RESEARCH ANALYSIS REPORT

ESTIMATION OF AWARENESS AND USE OF *IQOS* AMONG UNDERAGE INDIVIDUALS 13-20 YEARS OF AGE

Analysis of Relevant Data from the ALCS Underage Tobacco Use Survey
(Short Title: Analysis of UTUS)

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TABLE OF CONTENTS

1. INTRODUCTION

1.1. Background

Philip Morris Products S.A. (PMP S.A.) developed the *IQOS* Tobacco Heating System and Marlboro HeatSticks (hereinafter referred to as *IQOS*) as novel tobacco and nicotine-containing products with the potential to reduce harm or the risk of tobacco-related disease associated with smoking cigarettes. PMP S.A. submitted Modified Risk Tobacco Product Applications for *IQOS* to the U.S. Food and Drug Administration (FDA) seeking authorization to market the products as modified risk tobacco products. On July 7, 2020, FDA issued "Modified Risk Granted Orders – Exposure Modification" authorizing *IQOS* to be marketed with a reduced exposure claim. The Orders are conditioned upon agreement to conduct postmarket surveillance and studies (PMSS) in accordance with protocols approved by FDA. This document is prepared as part of the PMSS program for *IQOS* pursuant to the Orders.

1.2. Rationale

The Federal Food, Drug and Cosmetic Act (FDCA) directs the Food and Drug Administration (FDA) to condition an exposure modification order received under FDCA § 911(g)(2) on the MRTP applicants' agreement to conduct PMSS (FDCA §§ 911(g)(2)(C)(ii)). "The outcomes evaluated in postmarket surveillance and studies should focus on the effect of the MRTP on consumer perception, behavior and health under real world conditions of use" (Food and Drug Administration, 2012). For this reason, ALCS[1] on behalf of the applicant, PMP S.A., plans to conduct certain components of PMSS to assess the effect of the MRTP among U.S. consumers. The program consists of a collection of data over time that supports an assessment of *IQOS* in the postmarket setting.

The current research analysis to estimate awareness and use of *IQOS* among underage individuals 13 to 20 years of age is one component of the PMSS program. Specifically, it uses data relevant to *IQOS* from ALCS's ongoing Underage Tobacco Use Survey (UTUS) to address FDA's requirement for *IQOS* PMSS monitoring of youth and young adults below the legal age to purchase tobacco products[2].

[1] Altria Client Services (ALCS) and the parent of PMP S.A., Philip Morris International Management S.A., have entered into a distribution agreement by which ALCS and its affiliates have exclusive rights to distribute and sell *IQOS* in the U.S. after FDA authorization. ALCS affiliate PM USA markets *IQOS* in the U.S. Therefore, PMSS that involves the study of consumers and consumption in the U.S. will be conducted by ALCS to be submitted as part of PMSS reporting by PMP S.A.

[2] In the "Modified Risk Granted Orders-Exposure Modification" (July 7, 2020), FDA indicated that "…, given the novelty of these products and the uncertainty related to the impact of modified risk information on youth, your studies must be designed to monitor individuals under the age of 18 to assess: (a) youth awareness of *IQOS*, to evaluate how effectively your marketing is limiting unintended exposure to youth, and (b) youth use of the *IQOS* system, to help ensure that marketing of the MRTPs does not have unintended consequences for youth use. Your surveys must also monitor young adults below the legal age to purchase tobacco products (i.e., ages 18-20).

2. PURPOSE AND OBJECTIVES

2.1. Purpose

The purpose of this analysis is to estimate the awareness and use of *IQOS* among underage individuals based on relevant data from a U.S. nationwide population-based survey.

2.2. Objectives

The objectives of this analysis are to:

1) Estimate awareness of *IQOS* among underage individuals
2) Estimate ever and past 30-day *IQOS* use among underage individuals
3) Estimate lifetime use behavior among underage ever users of *IQOS*
4) Estimate past 30-day use behavior among underage past 30-day *IQOS* users

Use behaviors include exclusive, dual and poly tobacco use with *IQOS* and frequency of use. Note that in our reporting approach (described in Section 4) depends on the number of *IQOS* users identified in the UTUS dataset. Outcomes based on subgroups of underage individuals (e.g., estimates based on those aware of *IQOS*, or ever or currently using *IQOS*) will be reported when there are at least 50 respondents in that subgroup.

3. OVERVIEW OF ALCS' UNDERAGE TOBACCO USE SURVEY (UTUS)

We analyzed data from the ALCS Underage Tobacco Use Survey, an on-going national cross-sectional survey of non-institutionalized household dwelling underage individuals (age 13-20) living in the United States (50 states and the District of Columbia). The study assesses the prevalence of tobacco use, patterns of tobacco use, sources of access to tobacco products, and intention to stop using among 13 to 20-year-old tobacco users.

ALCS developed the UTUS to support its underage tobacco prevention and regulatory research and engagement efforts. The UTUS was designed to provide a timely assessment of use behaviors among underage individuals across a range of tobacco product categories. ALCS communicated with FDA on November 15, 2019 its plan to launch the UTUS and shared relevant study materials, including the study protocol, questionnaire, and consent/assent forms.[3] The FDA acknowledged the communication and receipt of materials on Dec. 30, 2019. ALCS conducted a pilot study during the first quarter of 2020, launched the full study in May 2020 (Q2 administration), and plans to carry out regular, quarterly survey administrations into the future.

[3] There have been some modifications to the study materials since then.

The UTUS is designed to draw nationally representative samples of underage individuals 13-20 years of age using a probability-based sampling method. To better support surveillance of *IQOS* following the MRTP authorization, in quarter 2 of 2021, ALCS added a set of questions designed to specifically assess awareness and use behaviors related to *IQOS* among underage individuals ages 13 to 20. In addition, ALCS started to incorporate oversamples of underage individuals ages 13 to 20 living in US geographies where *IQOS* was available for sale (Atlanta, GA, Charlotte, NC, and Richmond, VA). Following the removal of *IQOS* products from the U.S. markets in late 2021, ALCS stopped oversampling regions in quarter 2 of 2022.[4]

3.1. UTUS Sample Design

The UTUS uses a repeated cross-sectional study design to draw probability samples of non-institutionalized, household-dwelling individuals 13-20 years of age living in the U.S. Study samples are drawn using a list-assisted, address-based-sampling approach utilizing housing unit addresses from the United States Postal Service (USPS) computerized delivery sequence file (CDS) and housing unit addresses flagged as being likely to have a person age 13 to 20 living at the address by the ABS vendor. Group quarters are not included on the sampling frame (e.g., military barracks, group homes, and correctional facilities). To sample housing units, addresses on the sampling frame are stratified by three age groups (13-15, 16-18, 19-20), four Census regions, and urban/rural classification, resulting in a total of 24 strata. Within each stratum, addresses are randomly selected. Within a sampled housing unit, a maximum of two individuals 13-20 years of age are randomly selected. The allowance of two persons per household is used in both US National Survey on Drug Use and Health, as well as the Population Assessment of Tobacco and Health survey.

Initial contact with households is made through a mailed survey invitation letter. Participation is voluntary and participants may choose to complete the survey by online self-administration or phone interview. Due to the unique sensitivities of surveying minors and young adults, the study protocol requires confidentiality, informed assent from all participants, and parent/guardian informed consent for participants 13-17 years of age. A designated Institutional Review Board (IRB) approved the UTUS protocol and oversees the survey.[5]

We launched a pilot execution of the UTUS in the first quarter of 2020 and commenced full execution in the second quarter. The pilot execution successfully demonstrated the ability to responsibly collect data, even during the COVID-19 pandemic. We administered quarterly data collections without disruptions through the pandemic.

[4] On January 14, 2022, Philip Morris Products S.A. submitted the *Premarket Tobacco Product Application Amendment and General Correspondence Submission* to LCDR Michael Gu regarding the *Adjustment to the Postmarket Surveillance and Studies (PMSS) Plan for MR0000059 - MR000061 and MR0000133.*

[5] See this public website for more information on the study design, survey instrument, data sharing policy, as well as updates of recent findings every 6 months: Underage Tobacco Use Survey - Altria Science

3.2. UTUS *IQOS* Module

The UTUS *IQOS* module includes questions about awareness, usage, and consumption specific to *IQOS*. See Section 6 for the respective UTUS questions underlying this analysis.

3.3. UTUS Study Duration

UTUS is fielded on a quarterly basis. For the current analysis, data from quarter 2 of 2022 to quarter 1 of 2023 were aggregated to comprise the most recent four-quarter period. The four study waves were conducted between April 26, 2022, and February 14, 2023[6].

3.4. UTUS Participant Recruitment

Once the sampled housing unit addresses are drawn, a series of four mailings are used to contact each sampled address. In addition, phone calls are made after the last mailing to housing units for which telephone numbers are available via the study vendor. In all cases, an adult household member is required to respond to the survey invitation by providing a housing-unit-specific Access Code, which is included in the mailings. Upon successfully entering the unique Access Code, the responding adult household member enumerates household members to determine if there is at least one member of the household (including students away at college) whose age is between 13 and 20 years. Households containing at least one resident aged 13 to 20 are then administered a household roster to establish a list of eligible study participants in each household. Upon completion of the roster, a maximum of two eligible individuals are randomly selected.

If a selected potential participant is between the ages of 13-17, consent from the participant's parent or legal guardian is required. For all selected individuals, assent is required before taking the survey. Participants can either go to a study website to complete the questionnaire (online self-administration) or call a toll-free telephone number to speak to an interviewer to complete the questionnaire (computer-assisted phone interview). As a summary, the process includes the following steps to determine eligibility, select study participants, obtain informed consent/assent and proceed to the main questionnaire:

1. Person completing the screener is asked, "Including yourself, how many people, in each of the following age groups, live in your household at least 50% of the time, or are college students living away from home some of the time?
2. 12 or younger, 13-20, 21-34, 35-54, or 55 or older
3. Continue with the screener questionnaire if they have person age 13 to 20 in the household."

[6] The quarter 2 2022 survey started fielding on April 26, 2022 and the quarter 1 2023 survey closed fielding on February 14, 2023.

4. Household roster is established with age, and sex for each member of household that is age 13-20.
5. Up to 2 members of the household that are age 13-20 are randomly selected.
6. If 1 or 2 minors are selected, collect parental consent.
7. After collecting participant assent, complete the survey.

Both household roster and the main survey can be completed in English or Spanish.

Using this method, a total of 5,753 individuals completed the survey between quarter 2 of 2022 and quarter 1 of 2023.

Participants were able to obtain a token of appreciation upon completion of the questionnaire (in the form of electronic gift cards). For participants aged 13-17 years, their parent/guardian was provided with instructions to obtain the token of appreciation and asked to pass it on to the child.

3.5. UTUS Participant Inclusion Criteria

To qualify for study participation, individuals had to meet the following study eligibility criteria:

a) Identify as English or Spanish speaking persons living in the United States;
b) Have access to internet and/or telephone;
c) 13 to 20 years of age;
d) Have sufficient abilities to complete the questionnaire (i.e., reading/responding to online survey instrument or listening/speaking to interviewer over the telephone);
e) 13-17-year-old individuals have received consent from their parent/legal guardian to participate and themselves assent to participate; and
f) 18-20-year-old individuals consent to participate.

3.6. Protection of Human Subjects in UTUS

A designated Institutional Review Board (IRB) approved the UTUS protocol and oversees the survey. Prior to each quarterly data collection, all relevant documents (e.g., survey protocol, informed parental consent statement, informed participant assent/consent statement, and questionnaire) had been submitted to an Institutional Review Board (IRB) for review and approval.

Participation in UTUS is voluntary. For study participants aged 13 to 17, parental/legal guardian consent is required and recorded through the survey instrument prior to administering the assent form to the minors. All study participants, including minors (age 13 to 17) and adults (age 18 to 20), were administered the informed assent form, and by stating that they would like to participate in the survey after being provided complete information about the study, provided their assent to participate. All participants and

parents/guardians of 13–17-year-olds could obtain a copy of the assent or consent statements if they wished.

3.7. Survey Weighting

Survey weights were derived for the combined four quarters data (Q2 2022 to Q1 2023). Survey weighting was carried out at the following stages:

Address Level

* Base Weights to reflect the selection probability for sampled addresses
* Exclusion of Non deliverable Addresses to restrict weighting to deliverable addresses present on sampling frame
* Adjustment for Screener Nonresponse to account for non-participation due to a screener not being completed

Person within Address Level

* Adjustment for Selection Within Household to reflect the selection probability for sampled persons within an address
* Adjustment for Parental Non-consent to account for non-participation due to parent/guardian not providing consent for selected minor to participate in survey
* Adjustment for Selected Person Nonparticipation to account for non-participation due to selected person not assenting to participate in survey or not providing a usable set of responses to the survey
* Adjustment to Person-Level Population Totals to control weighted counts of completed interviews to total population counts of persons aged 13-20 by characteristics for which estimates are desired and/or which are associated with survey variables of interest (e.g., sex, age category, race/ethnicity, census region, and urban/rural residence)

Weights were trimmed as appropriate, to lessen the impact of extreme weights. Following completion of survey weighting, all records for completed interviews were assigned a final weight which was used to calculate weighted estimates.

4. ANALYSIS APPROACH

Our analysis and annual reporting of *IQOS*-relevant information from UTUS for postmarket surveillance purposes is based on the four most recent study waves conducted, i.e., quarter 2, 2022 through quarter 1, 2023 combined data. A sufficient sample size is needed to ensure adequate precision of estimates (e.g., means and proportions) for the underage population as a whole and among *IQOS* brand users. With a sample size of approximately 5,000 annually, UTUS estimates are generally with reasonable precision. For example, when the point estimate is 1%, the 95% confidence interval (CI) is 0.7% and 1.3% for a sample size of 5,000 respectively. We therefore

report awareness of *IQOS* and use of *IQOS* (ever use and past 30-day use) outcomes with their 95% CIs.

For outcomes based on subgroups of underage individuals (e.g., outcomes based on subsets of those aware of *IQOS*, have ever used *IQOS* or used *IQOS* in the past 30 days), we plan to conduct analyses only when there are at least 50 respondents in the respective subgroup as smaller sample sizes can result in unreliable estimates of proportions. With this approach we seek to strike a balance between accurate representation of the data and meaningful interpretation of the results.

4.1. Analysis Objectives and Measures

In this section we provide definitions of outcome measures relevant for the current for *IQOS* PMSS report. Outcome measures are reported for the total study population, and by population subgroups with respect to sex, age, and race/ethnicity when there were at least 50 individuals in a given subgroup (e.g., 13-17-year-olds or 18-20-year-olds).

Objective 1: Estimate awareness and source of awareness of *IQOS* among underage individuals

- Awareness of *IQOS*: percentage of respondents who had seen or heard of *IQOS* before the study, i.e., those who answered "yes" to the question "Have you ever seen or heard of *IQOS* before this study?" (Table 1). Following the survey skip logic, participants who responded "I don't know" to this question did not receive any further questionnaire items from the *IQOS* module and are not included in this analysis.
- Source of awareness of *IQOS*: among individuals who were aware of *IQOS*, percentage of participants who had indicated how they first became aware of *IQOS* via selecting either one of the respective response options to the question "How did you first see or hear of *IQOS*?" (Table 2).

Objective 2: Estimate ever and past 30-day *IQOS* use among underage individuals

- Prevalence of past 30-day use of *IQOS*: Percentage of respondents who had used *IQOS* within 30 days prior to taking the survey. Past 30-day use of *IQOS* is operationalized as having ever used *IQOS* and used *IQOS* during the past 30 days (i.e., those who selected "*IQOS*" in question "During the past 30 days, what brand or brands of heated tobacco products did you use?" or selected "yes" to the question "During the past 30 days, did you use *IQOS*?"; Table 3).

- Lifetime ever use[7] of *IQOS*: Percentage of respondents who had ever used *IQOS* in their lifetime (i.e., those who selected "yes" to the question "Have you ever used *IQOS* before this study, even just one time?"; Table 3).

Objective 3: Estimate lifetime use behavior among underage ever users of *IQOS*

- Lifetime consumption of heated tobacco: percentages of respondents who had used 1, 2- 10, 11-99, and 100+ of HeatSticks with *IQOS* in their lifetime among ever users of *IQOS*.
- History of other tobacco use among ever *IQOS* users: percentages of respondents who had ever used
    - *IQOS* only
    - *IQOS* and at least one combusted tobacco product
    - *IQOS* and at least one non-combusted tobacco product
    - *IQOS* and both combusted and non-combusted tobacco products

Analysis requires a minimum of 50 ever users of *IQOS* in the sample to compute reliable estimates. Estimates for outcomes listed in objective 3 will be stratified by whether the HeatStick first used was menthol or non-menthol if sample size allows.

Objective 4: Estimate past 30-day use behavior among underage past 30-day *IQOS* users

- Use frequency: median (with interquartile rage) and mean (with standard deviation) for the number of days of *IQOS* use during the past 30 days among past 30-day *IQOS* users
- Amount consumed on days used: percentages of respondents who consumed the following number of HeatSticks with *IQOS* on the days they used *IQOS*:
    - ≤ 1 per day
    - 2-5 per day
    - 6-10 per day
    - >10 per day

[7] We do not consider lifetime ever use a prevalence measure because it deviates from the traditional definition of prevalence in significant ways and is better described as cumulative incidence among survivors (Streiner et al., 2009).

- Exclusive, dual, and poly tobacco users among past 30-day *IQOS* users: percentages of respondents who used the following in the past 30 days:
    - *IQOS* only
    - *IQOS* and at least one combusted tobacco product
    - *IQOS* and at least one non-combusted tobacco product
    - *IQOS* and both combusted and non-combusted tobacco products

Analysis requires a minimum of 50 past 30-day users of *IQOS* to ensure reliable estimate calculations.

4.2. Data Analysis

We provide summary statistics based on survey-weighted computation, such as point estimates of proportions including 95% CIs. All analyses were conducted using R statistical software version 4.1.0[8], including the use of the *tidyverse*[9], *survey*[10], and *srvyr*[11] packages. Data were weighted to account for participant selection probabilities, non-response patterns, and adjustments to person-level population totals. Taylor series approximation was used for calculating variances of estimates with *access code* as the primary sampling unit,[12] and the Strata defined as *str* using the following commands in R:

```
#str = (age-1)*100+(ur-1)*10+region
#svydesign (id = ~ access_code, strata = ~ str, weights = ~ WEIGHT_Q222_Q123, data = data)
#options (survey.lonely.psu = "adjust")
```

Outcome measures are reported for the total study population, and by population subgroups when there were at least 50 individuals in a given subgroup (e.g., 13-17-year-olds or 18-20-year-olds).

Answers of "don't know" were coded as missing for all above variables. UTUS participants who responded "I don't know" to the initial question from the respective *IQOS* module ("Have you ever seen or heard of *IQOS* before this study?") were not included in the current analysis.

[8] R Core Team (2022). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/..
[9] Wickham et al., (2019). Welcome to the tidyverse. Journal of Open Source Software, 4(43), 1686, https://doi.org/10.21105/joss.01686
[10] T. Lumley (2020) "survey: analysis of complex survey samples". R package version 4.0.
[11] Greg Freedman Ellis and Ben Schneider (2021). srvyr: 'dplyr'-Like Syntax for Summary Statistics of Survey Data. R package version 1.1.0. https://CRAN.R-project.org/package=srvyr
[12] The primary sampling units were households, and strata were age (13-15, 16-18, 19-20), urban/rural residence, and geographical regions. The geographical regions consisted of the four Census regions (Northeast, Midwest, South, and West).

5. RESULTS

A total of 5753 individuals aged 13 to 20 years participated in the UTUS between April 2022 and February 2023. About 1 in 5 participants replied "I don't know" in response to the initial question of the *IQOS* module (*Have you ever seen or heard of IQOS before this study?*) which prompted a skip of subsequent *IQOS* module questions and thus exclusion from further analysis (n=1,120).

5.1. Awareness of *IQOS* among underage individuals (Objective 2)

As shown in Table 1, an overall six percent of underage individuals had ever seen or heard of *IQOS* between March 2022 and February 2023.

14.98% of the 271 individuals who indicated awareness of *IQOS* (95% CI = 10.4% to 21.0%) also correctly identified the device via the respective survey question[13] and 39.58% [32.89, 46.68] replied to "not know". Underage young adults (18-20 years) were more likely to be aware of *IQOS* compared to youth (13-17 years; 8.25% vs. 4.81%).

[13] Correct identification of *IQOS* was defined as selecting "*This device only uses sticks containing actual tobacco*" to the survey question "*Which of the following best describes IQOS?"*.

Table 1: Estimated awareness of *IQOS* among 13–20-year-olds

Population Group	Sample size (*n*)	Awareness % (95% CI)
Overall	4629	5.96 (5.19, 7.0)
Gender		
Female	2344	5.69 (4.70, 6.89)
Male	2285	6.21 (5.18, 7.43)
Age		
13-17 Years	2697	4.81 (3.93, 5.87)
18-20 Years	1932	8.25 (6.96, 9.76)
Race/ethnicity*		
Non-Hispanic White	2564	4.61 (3.79, 5.61)
Non-Hispanic Black	571	5.83 (4.01, 8.40)
Hispanic	1175	7.82 (6.13, 9.93)
Others	319	7.59 (4.99, 11.38)

Source: UTUS data collected from April 2022 to February 2023. Percentages are derived from weighted data. *N*'s are derived from unweighted data. Sample sizes may vary in each subgroup due to missing responses.
*'Hispanic' category includes participants who answered "yes" to the first question (*Are you Hispanic, [Latino/Latina], or of Spanish origin?).* 'Non-Hispanic White' category includes those who answered "no" to the first question and selected "White" only to the second question (*What is your race? (select all that apply)).* 'Non-Hispanic Black 'category includes those who answered "no" to the first question and selected "Black" only to the second question. 'Others' category includes those who selected other options in the second question other than "Refuse to answer".
Abbreviations: UTUS = Altria Client Services Underage Tobacco Use Survey; CI = Confidence Interval.

Among those who had ever heard or seen of *IQOS* (n=271), the most common source of awareness was hearing about it from friends, peers, or classmates, followed by seeing advertisements at gas stations, convenience stores, or other retail stores (Table 2).

Table 2: Estimated source of awareness of *IQOS* among 13–20-year-olds who are aware of *IQOS* (n=271); % (95% CI)

Source	Overall (n=271)	13-17 (n=118)	18-20 (n=153)
Saw *IQOS* in person in a store, mall, convenience store	3.71 (1.79, 8.0)	3.83 (1.23, 11.31)	3.58 (1.55, 8.03)
Saw someone else using *IQOS*	7.40 (4.56, 12.0)	7.80 (3.75, 15.50)	6.93 (3.76, 12.42)
Saw it on social media (e.g., YouTube or Instagram)	10.25 (6.60, 16.0)	12.15 (6.74, 20.92)	8.04 (4.25, 14.67)
Advertisement at gas stations, convenience stores, or other retail stores	15.68 (11.20, 22.0)	14.16 (8.44, 22.80)	17.46 (11.21, 26.15)
Advertisement in newspapers or magazines	1.13 (0.40, 3.0)	1.17 (0.26, 5.14)	1.08 (0.26, 4.33)
Advertisement at festivals, nightclubs, and bars	0.42 (0.06, 3.0)	0	0.91 (0.12, 6.27)
Advertisement on websites or social media sites	3.59 (1.82, 7.0)	2.67 (0.77, 8.80)	4.67 (2.16, 9.83)
A friend/peer/classmate told me about it	45.29 (38.2, 53.0)	46.14 (36.12, 56.48)	44.31 (35.55, 53.43)
A family member told me about it	3.23 (1.55, 7.0)	3.59 (1.30, 9.54)	2.82 (0.99, 7.78)
Heard or read a story in the news	1.81 (0.68, 5.0)	1.21 (0.17, 8.36)	2.51 (0.86, 7.08)
Other, specify* __	1.36 (0.32, 6.0)	1.80 (0.25, 11.94)	0.86 (0.21, 3.43)
Don't know/do not recall	6.12 (3.72, 10.0)	5.49 (2.56, 11.40)	6.86 (3.53, 12.88)

Source: UTUS data collected from April 2022 to February 2023. Based on participant responses to the survey question '*How did you first see or hear of IQOS?'*. Percentages are derived from weighted data. *N*'s are derived from unweighted data. Sample sizes may vary in each subgroup due to missing responses.
*Three participants used the 'Other' write-in response option to specify where they had first become aware of *IQOS*, of which two indicated through a school/class context and one through work at a convenience store.
Abbreviations: UTUS = Altria Client Services Underage Tobacco Use Survey; CI = Confidence Interval.

5.2. Lifetime and past 30-day *IQOS* use (Objective 2)

A total of 27 individuals in the current dataset reported ever use of *IQOS*, six of which reported to currently (past 30-day) use *IQOS*.

As shown in Table 3, ever use and past 30-day use of *IQOS* was low among underage individuals and all subgroups (i.e., <1%).

Table 3: Estimated ever[#] and past 30-day[##] use of *IQOS* by demographic characteristics

Population Group	Base Sample (N)	Ever *IQOS* Use[#]; % (95% CI)	Ever *IQOS* Use[#]; participant count (n)s	Past 30-day *IQOS* Use[##]; % (95% CI)	Past 30-day *IQOS* Use[##]; participant count (n)
Overall	4629	0.57 (0.36, 0.91)	27	0.12 (0.05, 0.34)	6
Gender					
Female	2344	0.39 (0.19, 0.81)	10	0.15 (0.03, 0.61)	3
Male	2285	0.75 (0.43, 1.28)	17	0.11 (0.03, 0.34)	3
Age					
13-17 Years	2697	0.47(0.23, 0.96)	11	0.15 (0.05, 0.47)	4
18-20 Years	1932	0.79 (0.46, 1.33)	16	0.07 (0.02, 0.28)	2
Race/ethnicity*					
Non-Hispanic White	2564	0.44 (0.21, 0.94)	11	0.04 (0.01, 0.17)	2
Non-Hispanic Black	571	0.19 (0.05, 0.76)	2	0.10 (0.01, 0.71)	1
Hispanic	1175	1.07 (0.54, 2.11)	12	0.35 (0.1, 1.22)	3
Others	319	0.45 (0.11, 1.84)	2	0	0

Source: UTUS data collected from April 2022 to February 2023.
[#] Based on participant responses to the survey question 'Have you ever used *IQOS* before this study, even just one time?'
[##] Based on participant responses to the survey questions 'During the past 30 days, did you use *IQOS*? & During the past 30 days, what brand or brands of heated tobacco products did you use?'.
*'Hispanic' included participants who answered "yes" to the first question. 'Non-Hispanic White' included those who answered "no" to the first question and selected "White" only to the second question. 'Non-

Hispanic Black' included those who answered "no" to the first question and selected "Black" only to the second question. 'Others' included those who selected other options in the second question other than "refused".
Percentages are derived from weighted data. N's are derived from unweighted data. Sample sizes may vary in each subgroup due to missing responses. Stratified analysis by menthol and non-menthol HeatSticks was not conducted due to low estimates of overall use.
Abbreviations: UTUS = Altria Client Services Underage Tobacco Use Survey; CI = Confidence Interval.

Among the 21 individuals who had indicated use of *IQOS* but not within the past 30 days (i.e., *IQOS* ever-users), five had correctly identified the device while two had responded to "not know" to the respective survey question.

Of the six individuals who reported use of *IQOS* in the 30 days prior to taking the survey, three correctly identified *IQOS* and one had responded to "not know".

5.3. Lifetime use behavior among underage ever users of *IQOS* (Objective 3)

We did not conduct analyses for objective 3 because the number of ever *IQOS* users in the current dataset (n=27) was not sufficient to compute reliable estimates of use behaviors among the subsample of ever users of *IQOS* (see Section 4.1).

5.4. Past 30-day use behavior among underage past 30-day *IQOS* users (Objective 4)

We did not conduct analyses for objective 4 because the number of past 30-day *IQOS* users in the current dataset (n=6) was not sufficient to compute reliable estimates of use behaviors among the subsample of past 30-day users of *IQOS* (see Section 4.1).

6. APPENDIX 1 – SELECTED UTUS QUESTIONS RELATED TO *IQOS* AND RELEVANT TO CURRENT ANALYSIS REPORT

This appendix provides a list of UTUS survey questions relevant to the current analysis. The UTUS questionnaire is organized in two main parts: assessment of (1) awareness/ever use of various tobacco products, and (2) category-specific modules with questions about tobacco use behaviors in the past 30 days. Tobacco products included in the study are cigarettes, cigars, snuff/dip/chewing tobacco, e-cigarettes, hookah, pipe, snus, heated tobacco, and oral nicotine products.

To support postmarket surveillance requirements, an *IQOS*-specific module was added to the questionnaire in quarter 2 of 2021 and has been included in the UTUS assessment since. The questions from the module, including skip logic, are described here below:

AWARE / EVER USED

3h. And the next question is about heated tobacco products. Some people refer to these products as "heat-not-burn" tobacco products. "Heated tobacco products" heat tobacco sticks or capsules to produce a vapor. They are different from e-cigarettes, which heat a liquid to produce a vapor. Some brands of "heated tobacco products" include *IQOS*, glo™, and Eclipse®.

Have you ever seen or heard of "heated tobacco products" before this study?

Yes - 1

No - 2

(ASK Q.4h IF 'YES' AT Q.3h)

4h. Have you **ever used** a "heated tobacco product", even just one time?

Yes - 1

No - 2

3h1. Have you ever seen or heard of *IQOS* before this study?

Yes - 1

No - 2

Don't know -99

3h8. [Ask if 'Yes' at Q.3h1] How did you first see or hear of *IQOS*?

A friend/peer/classmate told me about it	-1
A family member told me about it	-2
Advertisement at gas stations, convenience stores, or other retail stores	-3
Advertisement in newspapers or magazines	-4
Advertisement at festivals, nightclubs, and bars	-5
Advertisement on websites or social media sites	-6
Heard or read a story in the news	-7
Saw *IQOS* in person in a store, mall, convenience store	-8
Saw someone else using *IQOS*	-9
Saw it on social media (e.g., YouTube or Instagram)	-10
Other, specify _____	-90
Don't know/don't recall	-99

3h9. [Ask if 'Yes' at Q.3h1] Which of the following best describes *IQOS*? [Rotate responses 1-4. Keep 1-3 together, rotating within these 3 responses. Always keep "Don't Know" last.]

This device only uses replaceable pods/cartridges/capsules	-1
This device only uses sticks containing actual tobacco	-2
This device uses both sticks containing actual tobacco ***and*** replaceable pods/cartridges/capsules	-3
This device is refilled using bottles of e-liquid	-4
[ALWAYS SHOW LAST] Don't Know	-99

4h1. [Ask if 'Yes' at Q.3h1] Have you ever used *IQOS* before this study, even just one time?

Yes	- 1
No	- 2
Don't know	-99

HEATED TOBACCO PRODUCT SECTION

These next questions are about the use of "heated tobacco products". Some people refer to these products as "heat-not-burn" tobacco products.

9h. [If Q4h is 'Yes'] When was the last time you used a heated tobacco product, even one or two times? (*Please select the first answer that fits.*)

Earlier today	-1
Not today but sometime during the past 7 days	-2
Not during the past 7 days but sometime during the past 30 days	-3
Not during the past 30 days but sometime during the past 6 months	-4
Not during the past 6 months but sometime during the past year	-5
1 to 4 years ago	-6
5 or more years ago	-7

12h. [If Q9h is 1-3] During the past 30 days, what brand or brands of heated tobacco products did you use? *(select all that apply)*

(Display brand list, only shows *IQOS* if 'Yes' at Q.4h1)

Eclipse	-1
Glo	-2
IQOS	-3
PAX	-4
Ploom Tech	-5
Some other brand not listed here	-90 (specify) __
Not sure	-99

IQOS-SPECIFIC SECTION

21hi. You mentioned earlier that you have used *IQOS* before this study. The next questions are about *IQOS*.

[Ask if 'Yes' at Q4h1] How many HeatSticks have you used with *IQOS* in your **entire life**?

1	-1
2 to 10	-2
11 to 20	-3
21 to 50	-4
51 to 99	-5
100 or more	-6

22hi. [Ask if 'Yes' at Q4h1] Menthol HeatSticks are HeatSticks that taste like mint. Was the first *IQOS* HeatStick you used menthol or non-menthol (regular)?

Menthol - 1

Non-Menthol- 2

Not sure -99

23hi. [Ask if 'Yes' at Q4h1 AND *IQOS* is not mentioned in Q12h; if *IQOS* is mentioned in Q12h, autofill this question with 'Yes' and move to 24hi] During the past 30 days, did you use *IQOS*?

Yes - 1

No - 2

Don't know -99

24hi. [If 'Yes' at Q23hi OR *IQOS* is mentioned in Q12h] During the past 30 days, on how many days did you use *IQOS*?

_ _ Number of days (1-30)

25hi. [If 'Yes' at Q23hi OR *IQOS* is mentioned in Q12h] During the past 30 days, on the days you used *IQOS*, about how many HeatSticks did you use with *IQOS* per day?

Less than 1 per day -1

1 per day -2

2 to 5 per day -3

6 to 10 per day -4

11 to 20 per day -5

More than 20 per day -6

26hi. [If 'Yes' at Q23hi OR *IQOS* is mentioned in Q12h] During the past 30 days, was the HeatStick you usually used with *IQOS* menthol or non-menthol?

Menthol	-1
Non-Menthol	-2
I did not have a usual type	-97
Not sure	-99