STUDY PROTOCOL

Protocol for a Japanese nationwide repeated cross-sectional study to assess tobacco and nicotine product use behaviour after market introduction of tobacco heating products (THPs) [version 1; peer review: 1 approved, 1 approved with reservations]

Jason Adamson ¹, Claudia Kanitscheider², Krishna Prasad¹, Oscar M. Camacho¹, Elisabeth Beyerlein², Yoga Keralapura¹, Christopher Proctor ¹, James Murphy¹

¹Research & Development, British American Tobacco, Southampton, UK

²Kantar Health Division, Kantar, Munich, Germany

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Abstract

Background - In recent years there has been a proliferation of alternative tobacco and nicotine products that reduce consumers' exposure to harmful substances and therefore have the potential to reduce risk to health. Post-market surveillance enables the evaluation of newly introduced tobacco and nicotine products (aka potentially reduced risk products (PRRPs)) at a population level. This study aims to investigate tobacco and nicotine consumer demographics and discover how people are using these products, and characterise behavioral trends as transitions between tobacco heated products (THPs) and other nicotine products. These behavioural aspects, in conjunction with the intrinsic risk of the product, are essential for assessing the potential health effects and establishing a population risk assessment.

Design and methods - This epidemiological cross-sectional study will collect data using a self-administered study instrument from the general Japanese population aged 20 years and older. The targeted sampling size is up to 5,000 participants per study wave. The study addresses the following objectives: estimation of tobacco and nicotine use prevalence; characterisation of product usage by product type; changes in use behaviour in general, with particular emphasis on the introduction of THPs in the time period of one year; risk perceptions of different tobacco products and no tobacco usage; and participant perceived health status and quality of life.

Discussion - The description of tobacco and nicotine product use

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Approval Status

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1. Thomas Verron , Imperial Brands plc, Paris, France Xavier Cahours , SEITA-Imperial Brands, Paris, France		
2. Axel Klein , ACK Consultants, London, UK DAI, Bethesda, USA		
Any reports and responses or comments on the article can be found at the end of the article.		

behaviour, the estimation of prevalence data, the measuring of product-specific risk perception and the change of tobacco use behaviour within one year will allow for a comprehensive assessment of the effect of introducing THPs into a market. These data could also be used to inform a system dynamics population model in order to estimate the public health impact of introducing a THP into the Japanese market.

Keywords

Post-market surveillance, Population studies, Cross sectional survey, Tobacco Heating Products (THPs), Harm reduction

Corresponding author: Jason Adamson (jason_adamson@bat.com)

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Introduction

Tobacco is used by more than one billion people globally [MacKay *et al.*, 2006], and combustible tobacco is the most common form of tobacco use. Epidemiological data has concluded that smoking significantly increases the risk of diseases such as cardiovascular disease, COPD and lung cancer [US Department of Health and Human Services, 2014]. Tobacco Harm Reduction is a concept described, amongst others, by the Institute of Medicine (IOM) in their monologue *Clearing the Smoke* [Stratton *et al.*, 2001], which summarised that population health could be improved by replacing high-risk combustible tobacco products like cigarettes with innovative lower risk tobacco and nicotine products. This has led to an increase in alternative tobacco and nicotine products that have the potential to reduce exposure to harmful substances and reduce individual health risk. Some have termed such innovations as *potentially reduced risk products*, or PRRPs, and include electronic cigarettes (e-cigarettes), tobacco heating products (THPs), and oral tobacco products like Scandinavian style snus, amongst others.

The US Institute of Medicine (IOM) outlined standards for studies assessing the effectiveness of potentially reduced risk products (PRRPs) and implications of their market introduction [IOM, 2012]. Providing data to support the evaluation of behaviour/usage patterns of these new products is one of the important factors in assessing population health risk reduction. For this purpose, not only current tobacco users, but also non-users (never users and former users) must be taken into account. This inclusive approach is pursued to ensure that the population as a whole can benefit from the introduction of PRRPs into a market (not just current combustible tobacco users).

Consumer comprehension of risk perception associated with PRRP use is also crucial for acceptance and continued use, and depends on consumer exposure to product information and peer-to-peer communication [Pepper *et al.*, 2015; Roditis & Halpern-Felsher, 2015]. In addition to risk perception, acceptance and continued use of new products depend on perceived benefits for users. Studies about quality of life (QoL) assessing smoking cessation suggested wellbeing improvements [Piper *et al.*, 2012]. Therefore, it is reasonable for survey based studies to explore the impact of switching to PRRPs on QoL and short-term health effects.

Several groups, tobacco industry [Murphy *et al.*, 2017; Smith *et al.*, 2016] and independent [Berman *et al.*, 2015; Farsalinos & Polosa, 2014], have published scientific assessment frameworks which outline the studies that should be conducted and comparator products that should be used to assess the emissions, exposure to harmful and potential harmful constituents (HPHCs) and risks of using PRRPs relative to combustible tobacco smoking. Each of these frameworks describe the requirement of assessing the risk profile of the PRRP at a population level.

British American Tobacco's (BAT's) approach to population risk profiling for PRRPs is informed by leading national and international public health agencies [CDC, 2012; FDA, 2012; WHO, 2012]. Their recommendations on population based

studies allow for the evaluation of the effect of introducing new products on consumer perception, behaviour and health [FDA, 2012]. The overarching objectives of BAT's surveillance programme are to:

- monitor in-market use-behaviours of tobacco and nicotine consumers in the population
- evaluate population perceptions of PRRPs (both users and non users of tobacco and nicotine products)
- evaluate the benefits and risks of PRRPs on the health of individuals and on the population as a whole
- use survey generated and market based data to inform a system dynamic population model [Hill & Camacho, 2017] to assess the impact of introducing one or multiple PRRPs on population morbidity and mortality
- identify and collect any adverse events related to BAT's PRRPs after they are launched in all markets (not just in Japan where this study is conducted)

Tobacco heating products (THPs) are just one sub-category of PRRP and contain tobacco that is heated (in a device, or with hot air passing through tobacco) but in contrast to cigarettes is not lit therefore cannot burn, thus there is no combustion [Eaton *et al.*, 2018; Simonavicius *et al.*, 2018; Smith *et al.*, 2016]. The lower temperatures of the THPs heating profile (a maximum of 240°C), compared to combustion temperatures within the lit end of a cigarette (greater than 950°C), results in reduced toxicant emissions [Forster *et al.*, 2018a; Mallock *et al.*, 2018; Schaller *et al.*, 2016] which in turn, results in lower biomarker of exposure (BoE) to HPHCs in humans compared to conventional combustible cigarettes [Gale *et al.*, 2017; Schaller *et al.*, 2016].

The aforementioned studies have demonstrated that THPs have potential to reduce harm to the individual user, however, the intrinsic risk of the product should also be contextualised within use behaviour patterns after market introduction to enable *population* risk assessment. Population use patterns would further be linked to consumer risk perception – such as how do non-users, cigarette smokers, solus THP users and dualist (THP and cigarette) users view the risk of THPs – and ultimately how a consumer switch or gradual transition away from cigarette consumption to solus THP use may lead to significant improvements in smoking related health effects and self-perceived quality of life.

Japan is a major market for THPs, in a nation with high smoking prevalence, in particular among men [Levin, 2013]. Of males 15 years and older in Japan in 2015, smoking prevalence (using tobacco daily) was 33.7%; by contrast, prevalence in the UK and US was 19.9% and 19.5% respectively (Tobacco Atlas, 2018). In addition to the individual harm reduction potential already described [Forster *et al.*, 2018a; Gale *et al.*, 2017; Haswell *et al.*, 2018; Jaunky *et al.*, 2018; Mallock *et al.*, 2018; Schaller *et al.*, 2016; Smith *et al.*, 2016], THPs are likely to resonate very well in Japan given the strong cultural values of order, cleanliness, quality and respect for others [Hair *et al.*, 2018], and these could be potential driving factors for Japanese

consumers switching from combustible cigarettes to THPs. Thus reduced residual odour on consumers' clothes and hair [Forster *et al.*, 2018b], reduced teeth staining [Dalrymple *et al.*, 2018], reduced side stream smoke, no ash and improved indoor air quality versus combustible cigarettes (Ichitsubo & Kotaki 2018; Forster *et al.*, 2018b; Mitova *et al.*, 2016; Mottier *et al.*, 2016) may be considered strong additional motivations for some Japanese consumers switching from cigarettes to THPs.

In Japan, several different tobacco heating products are currently available on the market [Tabuchi *et al.*, 2018]. *iQOS* from Philip Morris [Smith *et al.*, 2016] was launched countrywide in 2014 after having been tested in selected regions. BAT's THP *glo* [Eaton *et al.*, 2018] entered the market at the end of 2016 with a city-launch in Sendai. *ploom TECH* from Japan Tobacco was introduced in central Tokyo in June 2017 [Reuters, 2018]. All three THPs are referred to in the study instrument (Appendix 1). More recently, Korean Tobacco and Ginseng (KT&G) released their THP *Lil* in Seoul in November 2017 [Tobacco Reporter, 2017]. *Lil* was not included in the survey at the time of the pilot study due to its nascent release in South Korea, but may still be accessible to consumers in neighbouring Japan. Additionally there are numerous and diverse THPs emerging from other markets (such as China). Despite this rapidly evolving and innovative product category, this study will allow us to explore the effect of the availability of THPs on the Japanese population as well as to investigate use patterns within this specific consumer product category.

The following sections of this manuscript will describe the study details, from instrument design and participant selection, through to ethics approval.

Study aim and design

The aim of this study is to describe the usage patterns of tobacco and nicotine containing products in Japan. This includes the estimation of prevalence rates for overall tobacco use, and by product type as well as usage pattern (solus product use, for example someone who only smokes cigarettes or only uses THPs; dual product use, someone who smokes cigarettes and uses THPs; and multi product use, someone who uses two or more different tobacco and/or nicotine products). In addition, information about frequency and amount of product use is collected as well as intention to quit for cigarette smoking and different THPs. The effect of the market introduction of THPs on the population as a whole will be evaluated for: initiation rates among tobacco non-users and former users; consumer switching rates from cigarettes to THPs, and back again to cigarettes (switch back); initiation of dual use; switching from solus THPs to dual use or solus cigarette smoking (gateway effect) and re-initiation rate of tobacco use among former tobacco users. Risk perception of different tobacco products and health-related QoL are also assessed, as well as smoking related short-term health effects among different tobacco user groups.

The tobacco use behaviour of the Japanese population will be characterised by the collection of data on a regular basis over a defined time period. This allows the assessment of usage

behaviour at specific time points (point prevalence) and also to explore changes on an individual level within the last 12 months. A repeated, nationwide, population-representative cross-sectional survey is chosen to fulfil the study requirements. A pilot study (in Sendai, Tokyo and Osaka only) was implemented to test the envisaged approach in the first year (2018). The results of the pilot study are used to optimise the conduct of the first nationally representative wave commencing in 2019.

Participant selection

A geographically stratified three-stage probability sampling will be applied. The sampling universe comprises all persons aged 20 years and older (which is the legal age to consume tobacco in Japan) living in private households in Japan. Additional inclusion criteria are that the participant is able to speak and read Japanese, and be willing to participate after selection and the information about the study was provided. Pregnant and breast-feeding participants are eligible to participate, as are employees of legal, journalistic, media and tobacco industries; there is no recruitment bias. The only exclusion criterion additional to the legal age of smoking are any persons belonging to the institutionalised population (currently living in prisons, military bases, mental facilities, homes for the aged).

After the pilot study (in Sendai (Miyagi Prefecture, Tohoku region), Tokyo (Kanto region) and Osaka (Kinki region)) for subsequent study waves the nation will be stratified based on all 47 prefectures of Japan across nine regions (Chugoku, Hokkaido, Hokuriku, Kanto, Kinki, Kyushu, Shikoku, Tokai, Tohoku). In each of these nine regions, municipalities are stratified into four urbanisation degrees, based on the population of each municipality from the Basic Resident Registration population data: these are major cities (Government-designated metropolitan areas), large cities (>150,000 population, excluding major cities), medium cities (<150,000 population), and small towns.

First stage selection is based on the primary sampling units (PSU) which is a street block, selected by stratified random sampling. From the Basic Resident Registration population data (published by the Japanese Ministry of Internal Affairs and Communications (MIC)) within each stratum, 500 PSUs are selected in total proportionately to the population density. PSUs within each stratum are listed in ascending order of the municipality codes, and are selected by a randomly chosen starting number (no greater than the skip interval which is calculated as target population in each stratum divided by number of PSUs in the respective stratum). Second stage selection occurs within each PSU, all of the households are listed in ascending order of the street numbers, using the residential map database (ZENRIN Co Ltd. (ZENRIN)). A household starting number is randomly chosen to select the first household. In total, 50 households per PSU are chosen using regular numeric intervals and are listed on the household list for interviewers. Third stage selection occurs within the selected household and the individual respondent is selected by next birthday method (Salmon & Spicer Nichols, 1983). Only one individual is selected from each household.

The 20–24 year old population are identified in our sampling universe as a vulnerable group (more susceptible group) as this is most likely where tobacco product initiation takes place; additionally regulators are concerned that PRRPs may appear more attractive and appealing to this age group [FDA, 2012]. As THPs could be considered ‘high tech’ and aspirational products, youth and young adults could be more interested in such product positioning, and therefore this could raise some concern about youth appeal (Hair *et al.*, 2018). Additionally, based on fieldwork experiences in the past, this age group is under-represented in the applied sampling method, thus in our study the 20–24 year old population are oversampled to ensure robust estimates for this category. The oversampling quota will be assigned to each PSU. Once the target sample size is reached the interviewer will randomly select the household using the same method as for the main sample and uses the quota sampling method for selecting individual respondents aged 20–24 years. Questionnaires from oversampling are specifically marked (by participant ID only, thus participants are unaware of this) to differentiate them from the main sample as different weighting factors will be applied based on selection probability before merging them to one final sample.

Study measures

Estimation of prevalence

Prevalence estimates will be calculated for never tobacco users, ever tobacco users, former tobacco users, and current tobacco users, among current tobacco users by product type and for usage patterns (solus product use, dual product use, multi product use). Participants were classified as never, ever, current or former product user depending on if they have ever used the product, used them in the past, or are currently using them and if they smoked at least 100 cigarettes/consumables or used the equivalent amount of tobacco in their lifetime for the following products: manufactured cigarettes/roll your own cigarettes, pipes/kiseru, cigars/cigarillos, THPs (separately for *glo*, *iQOS*, *Ploom TECH*), e-cigarettes and smokeless tobacco products.

Characterization of product usage by product type

For users of the respective product and partially for former users the following details are collected: duration of product use, when they stopped using the product, frequency and amount of used product, flavour preferences, if applicable, and for current manufactured cigarettes/roll your own cigarettes and THPs their motivation to quit, ever tried to quit, last quit attempt and duration. Motivation to quit tobacco product use will be measured with the Contemplation Ladder [Amodei & Lamb, 2004; Biener & Abrams, 1991]. Tar level and time to first cigarette in the morning was additionally collected for current users of manufactured cigarettes/roll your own cigarettes. For the determination of nicotine dependency the Heaviness of Smoking Index (HSI) [Heatherton *et al.*, 1989] is used. This index consists of two questions considering the amount of smoked cigarettes per day and time to first cigarette smoking in the morning. The composite measure of nicotine dependency is derived from a six-point scale and then categorized as low (0–2), medium (3–4) and high (5–6) dependency.

The effect of the market introduction of THPs on tobacco use behaviour among tobacco users¹ is investigated by collating the following data:

- Initiation rate of THPs among combustible tobacco users within the last 12 months
- Switching rate for THPs: percentage of combustible tobacco users who switched from smoking to THPs within the last 12 months
- Dual use rate (smoking cigarettes and using a THP): percentage of combustible tobacco users who started usage of THPs in parallel to existing smoking behaviour within the last 12 months
- Poly-use of THPs: Percentage of current THP users using more than one THP in parallel
- Switching rate from THPs to cigarette smoking (gateway effect): percentage of THP users without smoking history who initiated THP use more than 12 months ago and who switched to solus cigarette smoking within the last 12 months
- Switching rate from THPs to dual use (gateway effect): percentage of THP users without smoking history who initiated use more than 12 months ago and who started smoking in parallel to usage of THPs within the last 12 months
- Relapse/switch back rate from THPs to smoking: percentage of THP users with smoking history who initiated use more than 12 months ago and who re-initiated cigarette smoking in parallel to usage of THPs within the last 12 months or who switched back to solus smoking within the last 12 months
- Cessation rate: Percentage of tobacco users who quit using tobacco products in the last 12 months: overall and by product type

The effect of the market introduction of THPs on tobacco use behaviour among tobacco non-users² is investigated by collating the following data:

- Initiation rate of THPs among never and former tobacco users within the past 12 months
- Re-initiation rate of tobacco products: percentage of former tobacco users who re-initiated tobacco use after a stop period of at least 12 months

Risk perception

Perception of health risk is assessed separately for cigarettes, THPs and no tobacco use in terms of development of lung cancer, respiratory disease and heart disease respectively

¹ Tobacco users are participants who were users of any tobacco product 12 months ago.

² Tobacco non-users are participants who did not use any tobacco products 12 months ago.

(indirect measure) with a 7-point scale ranging from “No risk=1” to “Substantial risk=7”. Furthermore, perceptions about the health risk of developing these three diseases from smoking cigarettes compared to using THPs (direct measure) is assessed with the following question: “Compared to continuing to smoke conventional cigarettes, using heated tobacco products has 1-a greater health risk; 2-the same level of health risk; 3-less health risk; 4-no health risk at all; or 5-I don’t know or not sure”. The comparison to cigarettes was chosen as it is the predicate product, and due to its predominant use compared to very small acceptance of other tobacco products, and the ban on e-cigarettes with nicotine containing liquids in Japan.

Global and health-related quality of life (QoL)

QoL is assessed among all study participants to explore differences based on tobacco usage behaviour. Global QoL is rated with a single question: “In general, would you say your quality of life is 1-Excellent; 2-Very good; 3-Good; 4-Fair; or 5-Poor”. Health-related QoL was measured separately for physical health, mental health, and overall health using the same 5-point scale. Additionally, 12-month prevalence of smoking-related short-term health effects is measured for 14 conditions related to teeth, mouth, nose, eyes, skin, lung, athletic ability and addiction to nicotine.

Questionnaire administration

A paper-based questionnaire will be used for data collection (see Extended data (Adamson, 2019)). Prior to fieldwork the questionnaire was forward and back translated to check for accuracy. Thereafter the questionnaire was pre-tested by the fieldwork provider Nippon Research Centre (NRC) with face validation interviews comprising a small sample of participants representing current and never tobacco and nicotine users. The pre-test was implemented to ensure completeness of skip logic as well as to highlight any questions or sections that may have caused uncertainty for the participant. No major issues were identified at the pre-test stage thus the questionnaire was approved for study use. In addition to the above listed study measures, sociodemographic information is collected for all participants as gender, age, region (prefecture), education, employment status, income band, number of persons per residence and marital status. In order to minimize the influence of social desirability of tobacco use on participant response as best possible, and to allow respondents to document honest tobacco product use behaviour, the questionnaire will be self-administered. As with any self-administered questionnaire the quality of the results will be dependent on the honesty of the participant in their responses, as well as potential selection bias, recall bias, and incentive value. The completion of the questionnaire should take approximately 4 to 5 minutes for never users and 15 to 25 minutes for former and current tobacco users depending on the number of different products used. This approach was based on the successful completion of other consumer based studies in Japan.

Study sample size calculation

This study is descriptive in nature thus no statistical hypotheses are tested. Proportions and rates will be estimated based on the overall population as well as for subgroups of interest like users

of tobacco or nicotine-containing products, smokers and users of THPs. In Japan the smoking rate at the time of this study was 19.8%; stratified by gender the proportion of men smoking cigarettes was 31.1% and the proportion of women was 9.5% [Ministry of Health, Labour and Welfare (MHLW) 2016].

To allow for subgroup analyses and further stratification, a sufficient number of observations per cell is needed [Kish, 1995]. Thus, taking into account smoking prevalence and expecting a male to female ratio of approximately 3:1, a sample size of N=5,000 is chosen.

The 95% confidence intervals (CIs) are estimated using a conservative exact method proposed by Clopper and Pearson [Clopper & Pearson, 1934]. We accounted for variance inflation due to clustering in k PSUs and m subjects per sampling unit in terms of effective sample size (ESS). The ESS bases on the intra-class correlation coefficient ρ as a relative measure of homogeneity of sampling units and is calculated as $ESS = (m*k)/(1 + \rho * (m-1))$ [Killip *et al.*, 2004].

With N=5,000 respondents randomly sampled, i.e. $m=10$ subjects per sampling unit, $k=500$ PSUs and $\rho=0.02$ (intra-class correlation coefficient) [Adams *et al.*, 2004] the resulting ESS is $n=4,237$. With an anticipated proportion $p=0.20$ (20%) of tobacco product users in Japan the absolute precision will be estimated as $e=\pm 0.012$ on a 95%-confidence level.

For the pilot study, as only three areas in Japan were selected, with 200 PSUs, a reduced sample size of N=4,000 was considered sufficient. This pilot enables assessment of the envisaged study procedures and to decide if the collected data answer the study objectives during following nationwide waves. An additional sub-sample of 150 subjects for the pilot will be included for the age group 20–24 years as this group could be paramount to understand nicotine and tobacco product use initiation (as previously discussed).

Data collection process

After identification of the target household by sampling the interviewer will visit the household and deliver a postcard containing an explanation of the purpose of the study, a request to participate and contact information (postcard is proprietary to the study fieldwork provider NRC). The interviewer will visit the household on a different day to make a first personal contact. Once the target person in the household has been identified and has agreed to meet/talk to the interviewer, the interviewer will explain the purpose of the study, hand out the Participant Information Letter (proprietary to NRC), and answer questions if necessary. If the target person agrees to participate in the study, the interviewer will provide the questionnaire and request completion. In cases where the participant is able to fill in the questionnaire immediately the interviewer will wait with the participant until the questionnaire is completed. In cases where the participant is not able to fill in the questionnaire immediately, or another household member is met, the interviewer will come back at a later time to collect the completed questionnaire.

If no member of the household is available the interviewer will put the Participant Information Letter describing the date of visit and the possible date of the next visit in the mail box, and will come back for the maximum of three additional times on different days at different times. If the target person in the household cannot be contacted and the questionnaire cannot be filled in by them, the interviewer proceeds to the next household on their list.

The interviewer will check the returned data for completeness/correctness and in case discrepancies are detected the interviewer will ask the participant to clarify these issues and/or complete missing parts of the questionnaire. Completed questionnaires are returned in person or per secured postal mail to the fieldwork provider's facility for data entry. For the completion of the questionnaire all study participants (whether they are a tobacco/nicotine consumer or not) will receive a small incentive in the form of a cash voucher (¥1,000 = ~\$9 USD).

Data management

Question routing (skip logic) is applied to guide the participant through the questionnaire. Data of collected paper questionnaires are entered manually by two independent persons into a proprietary electronic data capture (EDC) system (proprietary to Kantar Health GmbH) which is validated according to FDA 21 Code of Federal Regulations Part 11 (FDA 21). All data received will be mapped into a pre-defined format of Clinical Data Interchange Standards Consortium Study Data Tabulation Model (CDISC SDTM). The SDTM will then be transformed into Analysis Data Model (ADaM) data for analysis purposes.

Data analysis

All analyses are exploratory and descriptive. Categorical variables will be analysed by frequency tables (total number of observations, number of missing values as additional categories, absolute and relative frequencies). Continuous variables will be reported as summary statistics (total n, number of non-missing and missing values, mean, standard deviation, median, minimum, maximum, and quartiles). For study objectives, 95% confidence intervals will be displayed for the mean of continuous data or frequencies, respectively.

Weighting will be applied to adjust for probabilities of selection of a respondent and non-response with adjustment according to known characteristics of the population. Data will be presented for unweighted and weighted data.

Ethical study conduct and participant confidentiality

This study is an epidemiological population survey and is conducted in accordance with the most current versions of the Declaration of Helsinki [World Medical Association, 2013], the guidelines for Good Epidemiological Practice [Public Policy Committee ISoP, 2016] and local laws and regulations. The study is conducted in accordance with the most current version of Marketing Research Guideline and Personal Information Protection Guideline that JMRA (Japan Marketing Research Association) have established. Those guidelines also comply with ICC/ESOMAR codes of conduct.

At the beginning of April 2018, an independent ethics committee (IEC) in Japan consisting of 9 members (clinical and legal) were informed about the intended data collection and all required documents were provided, including protocol, participant information letter and questionnaire. The IEC from Kitama-chi Clinic, Tokyo, reviewed the study documents and approved study conduct on 17th April 2018 before fieldwork commenced (study reference: *Repeated Cross-Sectional Study to Assess Tobacco and Nicotine Usage Patterns and Behaviour After Market Introduction of glo in Japan*).

During fieldwork, potential participants will be informed about the study purpose, their requested tasks, time of involvement, data confidentiality and data protection, incentive (¥1,000 voucher) and contact details in case of questions. By completing the paper questionnaire, the participant implicitly gives consent to participate in this study.

All participating research parties will ensure compliance with national and international data protection regulations. Every effort will be made to protect participant confidentiality according to Directive 95/46/EC and the Japanese Act on Protection of Personal Information (APPI).

Adverse events, product complaints and/or misuse

To comply with BAT's product surveillance obligations, there was study monitoring for adverse effects, product complaints, and product misuse for the THP *glo* (this monitoring occurs for all BAT PRRPs in each market they are sold). The study questionnaire does not actively ask for any product related adverse events (AEs) or product complaints which occurred by using *glo*. But in case study participants report anything to the interviewer or the interviewer detects any AEs participants experienced during or after the use of *glo*, this information will be transferred to BAT's local and central Quality Performance Teams. AEs, complaints or misuse regarding other THPs or cigarettes are out of scope and will not be recorded. In case of *glo* product complaints the interviewer will advise the participant to call the designated Customer Care Hotline. Frequency and type of product misuse is assessed for *glo* users in terms of if they ever tried to light a tobacco consumable and smoke it like a conventional cigarette, ever tried to use the device with another different consumable, and/or ever tried to reuse once more an already heated tobacco consumable.

Limitations of the research methods

It could be assumed that in studies on self-reported smoking behaviour that respondents might hesitate to reveal information about their tobacco consumption in the context of a study, and instead provide answers according to social desirability. In order to address this issue, the questionnaire is designed for self-administration to minimise the effect of providing socially desirable responses. Using a non-computer-assisted data collection method in combination with a self-administered questionnaire bears the risk of incomplete and inconsistent data. This will be mitigated by giving clear instructions on how to complete the questionnaire, and by formatting the questionnaire in an intuitive way with clear routing. In addition, finished questionnaires are checked by the interviewer for completeness and

consistency of the provided answers during collection at the household.

The results of this study will be representative for the Japanese population taking into account the local cultural and regulatory environment. Thus, transferability of study outcomes to other countries might be limited.

Dissemination of information

Results from this study will be shared in publication and at conference(s).

Study status

The pilot study was fully executed as of April 2019 and the pilot data are currently being drafted into publication. Fieldwork for the first nationwide wave also finished in April 2019; after completion of the data life cycle and reporting the nationwide results will be published.

Conclusion

Population studies, including post-market surveillance and cross sectional surveys such as the study protocol described herein, support the evaluation of the introduction of PRRPs at a population level, in terms of consumer perceptions of product risks, behaviours and impact on public health. Analytical assessments of toxicant emissions (in vapour), pre-clinical assessments and clinical study data have all provided evidence that suggests THPs have the potential to be reduced risk alternatives compared to continued smoking. The post-market assessment of the product gives a more complete understanding of population/public health impact (uptake, switching, quitting, misuse, risk perception, quality of life, etc). Monitoring these behaviours is a regulatory requirement in certain markets, and prevalence data and observations from this study will contribute to new understanding of THP use in Japan, as well as support the areas of epidemiological science for assessing long-term usage of THPs.

Declarations

Ethics approval and consent to participate

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. An Independent Ethics Committee from Kitamachi Clinic, Tokyo, reviewed the study documents and approved study conduct on 17th April 2018, prior to fieldwork initiation. Potential

participants were informed about the study details before participation, and by agreeing to complete the paper questionnaire thereafter the participant implicitly gave consent to participate in this study.

Data availability

Underlying data

No data are associated with this article

Extended data

The study postcard and participant information letter are proprietary to Nippon Research Centre (NRC), the fieldwork provider for this study, and therefore cannot be shared. The study questionnaire is openly available from Open Science Framework.

Open Science Framework: Protocol for a Japanese nationwide repeated cross-sectional study to assess tobacco and nicotine product use behaviour after market introduction of Tobacco Heating Products (THPs). <https://doi.org/10.17605/OSF.IO/JECDN> (Adamson, 2019).

This project contains the following extended data:

- Appendix_1_Questionnaire.pdf (study questionnaire)

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Axel Klein

¹ ACK Consultants, London, UK

² Support to West Africa Integrated Maritime Security, DAI, Bethesda, Maryland, USA

The paper is interesting and makes good points convincingly about the benefits of THR (Tobacco Harm Reduction) with a single country case study. The first thing to strike the reader are significant variations in the quality of writing which suggests that different authors are responsible for different sections. Unfortunately, the flaws in some of the sections detract from the quality of the other sections and the science undergirding the efforts, so it is not ready for indexing as yet.

For clarity's sake it would have been good to inform readers earlier in the text that nicotine containing e-liquids are prohibited in Japan.

A couple of additional questions:

- What I am not sure about is the use of the term 'potential' here - surely a reduction in toxicant emission and lower biomarkers of exposure reduces harm, not potentially but actually.
- The study of Japan is welcome, but the cultural essentialism smacks of stereotyping even when cast in positive terms: "*resonate very well in Japan given the strong cultural values of order, cleanliness, quality and respect for others [Hair et al., 2018]*". At least, they sit uncomfortably with the above described high incidence of smoking - how did they get away with their stained teeth and inconveniencing others with their smoke, ash and cigarette butts?

Finally, there is the above mentioned problem with the language in some sections of the text, including a welter of spelling errors and typos make this paper unacceptable right now. A thorough copy edit is required and some sentences need to be reformulated. A few examples:

1. "*in their monologue Clearing the Smoke [Stratton et al., 2001]*," = surely monograph not monologue, though it may appear that way.

2. "Summised"- I am unsure whether the authors mean 'summarised' or 'surmised' here.

3. "Providing data to support the evaluation of behaviour/usage patterns of these new products is one of the important factors in assessing population health risk reduction. For this purpose, not only current tobacco users, but also non-users (never users and former users) must be taken into account" - garbled - rephrase and simplify.
4. "Studies about quality of life (QoL) assessing smoking cessation suggested wellbeing improvements" - well, what exactly improved wellbeing? Smoking continuation perhaps? It is not clear from this sentence.
5. "Several groups, tobacco industry [Murphy et al., 2017; Smith et al., 2016] and independent [Berman et al., 2015; Farsalinos & Polosa, 2014]," - missing subject
6. "is not lit" - should be 'are'

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: In 2020 I organised a webinar that received financial support from the FSFW - who I think also funded the research that I reviewed. In 2018 I received a grant to conduct Gap analysis for transitioning farmers and other stakeholders out of the tobacco industry in Malawi.

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.

Reviewer Report 24 July 2019

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Thomas Verron

Imperial Brands plc, Paris, France

Xavier Cahours

SEITA-Imperial Brands, Paris, France

This is a well written manuscript that provides experimental design on an important topic. However, to enhance reader comprehension, some points should be addressed prior to indexing.

Introduction

This publication described a repeated cross-sectional study, can the author give details about the number of studies (waves) they want to perform and the frequency?

Study aim and design

The participant section should be clarified for a better understanding, e.g.:

- ADD: a clear definition of stratum should be mentioned (Prefecture?)
- ADD: Small towns: population lower than?
- ADD: The total number of PSUs.
- EXPLAIN: How are households ordered in PSU to apply a regular numeric interval?
- EXPLAIN: Why do the authors apply the next birthday method, compared to other methods, such as the last birthday method?

Using the sampling described, i.e. 500 PSUs * 50 households/PSU * 1 person/household + the young adult sample for the oversampling quota, more than 25,000 will be contacted, and in the study sample size calculation paragraph only 5,000 were interrogated. Can the authors explain this difference?

There is no information about the type and sources of questionnaires used for this cross-sectional study. For instance, do they use questionnaires developed and validated for the US market and translated to Japanese or developed and validated for the Japanese market?

Data availability

Can we access to the appendix_1_Questionnaire.pdf (study questionnaire)?

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: I am currently an employee of Imperial Brands. However, I would to state

that by agreeing to peer review this manuscript, I provided essential neutral assessment. As such, you can be guaranteed that I had no conflicts of interest that could be seen to prevent me from acting in an impartial manner.

Reviewer Expertise: Data Analytics Research (Statistics, Datamining)

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

Author Response 31 Jul 2019

Jason Adamson, British American Tobacco, Southampton, UK

Thank you for the review comments. The study was designed to conduct 1-2 waves per year up to three years, or until sufficient data is collected to gain understanding of THP use in Japan and enable calculations of product use transitions. For nationwide waves stratification is by region and urbanization degree. In order to stratify the nation, all municipalities in Japan are classified into nine regions, based on the 47 prefectures. In each of the 9 regions, municipalities are stratified into four urbanization degrees, based on the population of each municipality from the *Basic Resident Registration* population data. 'Small towns' is an official classification: medium cities are "cities less than 150,000 population" and small towns are "towns and villages not classified as cities".

The total number of PSUs selected was 200 for the pilot wave and 500 for the nationwide waves. PSUs are allocated in batches each year and differently for various fieldwork providers. In addition, not every sample point is available for every study as some of them can be blocked due to other studies running in parallel. For the random selection of 500 PSUs, all available PSUs within each stratum are listed in ascending order of the municipality codes assigned to each street block at the time of sampling. The total number of PSUs is 176,815. Participant selection by next birthday method was applied uniformly throughout all study waves; other methods are available and although each may introduce selection bias this would be deemed insignificant. Next birthday method is the usual method employed in Japan.

Indeed, to collect responses from 4,000-5,000 respondents, interviewers would need to approach more than 25,000 houses and this is standard procedure for production of contact lists based on the experience of the fieldwork provider. Not all listed households can be reached, not all participants fulfil the inclusion criteria (e.g. able to speak and read Japanese) and not all households are willing to participate. In the fieldwork report after each wave we have a detailed list for non-response/non-participation.

The complete study instrument is original and was designed by BAT and Kantar in English with sections of the survey composed of validated tools (in the method section those standard/validated instruments used are mentioned). Though the rest of the instrument is not validated its design follows good practice. The instrument was then translated into Japanese and back translated to ensure accuracy. A small 'face validity' assessment was conducted in Japan to ensure the instrument was correct, had accurate skip logic and posed no obvious issues or confusions to participants. A post-hoc instrument validation

assessment is also currently being conducted. After each wave, feedback from participants and interviewers is used to improve upon and clarify portions of the instrument. The study instrument (English version) is open access and available on the Open Science Framework [here](#) (note that it may not be viewable in certain browsers).

Competing Interests: N/A (Authors' response to peer review)

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