

Tobacco Use, Perceptions, and Characteristics of Adults Who Use IQOS® in the United States: Findings from a Cross-Sectional Study

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Abstract

Background

The smoke-free heated tobacco product *IQOS*® was introduced in the United States (US) in 2019 and authorized by the US Food and Drug Administration as a modified risk tobacco product (MRTP) in 2020. The aim of this study was to describe selected sociodemographic characteristics of adults who used *IQOS*® (AUI), tobacco use patterns relevant to *IQOS*® use (e.g., tobacco use history, exclusive and dual-use, switching from cigarette smoking, etc.), risk perceptions of *IQOS*®, and understanding of *IQOS*® MRTP messages among AUI.

Methods

The IQOS® cross-sectional Postmarket Adult Consumer Study was a study of AUI aged \geq 21 years who were recruited from an IQOS® consumer database via direct mail and emails. Participants completed the online survey between September and November 2021.

Results

The survey was completed by 645 current and 43 former AUI who had used at least 100 Marlboro® *HeatSticks*® prior to the assessment. Of the 688 participants, 61% were male, 73% were non-Hispanic white, and the mean age was 45. The vast majority (99%) of AUI had ever smoked combusted cigarettes before first trying *IQOS*®. At the time of assessment, 49% were still smoking after an average of 1 year of *IQOS*® use. Among those, 83.6% smoked fewer cigarettes compared to before first trying *IQOS*®. Among all AUI, over 80% had never used a cessation treatment or had not used it in the past 12 months. Approximately 80% of AUI demonstrated correct understanding of the MRTP message.

Conclusions

This study is the first to provide evidence that *IQOS*® can help adult smokers in the US completely switch away from cigarettes or reduce smoking.

Background

Cigarette smoking is a leading contributor to mortality and morbidity worldwide [1]. In the United States (US), smoking contributes to an estimated 500,000 premature deaths and an expenditure exceeding \$170 billion in medical costs to treat smoking-related lung and cardiovascular illnesses annually [2]. Although quitting is the best way to mitigate health risks from smoking, it remains challenging for many smokers. Despite 70% of smokers wanting to quit smoking and more than half making a quit attempt each year [3], the majority of those who attempt to quit relapse within 12 months [4–7]. Individuals who smoke make many attempts before quitting successfully, rendering the quitting journey a protracted relapsing process [7, 8]. Given that health risks from cigarette smoking are mainly attributed to harmful constituents generated through combustion, smokers who are unable or unwilling to quit can benefit from switching to smoke-free tobacco products such as *IQOS*® [9–12].

IQOS® is a smoke-free tobacco product that heats a tobacco rod (Marlboro *HeatSticks*®) to temperatures below the level of combustion and produces an aerosol with substantially reduced (i.e., 90–95% lower) levels of harmful and potentially harmful constituents (HPHC) compared to cigarette smoke, while delivering similar levels of nicotine [13–15]. As of January 2023, *IQOS*® is available in 75 countries since its first debut in Japan in 2014.

Evidence to date supports the role of *IQOS*® in tobacco harm reduction. *IQOS*® uptake by Japanese smokers has been rapid [16], and recent data suggests that the majority of individuals who used *IQOS*® have switched to exclusive *IQOS*® use and stopped smoking in Japan [17]. Moreover, individuals who used heated tobacco products exclusive of smoking had favorable health-related biomarker profiles compared to smokers [18]. In a prospective study of 38 Italian smokers with chronic obstructive pulmonary disease (COPD) who started to use *IQOS*®, 58% stopped smoking within 3 years, and those who were still smoking significantly reduced their cigarette consumption (mean cigarette consumption dropped from 21 per day at baseline to 3.7 per day at the last follow-up). Most importantly, consistent improvements were observed in respiratory symptoms, exercise tolerance, quality of life, and rate of disease exacerbations whereas no such change was observed among individuals who smoked cigarettes during the same follow-up period [19]. These results suggest that switching from cigarette smoking to *IQOS*® may be associated with long-term health benefits.

The US Food and Drug Administration (FDA) authorized the marketing of *IQOS*® in the US in April 2019 and subsequently granted a Modified Risk Tobacco Product (MRTP) order in July 2020 authorizing the use of a reduced exposure claim for *IQOS*®. The claim is:

"AVAILABLE EVIDENCE TO DATE:

- The IQOS® system heats tobacco but does not burn it.
- This significantly reduces the production of harmful and potentially harmful chemicals.
- Scientific studies have shown that switching completely from conventional cigarettes to the *IQOS*® system significantly reduces your body's exposure to harmful or potentially harmful chemicals."

IQOS® was first introduced to the US in Atlanta (Georgia) in October 2019. Marketing expanded to Charlotte (North Carolina), Richmond (Virginia), and Northern Virginia before it was removed from all US markets in November 2021 as a result of a Cease-and-Desist Order (CDO) issued by the United States International Trade Commission (ITC)¹. Three types of *HeatSticks*® were sold: Amber/Regular (non-menthol), Green/Smooth menthol (menthol) and Blue/Fresh menthol (menthol).

This study aimed to (i) characterize adults who used *IQOS*® (AUI) and their history and patterns of tobacco use, as well as tobacco cessation treatment use; (ii) describe risk perceptions of *IQOS*® and the understanding of the MRTP claim; and (iii) describe complete switching from cigarette smoking to *IQOS*®, transitions to/back to cigarette smoking, and quitting behaviors relevant to *IQOS*® among AUI. We used data from the 2021 *IQOS*® Cross-sectional Postmarket Adult Consumer Study to provide the first evidence about the potential role of *IQOS*® in tobacco harm reduction in real-world settings in the US.

Methods

Study Design, Study Population, and Recruitment

The current study was cross-sectional in design. The study population consisted of adults, 21 years of age or older, who had used at least 100 Marlboro *HeatSticks*® with *IQOS*® prior to the assessment. Individuals were excluded if (i) they were unable to read, speak, or understand English; (ii) they or their first-degree relative were current or former employees of the tobacco industry, the Central Research Organization, or any market research firm; or (iii) they or their first-degree relative were currently involved in litigation against any tobacco industry entity.

In this study, we recruited AUI from the *IQOS*® consumer database, which covered approximately 70% of individuals who purchased an *IQOS*® device. We sent invitations by both direct mail and email (if available) to all individuals in the database who agreed to be contacted for research purposes. Figure 1 depicts the recruitment process and final sample. Data were collected between September 15 to November 14, 2021. In brief, of the 19,258 individuals invited, 2022 (10.5%) completed the screener; of the 698 eligible individuals who consented to participate, 688 (98.6%) completed the survey.

Assessment and Definitions

All eligible participants, regardless of the mode of recruitment, self-administered the questionnaire online. Upon completion of the questionnaire, participants were provided instructions to obtain a \$40 electronic gift card. The study was approved by Sterling Institutional Review Board (IRB ID #: 9102-HCheng). More details can be found in a previous publication (https://www.qeios.com/read/VKD77J).

The assessment consisted of modules of questions on the history of use of various tobacco products (including *IQOS*®, cigarettes, cigars, pipe, hookah, e-cigarettes, smokeless tobacco, and oral tobacco-derived nicotine products) with more detailed questions on *IQOS*® and cigarettes. Additional modules included risk perceptions and understanding of claim-related information, demographic characteristics, and diagnoses of selected physical and mental conditions.

In this study, we defined ever use as a "yes" response to the question "Have you EVER used/smoked ... EVEN ONE TIME?" Current use was defined as "every day" or "some days" responses to the question "Do you now use/smoke ... every day, some days or not at all?" Former use was defined as a "yes" response to the ever use question and "not at all" response to the current use question. Established cigarette smoking and IQOS® use were defined as having smoked at least 100 cigarettes or used at least 100 HeatSticks® in lifetime. Menthol/non-menthol preference was assessed using the question "Which one type of HeatSticks® are you CURRENTLY using most often?" Responses of "Green Menthol (previously 'Smooth Menthol')" and "Blue Menthol (previously 'Fresh Menthol')" were classified as preferring menthol; responses of "Amber (previously 'Regular')" were classified as preferring non-menthol. We identified menthol/non-menthol cigarette preference via questions about the type of cigarettes smoked most often.

In this study, we asked time-centered questions to establish a temporal sequence of smoking and *IQOS*® use to assess changes in smoking behaviors after first trying *IQOS*®. For example, we classified current smokers before first trying *IQOS*® as individuals who answered "every day" or "some days" to the question "during the 30 days before you first tried *IQOS*®, did you smoke cigarettes every day, some days or not at all?". Using this approach, we defined individuals who had completely switched as current established AUI who (i) had smoked at least 100 cigarettes in lifetime, (ii) were currently smoking during the 30 days before first trying *IQOS*®, (iii) were not smoking at the time of assessment, and (iv) smoked their last cigarettes after trying *IQOS*® (via the question "Was the last time you smoked cigarettes...?" with response options "Before trying *IQOS*® for the first time" and "After trying *IQOS*® for the first time".

Perceived health risks were assessed using the validated 18-item Perceived Health Risk scale, which has shown good psychometric properties [20]. Two batteries of questions were asked for cigarette smoking and *IQOS*® use, respectively. Each item was rated on a 5-point Likert-type scale ranging from 0 (no risk) to 4 (very high risk). An overall score was calculated by summing all items in the scale (possible range 0 to 72), with higher scores

representing greater perceived health risk [20]. The understanding of the MRTP message was assessed using two questions shown in Table 1.

Table 1

Questions to Assess the Understanding of the Modified Risk Tobacco Product Message.

Based on what you know or believe, please complete the following: Smokers who switch completely from cigarettes to *IQOS*:

- Have more exposure to harmful or potentially harmful chemicals
- Have the same exposure to harmful or potentially harmful chemicals
- Have less exposure to harmful or potentially harmful chemicals (correct answer)
- Have no exposure to harmful or potentially harmful chemicals
- Don't know

IF "HAVE LESS EXPOSURE..." SELECTED

Based on what you know or believe, what do smokers need to do in order to reduce their body's exposure to harmful or potentially harmful chemicals?

- Stop smoking cigarettes completely and only use IQOS® (correct answer)
- Smoke fewer cigarettes and also use IQOS®
- Keep smoking the same amount of cigarettes and also use IQOS®
- Don't know

Demographic characteristics included sex (male or female), age, race/ethnicity, level of education, household income, employment status, and marital status. Lifetime history of physical conditions was assessed using the question "Have you ever been told by a doctor, nurse, or other health professional that you had...?" Options included cardiovascular conditions, respiratory conditions, cancers, and diabetes (see Table 3 for details). Lifetime history of mental conditions were assessed using two questions: "A mental illness or disorder refers to a wide range of mental health conditions or disorders that affect your mood, thinking and/or behavior. Has a doctor, nurse or other health professional ever told you had a mental health condition such as depression, stress or problems with emotions?" and "Are you now taking medicine or receiving treatment from a doctor, nurse, or other health professional for a mental health condition or emotional problem?" All information was based on self-report.

Analysis

Descriptive statistics were used to summarize outcome variables. For categorical variables, frequencies and proportions (95% confidence intervals; CIs) were generated. For numeric variables (e.g., age), means (95% CI) and medians (interquartile ranges; IQRs) were calculated. Estimates (e.g., proportions and means) were presented for current and ever AUI, respectively. Demographic characteristics and *IQOS*® use behaviors were further stratified for AUI who preferred menthol and non-menthol Marlboro® *HeatSticks*®. Estimates are not shown for former established AUI due to imprecision as a result of the small sample size (n = 43). Data analyses were conducted using SAS Version 9.4 (Statistical Analysis System, SAS Institute Inc., Cary, North Carolina, US).

Results

Characteristics of study participants

Of all established AUI, approximately 60% were males, and the mean age was 45 with the majority between 35 and 54 years of age. On average, current established AUI who preferred menthol *HeatSticks*® were younger than those who preferred non-menthol *HeatSticks*® (mean age = 43.1 [95% CI = 42.0, 44.3] and 47.3 [95% CI = 46.1, 48.6] respectively). Of all established AUI who had ever smoked cigarettes, 40.5% (95% CI = 36.9%, 44.3%) smoked menthol cigarettes most often. Individuals who were non-Hispanic white accounted for > 70% of established AUI. Differences in *HeatSticks*® varieties were observed across race/ethnicity groups; greater proportions of non-Hispanic white preferred non-menthol *HeatSticks*®, whereas greater proportions of non-Hispanic black and non-Hispanic Asians preferred menthol *HeatSticks*®. Approximately two thirds of established AUI had an annual family income greater than \$60,000, ~ 80% had at least some college education, and ~ 80% were in the workforce. Table 2 provides more detailed information about the demographic characteristics of the sample.

Table 2 Demographic Characteristics of Established AUI.a

	Ever Established AUI	Current Established AUI	Current Established AUI Who Prefer Menthol HeatSticks®	Current Established AUI Who Prefer non-Menthol <i>HeatSticks</i> ® % (95% CI)	
	% (95% CI)	% (95% CI)	% (95% CI)		
	n = 688	n = 645	n = 337	n = 308	
Sex					
Male	61.6 (58, 65.3)	61.1 (57.3, 64.9)	61.1 (55.9, 66.3)	61.0 (55.6, 66.5)	
Age					
Mean	45.0 (44.1, 45.9)	45.1 (44.3, 46)	43.1 (42, 44.3)	47.3 (46.1, 48.6)	
Median (Interquartile range)	43.5 (36, 54)	44 (36, 54)	41 (35, 50)	47 (39, 55.5)	
21-24	2.0 (1.0, 3.1)	2.0 (0.9, 3.1)	1.8 (0.7, 3.8)	2.3 (0.9, 4.6)	
25-34	17.6 (14.7, 20.4)	16.9 (14, 19.8)	22.6 (18.1, 27)	10.7 (7.3, 14.2)	
35-44	32.3 (28.8, 35.8)	32.4 (28.8, 36)	35.9 (30.8, 41)	28.6 (23.5, 33.6)	
45-54	25.9 (22.6, 29.1)	26.7 (23.3, 30.1)	24 (19.5, 28.6)	29.6 (24.5, 34.6)	
55-64	16.3 (13.5, 19)	16 (13.1, 18.8)	11 (7.6, 14.3)	21.4 (16.9, 26)	
65+	6.0 (4.2, 7.7)	6.1 (4.2, 7.9)	4.8 (2.5, 7)	7.5 (4.5, 10.4)	
Race/Ethnicity					
Hispanic/Latino	5.8 (4.1, 7.6)	6.1 (4.2, 7.9)	5.9 (3.4, 8.5)	6.2 (3.5, 8.9)	
Non-Hispanic White	73.0 (70.0, 76.3)	71. 8 (68.3, 75.3)	62.9 (57.8, 68.1)	81.5 (77.2, 85.8)	
Non-Hispanic Black	5.5 (3.8, 7.2)	5.7 (3.9, 7.5)	8.3 (5.4, 11.3)	2.9 (1.3, 5.5)	
Non-Hispanic Asian	13.2 (10.7, 15.8)	14 (11.3, 16.6)	20.2 (15.9, 24.5)	7.1 (4.3, 10.0)	
Non-Hispanic Native Hawaiian or other Pacific Islander	< 0.1 (< 0.1, 0.5)	< 0.1 (< 0.1, 0.6)	< 0.1 (< 0.1, 1.1)	< 0.1 (< 0.1, 1.2)	
Non-Hispanic American Indian or Alaska Native	1.2 (0.5, 2.3)	1.2 (0.5, 2.4)	1.8 (0.7, 3.8)	0.7 (0.1, 2.3)	

T					
	Ever Established AUI	Current Established AUI	Current Established AUI Who Prefer Menthol <i>HeatSticks</i> ®	Current Established AUI Who Prefer non-Menthol <i>HeatSticks</i> ®	
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	
	n = 688	n = 645	n = 337	n = 308	
Non-Hispanic Other	1.3 (0.6, 2.5)	1.2 (0.5, 2.4)	0.9 (0.2, 2.6)	1.6 (0.5, 3.8)	
Household Income					
<\$60,000	33.6 (30.1, 37.1)	32.9 (29.2, 36.5)	35.6 (30.5, 40.7)	29.9 (24.8, 35)	
\$60,000-\$74,999	9.7 (7.5, 12.0)	9.8 (7.5, 12.1)	10.4 (7.1, 13.6)	9.1 (5.9, 12.3)	
\$75,000-\$99,999	18 (15.2, 20.9)	18.3 (15.3, 21.3)	17.5 (13.5, 21.6)	19.2 (14.8, 23.6)	
\$100,000-\$149,999	18.2 (15.3, 21.1)	18.1 (15.2, 21.1)	19.3 (15.1, 23.5)	16.9 (12.7, 21.1)	
\$150,000 and over	13.8 (11.2, 16.4)	14 (11.3, 16.6)	10.4 (7.1, 13.6)	17.9 (13.6, 22.1)	
Prefer not to answer	6.7 (4.8, 8.6)	7.0 (5.0, 8.9)	6.8 (4.1, 9.5)	7.1 (4.3, 10.0)	
Education					
High School or Less	19.2 (16.2, 22.1)	19.4 (16.3, 22.4)	18.4 (14.3, 22.5)	20.5 (16.0, 25.0)	
Some college	28.5 (25.1, 31.9)	27.1 (23.7, 30.6)	26.4 (21.7, 31.1)	27.9 (22.9, 32.9)	
Associate's degree	12.4 (9.9, 14.8)	12.7 (10.1, 15.3)	15.1 (11.3, 19.0)	10.1 (6.7, 13.4)	
Bachelor's degree	26.0 (22.7, 29.3)	26.5 (23.1, 29.9)	27.6 (22.8, 32.4)	25.3 (20.5, 30.2)	
Master's degree	11.1 (8.7, 13.4)	11.3 (8.9, 13.8)	9.5 (6.4, 12.6)	13.3 (9.5, 17.1)	
Professional school degree	0.6 (0.2, 1.5)	0.6 (0.2, 1.6)	0.3 (< 0.1, 1.6)	1 (0.2, 2.8)	
Doctorate degree	1.3 (0.6, 2.5)	1.4 (0.6, 2.6)	1.2 (0.3, 3)	1.6 (0.5, 3.8)	
Other	1 (0.4, 2.1)	0.9 (0.3, 2.0)	1.5 (0.5, 3.4)	0.3 (< 0.1, 1.8)	
Employment Status					
Employed for wages	63.8 (60.2, 67.4)	63.9 (60.2, 67.6)	66.2 (61.1, 71.2)	61.4 (55.9, 66.8)	

	Ever Established AUI	Current Established AUI	Current Established AUI Who Prefer Menthol <i>HeatSticks</i> ®	Current Established AUI Who Prefer non-Menthol <i>HeatSticks</i> ®
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
	n = 688	n = 645	n = 337	n = 308
Self-employed	15.7 (13.0, 18.4)	16.1 (13.3, 19.0)	14.0 (10.3, 17.7)	18.5 (14.2, 22.8)
Not employed	20.5 (17.5, 23.5)	20 (16.9, 23.1)	19.9 (15.6, 24.1)	20.1 (15.7, 24.6)
Marital Status				
Married	53.8 (50.1, 57.5)	55.0 (51.2, 58.9)	53.1 (47.8, 58.4)	57.1 (51.6, 62.7)
Widowed	1.2 (0.5, 2.3)	1.2 (0.5, 2.4)	1.2 (0.3, 3.0)	1.3 (0.4, 3.3)
Divorced	14.5 (11.9, 17.2)	14.4 (11.7, 17.1)	12.5 (8.9, 16.0)	16.6 (12.4, 20.7)
Separated	2.2 (1.1, 3.3)	1.9 (0.8, 2.9)	2.4 (1.0, 4.6)	1.3 (0.4, 3.3)
Never married	16.9 (14.1, 19.7)	16.9 (14.0, 19.8)	20.2 (15.9, 24.5)	13.3 (9.5, 17.1)
Living with partner	8.7 (6.6, 10.8)	7.8 (5.7, 9.8)	8.0 (5.1, 10.9)	7.5 (4.5, 10.4)
Do not wish to answer	2.8 (1.5, 4.0)	2.8 (1.5, 4.1)	2.7 (1.2, 5.0)	2.9 (1.3, 5.5)

^aData are from the Altria Client Services Cross-Sectional Postmarket Adult Consumer Study – 2021.

Just over half of AUI reported they had never received any physical diagnoses included in this study (52.6%; 95% CI = 48.9%, 56.4%; see Table 3 for more details). The most common conditions reported were hypertension (24.0%, 95% CI = 20.8%, 27.2%) and high cholesterol (21.5%, 95% CI = 18.4%, 24.6%). Approximately a quarter of participants reported they had ever had a mental health condition (26.3% 95% CI = 23.0%, 29.6%).

Table 3
Lifetime Diagnosis of Selected Health Conditions among Established AUI.a

Lifetime Diagnosis of Selected He	Ever Established AUI (n = 688)	Current Established AUI (n = 645)			
	% (95% CI)	% (95% CI)			
Physical Condition					
A heart attack, also called myocardial infarction	2.8 (1.5, 4.0)	2.6 (1.4, 3.9)			
Angina, also called angina pectoris (chest pain or discomfort)	1.7 (0.8, 2.7)	1.7 (0.7, 2.7)			
Congestive heart failure	0.7 (0.2, 1.7)	0.8 (0.3, 1.8)			
Coronary heart disease	1.0 (0.4, 2.1)	1.1 (0.4, 2.2)			
High blood pressure (hypertension)	24.0 (20.8, 27.2)	23.9 (20.6, 27.2)			
High cholesterol (hyperlipidemia)	21.5 (18.4, 24.6)	21.6 (18.4, 24.7)			
Stroke	1.3 (0.6, 2.5)	1.4 (0.6, 2.6)			
Any other heart condition or heart disease	1.0 (0.4, 2.1)	1.1 (0.4, 2.2)			
COPD	4.1 (2.6, 5.6)	4.3 (2.8, 5.9)			
Chronic bronchitis	3.6 (2.2, 5.0)	3.6 (2.0.1, 5)			
Emphysema	0.7 (0.2, 1.7)	0.6 (0.2, 1.6)			
Asthma	9.6 (7.4, 11.8)	9.8 (7.5, 12.1)			
Apnea (pauses in breathing during sleep)	7.4 (5.5, 9.4)	7.1 (5.2, 9.1)			
Any other respiratory or lung condition	0.3 (< 0.1, 1.1)	0.3 (< 0.1, 1.1)			
Cancer	3.3 (2.0, 4.7)	3.1 (1.8, 4.4)			
Diabetes	6.7 (4.8, 8.6)	6.7 (4.7, 8.6)			
None of the above	52.6 (48.9, 56.4)	53 (49.2, 56.9)			
Mental Health Condition					
Yes	26.3 (23.0, 29.6)	25.7 (22.4, 29.1)			
No	69.3 (65.9, 72.8)	69.8 (66.2, 73.3)			
Don't know	4.4 (2.8, 5.9)	4.5 (2.9, 6.1)			
Taking Medication or Receiving Treatment for a Mental Health Condition or Emotional Problem					
Yes	17.7 (14.9, 20.6)	17.5 (14.6, 20.5)			
No	79.7 (76.6, 82.7)	80 (76.9, 83.1)			
Don't know	2.6 (1.4, 3.8)	2.5 (1.3, 3.7)			

Ever Established AUI (n = 688)	Current Established AUI (n = 645)	
% (95% CI)	% (95% CI)	

AUI: Adults who use IQOS®; CI: confidence interval; COPD: chronic obstructive pulmonary disease

Tobacco Use History and Cessation Treatment Use History

As shown in Table 4, 99% of established AUI had smoked cigarettes and > 90% were smoking cigarettes before they tried IQOS® for the first time. In contrast, at the time of assessment only 49% were smoking. At the time of the assessment, current established smokers (n = 326) had an average of 24.0 (95% CI = 22.6 to 25.4) years of smoking history; former established smokers (i.e., AUI who had stopped smoking; n = 329 2) had an average of 20.9 (95% CI = 19.6 to 22.3) years of smoking history. Approximately one third of established AUI were using e-cigarettes and about 16% were using cigars, and use of other tobacco products were less common (i.e., < 7%) before first trying IQOS®.

With respect to cessation treatment use, 51.2% (95% CI = 47.3-55.0%) had never used any tobacco cessation treatment, 31.3% (95% CI = 27.7-34.9%) had used it more than 12 months ago, 6.1% (95% CI = 4.2-7.9%) used it within the past 12 months but more than 30 days ago, and 4.2% (95% CI = 2.6-5.7%) used it within the past 30 days at the time of the assessment.

^aData are from the Altria Client Services Cross-Sectional Postmarket Adult Consumer Study - 2021.

Table 4
Types of Tobacco Products Used (%) Before First Tring IQOS® and at the Time of Assessment.

	Ever Established AUI			Current Established AUI				
	(n = 688)			(n = 645)				
	Before first trying IQOS®		Time of assessment	Before	Before first trying IQOS®		Time of assessment	
	Ever tried (%)	Ever established use (%)	Current use (%)	Current use (%)	Ever tried (%)	Ever established use (%)	Current use (%)	Current use (%)
Cigarettes	98.8 (97.7, 99.5)	91.9 (89.8, 93.9)	91.3 (89.2, 93.4)	49.1 (45.4, 52.9)	98.9 (97.8, 99.6)	91.6 (89.5, 93.8)	90.9 (88.6, 93.1)	49.0 (45.1, 52.9)
Cigars	62.2 (58.6, 65.8)	18.2 (15.3, 21.1)	16.6 (13.8, 19.4)	13.4 (10.8, 15.9)	61.4 (57.6, 65.2)	18.3 (15.3, 21.3)	16.4 (13.6, 19.3)	13.3 (10.7, 16.0)
Pipe filled with tobacco	22.0 (18.9, 25.0)	4.7 (3.1, 6.2)	2.6 (1.4, 3.8)	2.5 (1.3, 3.6)	21.4 (18.2, 24.6)	4.7 (3.0, 6.3)	2.6 (1.4, 3.9)	2.6 (1.4, 3.9)
Hookah	32.7 (29.2, 36.2)	4.2 (2.7, 5.7)	6.4 (4.6, 8.2)	4.9 (3.3, 6.6)	32.4 (28.8, 36.0)	4.2 (2.6, 5.7)	6.4 (4.5, 8.2)	5.1 (3.4, 6.8)
E-vapor products	71.7 (68.3, 75.0)	43.3 (39.6, 47.0)	33.3 (29.8, 36.8)	23.4 (20.2, 26.6)	71.6 (68.2, 75.1)	42.6 (38.8, 46.5)	32.7 (29.1, 36.3)	22.3 (19.1, 25.5)
Smokeless tobacco	25.3 (22.0, 28.5)	14.0 (11.4, 16.5)	5.5 (3.8, 7.2)	4.1 (2.6, 5.6)	24.3 (21, 27.7)	13.5 (10.9, 16.1)	5.6 (3.8, 7.4)	4.0 (2.5, 5.6)
Oral tobacco- derived nicotine products	20.8 (17.8, 23.8)	5.2 (3.6, 6.9)	6.0 (4.2, 7.7)	3.9 (2.5, 5.4)	19.8 (16.8, 22.9)	5.0 (3.3, 6.6)	5.4 (3.7, 7.2)	3.6 (2.1, 5.0)
Any tobacco other than IQOS	99.6 (98.7, 99.9)	95.8 (94.3, 97.3)	95.6 (94.1, 97.2)	67 (63.5, 70.5)	99.7 (98.9, > 99.9)	95.7 (94.1, 97.2)	95.5 (93.9, 97.1)	66.4 (62.7, 70.0)
AUI: Adults w	vho use I	QOS®						
Data are fror	n the Altr	ria Client Servic	es Cross-S	ectional Postma	arket Adu	It Consumer St	udy - 2021	

IQOS ® use

Overall IQOS® use

With respect to IQOS® use, AUI had an average of 1.2 years of IQOS® use (mean = 1.2, 95% CI = 1.1 to 1.2 for all established AUI; mean = 1.2, 95% CI = 1.1 to 1.3 for current AUI).

Among current AUI, one third were using IQOS® only (33.6%, 95% CI = 30.0–37.3%), 43.4% (95% CI = 39.6–47.2%) were using IQOS® and one other tobacco product (including 29.0% who were smoking cigarettes and 14.4% who were not smoking cigarettes), and 23.0% (95% CI = 19.7–26.2%) were using IQOS® and at least two other tobacco products (including 20.0% who were smoking cigarettes and 3.0% who were not smoking cigarettes). Almost 70% of current AUI used IQOS® every day during the 30 days prior to the assessment. Current AUI used a median of 15 HeatSticks® per day on days used (see Table 5).

Table 5
Use of IQOS® and IQOS® Marlboro HeatSticks® in Past 30 Days.a

	Current Established AUI	Current Established AUI Who Prefer Menthol <i>HeatSticks</i> ®	Current Established AUI Who Prefer non-Menthol HeatSticks®
	n = 645	n = 337	n = 308
# of days used IQOS® with Marlboro HeatSticks®, % (95% CI)			
0-9 days	5.6 (3.8, 7.4)	4.2 (2.0, 6.3)	7.1 (4.3, 10.0)
10−19 days	10.2 (7.9, 12.6)	9.2 (6.1, 12.3)	11.4 (7.8, 14.9)
20-29 days	15.5 (12.7, 18.3)	15.4 (11.6, 19.3)	15.6 (11.5, 19.6)
30 days	68.7 (65.1, 72.3)	71.2 (66.4, 76.1)	65.9 (60.6, 71.2)
Mean number of days used, mean (95% CI)	25.9 (25.3, 26.5)	26.3 (25.6, 27.1)	25.4 (24.5, 26.2)
Median number of days used, median (IQR)	30 (25, 30)	30 (26, 30)	30 (22, 30)
# of Marlboro® HeatSticks® used per day on days used, % (95% CI)			
Less than 1	1.1 (0.4, 2.2)	1.5 (0.5, 3.4)	0.7 (0.1, 2.3)
1	0.6 (0.2, 1.6)	0.6 (0.1, 2.1)	0.7 (0.1, 2.3)
2	1.4 (0.6, 2.6)	1.5 (0.5, 3.4)	1.3 (0.4, 3.3)
3	2.6 (1.4, 3.9)	2.7 (1.2, 5)	2.6 (1.1, 5.1)
4	1.55 (0.6, 2.5)	1.2 (0.3, 3)	2 (0.7, 4.2)
5-9	16.1 (13.3, 19.0)	16.3 (12.4, 20.3)	15.9 (11.8, 20)
10-14	22.6 (19.4, 25.9)	23.4 (18.9, 28)	21.8 (17.2, 26.4)
15-19	14.6 (11.9, 17.3)	14.5 (10.8, 18.3)	14.6 (10.7, 18.6)
20+	38.8 (35.0, 42.5)	37.4 (32.2, 42.6)	40.3 (34.8, 45.7)

	Current Established AUI	Current Established AUI Who Prefer Menthol <i>HeatSticks</i> ®	Current Established AUI Who Prefer non-Menthol <i>HeatSticks</i> ®
	n = 645	n = 337	n = 308
Median number of HeatSticks® per day on days used, median (IQR)	15 (10, 20)	15 (10, 20)	15 (10, 20)
Median number of HeatSticks® per day, median (IQR)	13 (7, 20)	12.5 (8, 20)	14 (7, 20)

AUI: Adults who use IQOS®; CI: Confidence interval; IQR: Interquartile range

^aData are from the Altria Client Services Cross-Sectional Postmarket Adult Consumer Study – 2021.

Menthol and Non-Menthol HeatSticks® preferences

The majority of current AUI had tried all three varieties of *HeatSticks*® (71%, 68%, and 56% for Amber, Green Menthol, and Blue Menthol, respectively) by the time of the assessment. Amber was the most common variety tried first (53%; 31% and 15% for Green Menthol and Blue Menthol, respectively); at the time of the assessment, nearly half indicated Amber *HeatSticks*® as the variety currently used most often (48%; 30% and 23% for Green Menthol and Blue Menthol, respectively).

Of the 316 individuals who were currently using *IQOS*® and cigarettes (i.e., dual use), 187 (59.2%) preferred non-menthol cigarettes, among whom 78.6% also preferred non-menthol *HeatSticks*®; 122 (38.6%) preferred menthol cigarettes, among whom 95.1% also preferred menthol *HeatSticks*®. There is little difference in frequency and amount of *IQOS*® use between those who preferred Menthol and non-Menthol *HeatSticks*® (see Table 5).

Perceptions of IQOS®

IQOS® was perceived as having lower health risk as compared to cigarette smoking (mean composite score of Perceived Health Risk scale = 43.8 [95% CI = 42.6 to 45.1] for IQOS®; mean composite score = 64.4 [95% CI = 63.0 to 65.7] for cigarette smoking).

With respect to the understanding of the MRTP message, 80.7% (95% CI = 77.7-83.6%) of ever established AUI correctly identified "less exposure" to harmful or potentially harmful chemicals when switching completely from cigarettes to IQOS®. Only 4.8% (95% CI = 3.2-6.4%) perceived "no exposure." Other participants answered "the same exposure" (8.6%, 95% CI = 6.5-10.7%), "more exposure" (95% CI = 95% CI = 9

Switching to IQOS® and Transitions to/back to cigarette smoking

Complete Switching to IQOS®

Among all current established AUI, 29.6% (95% CI = 26.1-33.1%) met our pre-defined "complete switching" from cigarette smoking criteria. Moreover, 50.9% of AUI were not smoking at the time of assessment (i.e., 49.1% of all

AUI were also smoking; see Table 4). The majority of individuals who were not smoking but did not meet the "complete switching" criteria were those who indicated that the last time they smoked cigarettes was within 30 days *before* first trying *IQOS*. (To meet the "complete switching" criteria, participants needed to indicate the last time they smoked was *after* first trying *IQOS*). It is possible that these individuals immediately switched to *IQOS*® and did not smoke a cigarette once they started using *IQOS*®. Therefore, we consider our estimate of "complete switching" a conservative estimate.

Among AUI who were also smoking at the time of assessment (i.e., dual use of IQOS® and cigarettes), 83.6% (95% CI = 79.4–87.8%) indicated that they smoked fewer cigarettes per day at the time of assessment compared to the 30 days prior to trying IQOS®; 2.4% (95% CI = 1.0–4.8%) indicated they smoked more, and 14.1% (95% CI = 10.1–18.0%) indicated they smoked the same number of cigarettes per day at the time of assessment compared to the 30 days prior to trying IQOS®.

Transition to or Back to Cigarettes

In this study, we observed no relapse of cigarette smoking after first trying *IQOS*® (defined as current use of cigarettes and having had smoked at least 100 cigarettes and having had not smoked cigarettes for less than 12 months prior to first trying *IQOS*®); we observed one individual who re-initiated cigarette smoking after first trying *IQOS*® (defined as current use of cigarettes and having had smoked at least 100 cigarettes and having had not smoked cigarettes for at least 12 months prior to first trying *IQOS*®).

Discussion

To our knowledge, this study is the first to describe characteristics of individuals who used *IQOS*® and comprehensively assess use behaviors and risk perceptions relevant to *IQOS*® use in a real-world setting among established AUI in the US. To summarize, our results showed that the vast majority of established AUI were existing smokers with an average of greater than 20 years of smoking history; more than 80% had either never used or had tried but stopped using tobacco cessation treatment. After an average of 1.2 years of *IQOS*® use, almost half of AUI were not smoking at the time of the assessment, and > 80% of participants who were still smoking indicated they had reduced their cigarette consumption. Over 80% of participants perceived *IQOS*® use as less harmful compared to cigarette smoking; few perceived *IQOS*® use as risk free.

These findings provide first-hand empirical evidence in a real-world setting to support the harm reduction potential of IQOS® in facilitating individuals who smoked cigarettes, especially among those who did not use cessation treatment or did not successfully quit smoking after trying cessation treatment, to switch to IQOS®. Our results extend findings from previous studies in other countries by documenting that the vast majority of individuals who used IQOS® smoked cigarettes when they first tried IQOS®, and few had never smoked a cigarette [21, 22]. These individuals had a relatively long smoking history (i.e., > 20 years on average). After an average of 1 year of IQOS® use, almost half of participants were not smoking combusted cigarettes anymore. Although not directly comparable, the portion of participants who became noncurrent smokers was one of the largest among smokefree products (e.g., e-vapor products) to the best of our knowledge [23–26].

Previous studies have found that young adults were more likely to use e-vapor products compared to older adults [27, 28]. In contrast, we found those who used *IQOS*® tended to be middle-aged or older adults and with a relatively long smoking history. In addition, the majority of participants had never tried a cessation treatment and another 31% tried but discontinued cessation treatment. Therefore, *IQOS*® may be particularly beneficial to those who are

older, have a long history of smoking, and did not use or were not successful using tobacco cessation treatment. Along with the finding of minimal uptake among individuals who had never smoked cigarettes, our results indicate that *IQOS*® is appropriate for the protection of public health.

With respect to *IQOS*® use, the majority of participants used *IQOS*® daily and used greater than 15 *HeatSticks*® per day on days used. This level of *IQOS*® consumption was generally in line with cigarette consumption among smokers in national surveys [29–31], and daily use of *IQOS*® has been associated with *IQOS*® use exclusive of cigarette smoking (vs. dual use of *IQOS*® and combusted cigarettes) [32, 33]. Taken together, these results suggest replacement of cigarettes with *IQOS*® use.

Correct perception of *IQOS*® risk can play an integral role in switching behaviors. In line with the large body of literature showing that individuals who perceive smoke-free tobacco products as less harmful compared to cigarettes were more likely to switched to such products from cigarette smoking [34, 35], a previous study has documented that individuals who used *IQOS*® exclusively (of smoking) were more likely to perceive *IQOS*® as less harmful than cigarettes as compared to those who used *IQOS*® and smoked cigarettes (i.e., dual use) [32]. Given this context, it is encouraging to observe that over 80% of participants of this study correctly identified the reduced exposure to harmful or potentially harmful chemicals when switching completely from cigarettes to *IQOS*®, and few participants incorrectly identified "no exposure."

With respect to *HeatStick*® varieties, we found an interesting pattern that suggests that menthol *HeatSticks*® were used and preferred by not only individuals who preferred menthol cigarettes, but also a sizable portion of those who preferred non-menthol cigarettes. That is, although Amber (or Original) was the most commonly ever (71%) and first (53%) tried variety, the two menthol varieties accounted for the majority of varieties used most often at the time of assessment. This is aligned with the observation that approximately 1 in 5 individuals who preferred non-menthol cigarettes preferred menthol *HeatSticks*®; in contrast, only 1 in 20 individuals who preferred menthol cigarettes preferred Amber (or Original) *HeatSticks*®. Although it is not clear why menthol *HeatSticks*® were more commonly preferred than Amber *HeatSticks*®, such findings support the potential role of menthol *HeatSticks*® varieties in continued *IQOS*® use.

In this study, we found that ever and current use of other tobacco products was more common among participants of this study (with e-vapor products being the most common) compared to that among smokers based on estimates from national surveys [36]. This may signal those individuals open to trying and using other tobacco products were more likely to try and use IQOS. When compared to the time before trying IQOS, we observed a \sim 30% reduction in e-cigarette use. It is possible that some participants were using e-vapor products to help stop cigarette smoking but were not successful; after start using IQOS, they stopped using e-vapor products. Future studies that assess reasons to stop using other tobacco products will shed new light on this topic.

Our findings should be interpreted with the following limitations in mind. First, the study is based on self-reported information. Although we are not aware of any validation studies on self-reported *IQOS*® use behaviors, the larger literature supports a reasonable validity of self-reported behaviors in tobacco research [37]. In addition, many measures relied on recalled information (e.g., behaviors during the 30 days before first trying *IQOS*®), for which recall bias cannot be ruled out. We tried to minimize recall bias by (i) asking about prominent behaviors generally easy to recall, such as whether they smoked cigarettes during the 30 days before first trying *IQOS*®, and (ii) limit the length of the recall period as short as possible (e.g., past 30 days). Second, it is estimated that approximately 70% of individuals who purchased *IQOS*® registered in the database. Moreover, of all individuals invited to

complete the eligibility assessment, only 10.5% did so. It is unknown whether individuals who registered in the database or responded to the invitation are representative of all AUI in the United States. Also, due to limited distribution of *IQOS*®, it is not clear whether these results would apply to all adults who smoke in the US. Nonetheless, we provided the first estimates of perceptions and behaviors related to *IQOS*® use from a sample large enough to produce meaningful results. Third, the study was conducted among AUI, so we cannot provide information about the prevalence of *IQOS*® use in the general US population. Finally, no definitive evidence can be drawn for causal relationships from this observational study. It is noteworthy that during the recruitment period, a notification was sent to *IQOS*® consumers on October 13, 2021 informing them that *IQOS*® would become unavailable after November 28, 2021. In consideration of the potential impact of this communication on consumer behaviors, we also conducted analyses only using data collected before that date (n = 463). Results from this subsample are generally in line with the results for the full sample.

Conclusions

Our results provide supportive evidence for the potential of *IQOS*® to help individuals who smoke switch to *IQOS*® by comprehensively assessing use behaviors and risk perceptions relevant to *IQOS*® use in a real-world setting among established AUI in the US.

Abbreviations

AUI

Adults who used IQOS®

CDO

Cease-and-Desist Order

CI

Confidence interval

FDA

Food and Drug Administration

HPHC

Harmful and potentially harmful constituents

IQR

Interquartile range

ITC

United States International Trade Commission

MRTP

Modified risk tobacco product

US

United States

Declarations

Ethics approval and consent to participate

The study was approved and overseen by Sterling Institutional Review Board (IRB ID #: 9102-HCheng). Participant consent was obtained from all participants.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

HGC, BN, ARV, and EGL are employees of Altria Client Services LLC. PM is an employee of Philip Morris International, and AH was an employee of Philip Morris International at the time of this study. Both companies are tobacco manufacturers.

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Authors' contributions

All authors designed the study. HGC, BN, and ARV acquired the data. HGC prepared the first draft. All authors reviewed and revised the manuscript. All authors approved the final version of the manuscript.

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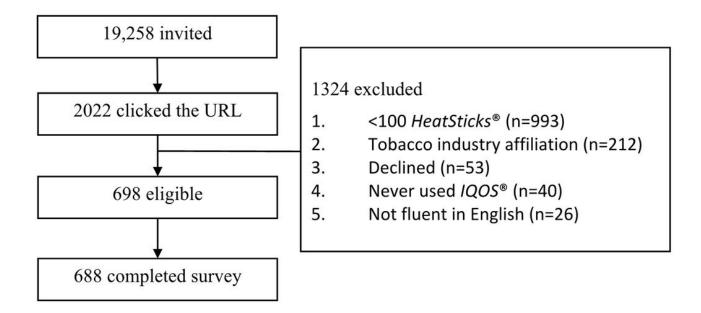
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Footnotes

1. The ITC issued a CDO prohibiting the importation, marketing, sale and distribution of *IQOS*® devices and Marlboro *HeatSticks*® on September 29, 2021. To comply with the CDO, Philip Morris USA stopped marketing

- and selling all IQOS® devices and Marlboro HeatSticks® as of November 28, 2021 in all channels.
- 2. Of the 329 former established smokers at the time of the assessment, 289 (88%) were smoking cigarettes during the 30 days prior to first trying *IQOS*® or smoked after first trying *IQOS*®, which suggested that they became former smokers after first trying *IQOS*®. Of the 30 participants who did not smoke during the 30 days prior to first trying *IQOS*® and indicated the last time they smoked was before trying *IQOS*®, 14 indicated they had not smoked for < 1 month before trying *IQOS*®, and 16 had not smoked for at least 12 months before first trying *IQOS*®, among whom 11 were using at least one type of tobacco product during the 30 days prior to trying *IQOS*®.

Figures



Flowchart of sample recruitment.