.9 (17.7%)	129.8 (13.9%)	169.1 (17.2%)
Missing	2.6 (0.0%)	2.3 (0.1%)	0.0 (0.0%)	0.4 (0.0%)

Note.

Data are N (%) unless otherwise stated. Values are shown after weighting to account for oversampling in the 2 0-24-year-old and 25-29-year-old age groups and, therefore, are given to one decimal place.

the final analysis. Thus, the final analysis included 5306 respondents, of whom 933.5 (17.6%) were current users, 984.2 (18.5%) were former users and 3388.4 (63.9%) were never users of tobacco products (weighted respondent totals). The results are presented after weighting and, therefore, numbers of participants are given to one decimal place. Tables 2 and 3 show the characteristics of participants in the sample.

Overall Tobacco and Nicotine Product Use

Of the individuals interviewed, nearly two-thirds had never used tobacco (Table 2). The rates of never use were about twice as high in women as in men (83.7% vs 42.6%). Never use overall was highest among respondents aged 20-24 years (83.5%). Approximately equal proportions of the remaining one-third of participants were current and former users.

Cigarettes (manufactured and roll your own) were the most common currently used tobacco and

nicotine product (N = 775.5, 14.6%) among the survey population, followed by THPs (N = 283.4, 5.3%), e-cigarettes (N = 83.8, 1.6%), and other tobacco products (N = 24.8, 0.5%). Of 933.5 current tobacco users, 602.0 (64.5%) smoked cigarettes exclusively and 113.7 (12.2%) used THPs exclusively. Exclusive use of cigarettes was proportionately higher among women than men (69.1% [158.0] vs 63.0% [444.0]), as was that of THPs (16.9% [38.5] vs 10.7% [75.2]). Exclusive THP use was highest in the age groups 25-29 years (17 [21.6%]) and 30-39 years (37 [20.5%]); however, and interestingly, the prevalence was much lower among 20-24-year-olds (6.5%, N = 2.7). By contrast, exclusive cigarette use was most common among the older age groups, ranging between 69.7% and 87.5% in the 4 age groups between 50 and 80+ years.

Current dual use of cigarettes and THPs was reported by 118.5 (12.7%) respondents. Dual use was observed more frequently in men than women (98.3 [13.9%] vs 20.2 [8.8%]) and was most common in

Table 3
Study Population Age Characteristics by Sex

Age (years)	Total (N = 5306.1)	Male (N = 2561.8)	Female (N = 2744.3)
20-24	306.9 (5.8%)	157.0 (6.1%)	149.9 (5.5%)
25-29	314.8 (5.9%)	161.2 (6.3%)	153.6 (5.6%)
30-39	759.0 (14.3%)	387.9 (15.1%)	371.1 (13.5%)
40-49	960.4 (18.1%)	489.3 (19.1%)	471.1 (17.2%)
50-59	799.9 (15.1%)	402.5 (15.7%)	397.5 (14.5%)
60-69	886.3 (16.7%)	433.7 (16.9%)	452.6 (16.5%)
70-79	879.3 (16.6%)	372.5 (14.5%)	506.8 (18.5%)
≥ 80	399.6 (7.5%)	157.9 (6.2%)	241.7 (8.8%)

Note.

Values are shown after weighting to account for oversampling in the 20-24-year-old and 25-29-year-old age groups and, therefore, are given to one decimal place.

the 20-24-year-old age group (14.0 [33.2%]) than in the other age groups (13.4-36.2 [12.0-16.6%] in the age groups between 25 and 59-years, 1.9-9.0 [2.2-6.9%] in the age groups between 60-79-years, and 0 in the ≥ 80-years age group). When exclusive and dual users were combined, the prevalence of cigarette use was 77.2% (N = 720.5), and THP use was 24.9% (N = 232.2). THP poly-use with e-cigarettes or other tobacco product was reported by 85.0 (9.1%) current tobacco users.

Manufactured and 'Roll Your Own' Cigarette Use

Current cigarette use in the overall survey population was reported by 775.5 (14.6%) respondents and was markedly higher among men than among women (591.8 [23.1%] vs 183.7 [6.7%]). 1102.6 (20.8%) respondents reported former use of cigarettes. Most (711.5 [93.3%]) current cigarette smokers reported daily use whereas only 49.8 (6.5%) respondents reported smoking cigarettes occasionally (average use on 10.2 (0.82 SE) of the past 30 days).

Daily users smoked an average of 15.6 (0.33 SE) cigarettes per day, with number slightly lower for women than men (13.6 [0.53 SE] vs 16.2 [0.39 SE]). Occasional smokers consumed a mean of 6.1 (0.82 SE) cigarettes on days they smoked.

Among current cigarette smokers, most preferred

no added flavor (472.9 [62.0%]), 223.7 (29.3%) preferred menthol and 63.8 (8.4%) preferred other flavors. The most common cigarette tar level was 1-3mg (287.6 [37.7%]), followed by 4-6mg (183.8 [24.1%]), 7-9mg (130.7 [17.1%]) and 10 mg or higher (137.5 [18.0%]). More women than men preferred lower tar levels (1-6 mg; 132.1 [72.3%] vs 339.2 [58.6%]).

Nicotine dependency scores were available for 711.5 current daily smokers and were mainly medium (360.3 [50.6%]) followed by low (311.1 [43.7%]) then high (38.7 [5.4%]). More men were classified as having a high nicotine dependence level (35.9 [6.6%]) than women (2.7 [1.6%]). Time to first cigarette after waking was 5 minutes in 198.7 (26.1%) current cigarette smokers and 6-30 minutes in 329.2 (43.2%).

Over one-fifth of current cigarette smokers (168.5 [22.1%]) had no thought of quitting and over one-fourth (209.9 [27.5%]) reported they would consider quitting someday. Only 74.0 (9.7%) were taking action to quit. Previous quit attempts were reported by 472.3 (61.9%) current smokers, among whom 339.3 (71.8%) had tried more than 12 months ago. When asked about their most recent quitting attempt, most (155.0 [32.8%]) had stopped for 8-29 days, compared with less than one day (61.3 [13.0%]), 1-7 days (61.3 [13.0%]) or one year or longer (63.0 [13.3%]).

Table 4
Self-reported Reasons for Use of Tobacco Heating Products among Current and Former Users

Reasons	Total (N = 336.7)	Male (N = 260.6)	Female (N = 76.1)
They might be less harmful to me than conventional cigarettes	205.3 (61.0%)	157.7 (60.5%)	47.6 (62.5%)
They might be less harmful to people around me than conventional cigarettes	193.2 (57.4%)	147.0 (56.4%)	46.1 (60.6%)
They produce no ash	176.2 (52.3%)	132.9 (51.0%)	43.2 (56.8%)
THPs don't smell bad	134.2 (39.8%)	105.4 (40.4%)	28.8 (37.8%)
THPs contain no tar	102.6 (30.5%)	80.2 (30.8%)	22.4 (29.4%)
I was curious about THPs	95.7 (28.4%)	80.3 (30.8%)	15.4 (20.2%)
THPs don't bother people who don't use tobacco	84.8 (25.2%)	64.2 (24.6%)	20.6 (27.0%)
I can use them in places where smoking conventional cigarettes isn't allowed	70.4 (20.9%)	58.7 (22.5%)	11.8 (15.4%)
Using a THP feels like smoking a conventional cigarette	57.8 (17.2%)	46.3 (17.8%)	11.5 (15.1%)
THPs can help me cut back on smoking conventional cigarettes	56.3 (16.7%)	48.3 (18.5%)	7.9 (10.4%)
It helps me to cope with stress and to relax	54.0 (16.0%)	35.8 (13.7%)	18.2 (24.0%)
I have a friend or family member who uses THPs	51.6 (15.3%)	30.2 (11.6%)	21.4 (28.1%)
They help me deal with cravings to smoke	34.8 (10.3%)	23.6 (9.1%)	11.2 (14.7%)
THPs can help me quit smoking	33.3 (9.9%)	25.2 (9.7%)	8.1 (10.6%)
THPs are new and innovative products	31.5 (9.4%)	27.7 (10.6%)	3.8 (5.0%)
Out of habit	13.7 (4.1%)	10.7 (4.1%)	3.0 (4.0%)
They deliver a real tobacco taste	11.9 (3.5%)	10.8 (4.2%)	1.1 (1.4%)
Other reason	4.0 (1.2%)	4.0 (1.5%)	0.0 (0.0%)

Note.

Values are shown after weighting to account for oversampling in the 20-24-year-old and 25-29-year-old age groups and, therefore, are given to one decimal place.

THP Use

Current THP use in the overall survey population was reported by 283.4 (5.3%) and former use was reported by 53.3 (1.0%). Of brands available in Japan, 590.2 (76.1%) current smokers had heard of iQOS, 449.7 (58.0%) of glo, 401.7 (51.8%) of Ploom TECH, and 129.0 (16.6%) of other THPs. Current or former use of iQOS was the most frequent (253.1 [75.2%]), followed by glo (94.1 [27.9%]), and Ploom TECH (85.3 [25.3%]). Daily use followed a similar pattern (iQOS 158.2 [86.6%] followed by glo 42.8 [67.2%], and Ploom TECH 33.6 [53.9%]).

Among all current tobacco product users, 113.7 (12.2%) used THPs exclusively and an additional

118.5 (12.7%) reported dual use with cigarettes. Average daily THP consumption was 14.3 (0.7 SE) tobacco sticks for iQOS, 14.5 (1.1 SE) tobacco sticks for glo, and 3.6 (0.2 SE) capsules for Ploom TECH. Occasional use in the previous 30 days was reported by 23.1 (12.7%) for iQOS, 20.9 (32.8%) for glo, and 28.7 (46.1%) for Ploom TECH, on a mean number of 8.4 (± 1.2), 10.3 (± 1.1), and 7.9 (± 1.2) days, respectively.

Among the 283.4 current THP users, 27.1 (9.6%) respondents reported THP poly-use. Most used 2 THPs (iQOS and Ploom TECH, 10.1 [3.6%], followed by glo and iQOS, 7.1 [2.5%]). Use of all 3 THPs was reported by 5.5 (1.9%) respondents.

Menthol was the most popular flavor of THP

Table 5
Self-reported Changes in Tobacco Use Behavior from 12 Months Prior to Survey

Tobacco product use 12 months prior to survey	Tobacco product use at time of survey				
	Total	Current exclusive cigarette use	Current exclusive THP use	Current dual user	Former tobacco products user
Total	940.6 (100.0% / 100.0%)	582.3 (100.0% / 61.9%)	103.5 (100.0% / 11.0%)	115.1 (100.0% / 12.2%)	48.4 (100.0% / 5.1%)
Exclusive cigarette user 12 months ago	688.1 (73.2% / 100.0%)	569.3 (97.8% / 82.7%)	14.6 (14.1% / 2.1%)	33.8 (29.4% / 4.9%)	36.4 (75.2% / 5.3%)
Exclusive THP user 12 months ago	91.2 (9.7% / 100.0%)	0.0 (0.0% / 0.0%)	82.0 (79.2% / 89.9%)	0.8 (0.7% / 0.8%)	2.7 (5.5% / 2.9%)
Dual cigarette and THP user 12 months ago	97.2 (10.3% / 100.0%)	10.7 (1.8% / 11.0%)	6.9 (6.7% / 7.1%)	76.0 (66.0% / 78.2%)	3.5 (7.2% / 3.6%)

Note.

Values are shown after weighting to account for oversampling in the 20-24-year-old and 25-29-year-old age groups and, therefore, are given to one decimal place. Percentages are presented as the % of the column followed by the % of the row. Some users transitioned to/from behaviors not included within the table.

consumable (209.4 [62.2%]), followed by no added flavor (71.6 [21.3%]), and non-menthol flavors (55.7 [16.5%]). Proportionately more women than men preferred menthol (75.6% [N = 57.6] vs 58.3% [N = 151.9] of responses).

Among current and former users, the most common reason for using a THP was that “they might be less harmful to me than conventional cigarettes,” followed by “they might be less harmful to people around me than conventional cigarettes,” and “they produce no ash” (Table 4). The use of THPs as a way to cut back on smoking conventional cigarettes, reduce cravings for cigarettes, or quit smoking were cited by small proportions of respondents, (16.7%, 10.3% and 9.9%, respectively; Table 4).

Changes in Tobacco Product Use

Product use 12 months before the survey was reported by 940.6 respondents (Table 5). Among the 688.1 respondents who reported being exclusive cigarette smokers 12 months previously, 48.4 (7.0%) had initiated the use of a THP at the time of the survey. Of these, 33.8 (4.9%) had changed to dual use and 14.6 (2.1%) had switched completely to THPs. The initiation rates were similar for men and women (35.7 [7.0%] and 12.7 [7.2%], re-

spectively). Among the 97.2 earlier dual users, 6.9 (7.1%) had switched completely to exclusive THP use at the time of the survey.

Exclusive THP use with no history of smoking 12 months previously was reported by 10.2 respondents, none of whom had switched to exclusive cigarette use and 0.8 had switched to dual cigarette and THP use. No former smokers who switched completely to using THPs had re-initiated cigarette smoking within the previous 12 months. For former tobacco product use overall, 2.9% had reinitiated the use of tobacco in the previous 12 months, with the proportion being higher among women than men (5.7% vs 2.1%).

Among 939.0 former cigarette smokers with no history of THP use, 9 (1.0%) had initiated using THPs in the previous 12 months, and among 3420.7 never tobacco product users, 6.2 (0.2%) reported starting to use THPs.

Quitting of all tobacco products in the previous 12 months was reported by 48.4 (5.1%) of 940.6 respondents (Table 5), with a total of 61.4 (6.5%) having given up cigarettes, and 16.9 (1.8%) having quit the use of THPs. Most (39.1 [80.7%]) users who quit all tobacco products had been using only one product (exclusive cigarette or THP use) 12

months earlier. The quit rates for all tobacco products among women and men were similar (11.5 [5.2%] vs 29.7 [4.1%]). No clear trends in tobacco cessation were observed by age.

When looking at exclusive users 12 months before the survey, only 36.4 (5.3%) of 688.1 cigarette smokers and 2.7 (2.9%) of 91.2 THP users quit using tobacco products altogether (Table 5).

DISCUSSION

Although cigarette smoking in Japan has declined consistently since its peak in the 1970s, smoking prevalence remains high.^{11,19,20} In 2018, prevalence was estimated to be 17.9%, equating to about 18.8 million smokers nationwide.²⁰ In this national survey, we found that cigarettes were by far the most frequent tobacco product used in the general population, but that THP prevalence was notable at 5.3%. Small proportions of people used e-cigarettes, which are currently illegal in Japan if containing nicotine, or other tobacco products. Thus, Japan can effectively be classed as a 2-category tobacco product market. We found minimal uptake of THP use among respondents with no history of tobacco product use.

The main reasons for THP use in Japan were perceived reduction in harm, both to self and others, compared to conventional cigarettes. Similar observations have been reported in previous studies, which have proposed a link to Japanese cultural values, including cleanliness and respect for others.^{11,12} Interestingly, in contrast to our pilot study one year earlier, reduction in harm to self was reported more frequently than reduction in harm to others.¹¹ Remarkably low priorities were given to using THPs as a way to cut back on cigarettes or quit smoking. We noted that the intention to quit was close to the overall and the combined proportions of respondents who had quit the use of cigarettes and all tobacco products in the 12 months prior to the survey.

In general, tobacco product use did not change dramatically in the 12 months before the wave 1 survey. The proportion of respondents starting exclusive or dual THP use was lower than in our pilot study but, because the proportion of users quitting THPs was lower than the proportion initiating THP use, the overall prevalence remained at around 5%.¹¹ Approximately 90% of exclusive

THP users 12 months before the survey continued to be so; only one participant switched to dual use and none switched to exclusive smoking. More than three-fourths of dual users continued dual use and switching to exclusive use of cigarettes or THPs was seen in around 7% each. The stability of THP use in the general population over time suggests that THPs are being used as a longer-term full or partial substitution for cigarettes by consumers.

The study has various strengths. A comprehensive approach was applied to estimate product-specific use and to collect data on tobacco and nicotine product consumption nationwide. The large sample size of this study allowed for robust prevalence estimations and subgroup analyses to be conducted, and the selection of participants by a stratified 3-stage sampling method allowed for national generalizability of results. When compared with Japanese data from 2018, the overall and sex-stratified prevalence rates were similar and appeared to follow year-on-year trends.^{20,21} Such data will be critical in aiding understanding of population use behaviors over time and are being used to support population modeling of long-term health impacts based on estimated transition rates across product use status. The self-administered data collection method was selected to minimize any bias that could arise from social desirability for answers.

Some limitations are also associated with this study. Questionnaires were self-administered and the results might have been subject to recall and/or reporting bias. However, this is a limitation inherent to all survey methods and there was no benefit to participants from answering the questions inaccurately or untruthfully. Previous surveys have shown that self-administered questionnaires adequately capture tobacco use in populations and that smokers estimate average daily cigarette consumption fairly accurately.^{22,23} The collection of cross-sectional data allowed only assessment of changes of use behavior; to assess use trajectories over time, longitudinal studies would be needed. It also could be argued that the overall response rate for the survey is relatively low. However, due to the method of calculation, the sampling method utilized, and previous experience, the response rate was deemed satisfactory by the research team and is comparable to other work conducted in Japan with this method. For example, over half of the households in the

listed sample could not be reached and were still included within the calculation of overall response rate. If considering only those households who were reached, the response rate for the listed sample increases to approximately 32%. The reasons for failure in the unlisted sample were not tracked in all cases; however it is likely that the prevalence of 'no qualified respondent' was high due to often seeking participants in specific age groups in the over-sampled population. Additionally, a publication investigating the relationship between declining response rates in Japanese cross-sectional surveys and bias concluded that low response rates do not necessarily lead to biased results.²⁴ It should be noted that the examined studies occurred over a decade ago and had response rates of approximately 50%. Lastly, despite the response rate, prevalence rates of tobacco use found in this study were comparable to those in other published surveys.^{20,21}

Conclusions

As the prevalence of conventional cigarette use continues to decrease in Japan, that of THP use is overall seemingly increasing among tobacco product users and remains stable in the general population. The use of other tobacco containing products in Japan appears to be negligible. Thus, most Japanese tobacco consumers use cigarettes or THPs exclusively or together. However, there is little uptake of THPs among never tobacco users or of exclusive smoking among ex-exclusive THP users, suggesting the gateway effect of THPs is negligible. Overall, the results of this survey suggest that THPs are being accepted as a long-term alternative to cigarette smoking in Japan. This first wave of the study supported the methodology and study instrument, which will continue to be used in the next wave.

IMPLICATIONS FOR TOBACCO REGULATION

The data collected from this study, such as use patterns, behavior, and transition rates, are key to assessing the reduced-risk potential of novel tobacco and nicotine products (such as THPs) at a population level. As an example, the National Academy of Medicine (NAM), formerly known as the Institute of Medicine (IOM), outlined a series of standards for scientific studies assessing potential modified risk tobacco products (MRTPs), and

stated that observational epidemiologic studies, such as this one, "play a critical and central role" in these assessments.³ Furthermore, post-market surveillance and studies are deemed essential by the US Food and Drug Administration (FDA) in their draft guidance for MRTTP applications.²⁵

This study provides regulators and scientists with key real-world data on tobacco and nicotine product use after the introduction of THPs in Japan. As the study population covers both current tobacco users and non-users, such as former users and never users, we can begin to understand the implications of THP introduction on the population and society as a whole. Given the early and relatively large uptake of THP use in Japan, there are likely many key learnings that other regulatory agencies can take from their approach.

Importantly, this study also provides regulators with further evidence of THP uptake being almost exclusively among current tobacco users in Japan, with negligible uptake among never tobacco users and no evidence of participants switching (gateway effect) from exclusive THP use to exclusive cigarette use. Finally, the data on real-world transition rates obtained from this study will be used to inform the population modeling of long-term health impacts of, for example, switching completely from smoking to THP use.

Human Subjects Approval Statement

The study protocol and surveillance tool were approved by an independent ethics committee at Kitamachi Clinic (Tokyo, Japan) prior to commencing data collection (study reference: *Repeated Cross-sectional Study to Assess Tobacco and Nicotine Usage Patterns and Behavior after Market Introduction of glo in Japan*).^{11,14}

Conflict of Interest Disclosure Statement

At the time of the study, JJ, JA, KP, OMC, YKB, and JM were employees of British American Tobacco. This work was fully funded by British American Tobacco (Investments) Limited.

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