Cross-Sectional Surveys on the Use of Tobacco Products in the General Population and in Users of IQOS in Germany, Italy, and London (2018-2020): Introducing the Study Protocols

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Introduction

Smoking is the leading cause of preventable disease and is responsible million of deaths worldwide each year. Even though nicotine is not risk-free, it is not the primary cause of smoking-related diseases. Smoking-related diseases, such as lung cancer, cardiovascular disease and emphysema, are caused primarily by harmful compounds formed when tobacco is burned, not by nicotine. There is little evidence that nicotine itself causes smoking-related diseases when decoupled from smoke. For smokers who won't quit, harm reduction implies striving for the complete elimination of smoked tobacco exposure by substituting it with the use of less harmful non-combusted forms of nicotine instead of smoking.

To this end, Philip Morris International (PMI) has developed a novel heat-not-burn product, the Tobacco Heating System (THS). THS was designed to generate an aerosol that generates substantially fewer toxicants than cigarette smoke by heating the tobacco at a temperature that avoids combustion. THS, which is commercialized under the brand name *IQOS*®, is marketed in more than 40 markets worldwide. In Italy and Germany, the product was launched in November 2014 and June 2016, respectively. In the U.K., *IQOS* was launched in Greater London as a test market in November 2016.

To estimate the prevalence of tobacco use including *IQOS* and assess product use patterns in these three markets, PMI launched three cross-sectional surveys in 2018 that will be repeated until 2021.

Survey Setting

In all three markets, the cross-sectional surveys are being conducted annually in two samples (i.e., a representative sample of the general population and a sample of *IQOS* users) over three consecutive years from 2018 to 2020. The sample frames and inclusion criteria are presented in Table 1.

General population sample

A total of 6,085 adults per year will be selected from the general population for each survey through multi-stage stratified sampling, assuming 1% *IQOS* uptake in each market.

In Germany and Greater London, the subjects are sampled randomly from the general population in three steps: area sampling (primary sampling point), household selection, and selection of target persons. The primary sampling points are the census data of the Work Group of German Market and Social Research Institutes (Arbeitskreis Deutscher Markt- und Sozialforschungsinstitute e. V. ADM-Sampling-System for face-to-face surveys) in Germany and Output Areas (OA, the smallest administrative unit) in Greater London. From each sample point, the target households are selected randomly. Within each household, the target respondent is identified through the next birthday method (i.e., the person in the household whose birthday is next).

In Italy, a stratified random probability sample is drawn according to a set of three different subpopulations or strata: 1) municipalities (140 in total), 2) electoral wards within the municipalities, and 3) individuals within the lists of the electoral wards. The sizes of the random samples from each strata are proportional to the strata population sizes (proportionate stratification).

In Germany and Italy, the surveys are conducted as part of a face-to-face computer-assisted personal interview (CAPI) omnibus. The omnibus is a syndicated survey with multiple participating clients, the questionnaires being divided into sections. Annually, the data is collected over six to seven waves, with more than 1,000 participants per wave. In Greater London, face-to-face interviews of the target participants are performed with CAPI. The annual data collection comprises four waves, with a minimum of 1,250 interviews per wave.

IQOS user sample

About 1,404, 1,384, and 1,246 IQOS users in Germany, Italy, and Greater London, respectively, will be selected randomly from the PMI *IQOS* user database, assuming that 63.4% of *IQOS* users fully converted to exclusive *IQOS* use. The participants will be invited to complete the survey online by computer-assisted self-interviews (CASI).

Table 1. Inclusion criteria and sample frames of the general population and *IQOS* users in cross-sectional surveys in Germany, Italy, and Greater London.

Samples	Sample frame	Inclusion criteria	Survey methods
General population	- Area sampling (primary sampling point): 258 regions sample points in Germany, 140 municipalities in Italy, and 305 OAs in London - Household (Germany and Greater London) or electoral ward selection (Italy) within the primary sampling point - Identification of target persons from the household (Germany and Greater London) or from the lists of the electoral wards (Italy)	- Aged ≥ 18 years - Currently residing in Germany, Italy, or Greater London - Able to read, write, and understand German, Italian, or English - Consent to participate in the survey	- Face-to-face omnibus CAPI (Germany and Italy) - Face-to-face CAPI Greater London)
IQOS users	- Random samples from PMI Germany, Italy, and UK *IQOS* user databases	In addition to the above criteria: - Has used more than 100 *IQOS* tobacco sticks in his or her lifetime - Is currently using *IQOS* - Has access to the internet - Is currently not employed by PMI or any of its affiliates	- Online CASI

Objectives

The objectives of the current surveys are to

(1) Estimate the prevalence of current tobacco- and nicotine-containing product use, including *IQOS*.
(2) Describe product use patterns (i.e., never-use, initiation, product use transition, cessation, re-initiation, and relapse).
(3) Explore the associations between self-reported health status and use of tobacco- and nicotine containing products in the general population as well as in a targeted sample of *IQOS* users in each country.
(4) Explore, among the targeted samples of *IQOS* users, the associations between patterns of tobacco- and nicotine-containing product use (including misuse) and motivation to use novel tobacco products, perceived quality attributes of *IQOS* (e.g., risk, aesthetic changes), and consumer satisfaction.

Survey Instruments

Survey Questionnaire and Outcome Measures

The survey questionnaire, consisting of three parts, was developed to address the survey objectives.

- The first part comprises a multidimensional smoking questionnaire (SQ), which was developed to standardize the assessment of cigarette smoking exposure covering the major dimensions of cigarette smoking. The adapted version of SQ is used to assess the exposure to other novel tobacco products, such as *IQOS*, e-cigarettes, PLOOM, and glo™. In addition, first product use, age of initiation, and quit attempt(s) are included in the SQ. The reasons for using *IQOS* and/or any other emerging tobacco products are collected.
- The second part assesses self-reported health status, which is included to explore associations with patterns of tobacco product use. In addition, the Self-Reported Changes Questionnaire, which records changes since starting using the product in a number of relevant domains where *IQOS* may have potential benefits (e.g., teeth coloring, breath smell, exercise capacity, skin appearance, etc.), is included in the *IQOS* user survey.
- The third part is specific to assess *IQOS* users' use experience and perceived risk. Information on the type and frequency of potential misuse of *IQOS* tobacco sticks and frequency of potential misuse of the *IQOS* electronic device is collected with a misuse questionnaire developed by PMI.

Along with the three components above, the demographic characteristics of the participants, including age, sex, income, education, occupation, and ethnicity, are collected. In Greater London, social grade based on occupation is rated by the interviewer for the general population survey.

Data Analysis

Data will be standardized to the 2010 world population and the population of each country (i.e., 2011 German population, 2011 Italian population, and census data of 2011 U.K. population). Three standardizations will be performed: 1) by age, 2) by sex, and 3) by age-sex combinations. Non-standardized and standardized data will be analyzed and summarized descriptively. Analyses will be stratified by the following factors: tobacco product used, sex, age, time since product initiation, and intensity of use. The trends in prevalence, initiation, and cessation rates as well as user behaviors will be presented based on annual data. The associations between patterns of tobacco product use and self-reported health status will be analyzed. In addition, for the population of *IQOS* users, the association between patterns of use (including misuse) with motivations to use, risk perceptions, perceived aesthetic changes, and consumer's satisfaction will also be explored.

Results

In all three regions, the first year data collection began in March 2018 for the general population and in April 2018 for *IQOS* users. First year data collection is planned to be completed by the end of 2018 for Germany and Italy and by the beginning of 2019 for Greater London. After the completion of the first year data collection, the second year data collection will start. In total, the annual data collection will be repeated for three consecutive years from 2018 to 2020. The results of the first year data analysis are expected to be available by June 2019.

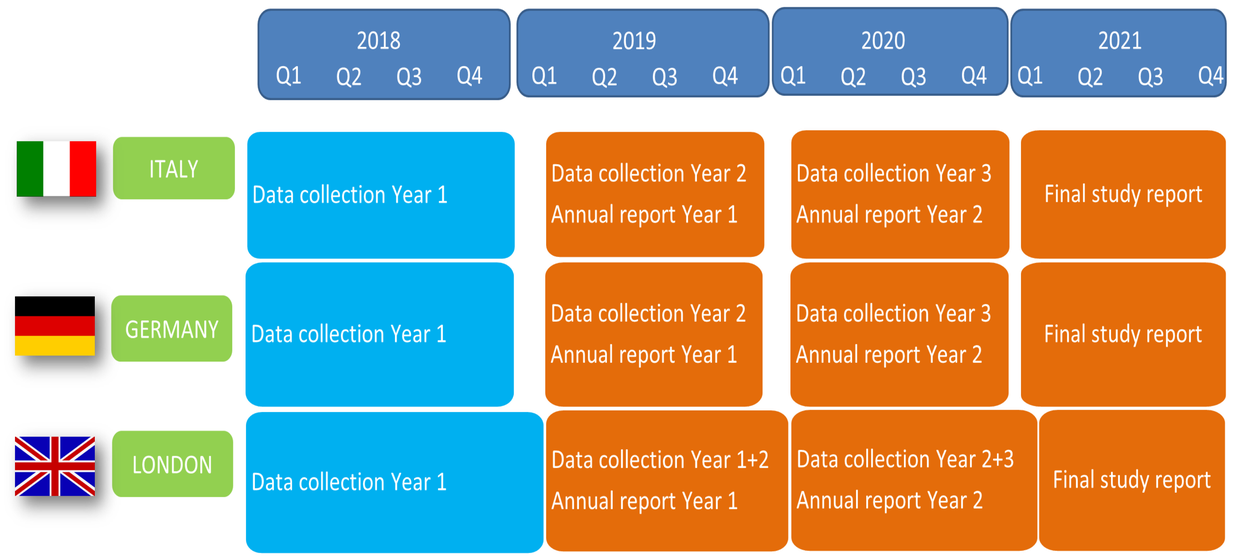

Figure 1. Study status and milestones of the current cross-sectional surveys on the use of tobacco products in the general population and in users of *IQOS* in Germany, Italy, and Greater London (2018-2020).

Conclusions

The current surveys aim to assess the prevalence of tobacco use and will provide insights into use patterns and associated factors. As the surveys will be conducted with similar design and at regular intervals in three markets, the results will allow for cross-regional and trend assessments.

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