










OPEN ACCESS

Awareness, trial and use of heated tobacco products among adult cigarette smokers and e-cigarette users: findings from the 2018 ITC Four Country Smoking and Vaping Survey

Connor R Miller ¹, Edward Sutanto ¹, Danielle M Smith ¹, Sara C Hitchman ², Shannon Gravely,³ Hua H Yong ⁴, Ron Borland,⁵ Richard J O'Connor,¹ K Michael Cummings ⁶, Geoffrey T Fong,^{3,7} Andrew Hyland,¹ Anne C K Quah,³ Maciej L Goniewicz ¹

► Additional material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/tobaccocontrol-2020-055985>).

For numbered affiliations see end of article.

Correspondence to

Dr Maciej L Goniewicz, Department of Health Behavior, Roswell Park Comprehensive Cancer Center, Buffalo, NY 14263, USA; maciej.goniewicz@roswellpark.org

Received 4 June 2020

Revised 4 August 2020

Accepted 19 August 2020

ABSTRACT

Objective To evaluate heated tobacco product (HTP) awareness, trial and current use among adult cigarette smokers and vaping product users in four countries with varying regulations governing HTP sales.

Design Data came from Wave 2 of the ITC Four Country Smoking and Vaping Survey, collected from February to July 2018. Respondents were current and former smokers and/or users of vaping products (18 years or older) from Canada (CA; n=3778), England (EN; n=4848), the USA (US; n=2846) and Australia (AU; n=1515). At the time of the survey, only Canada and England permitted the sale of contemporary HTPs (eg, IQOS).

Results Overall, 30.2% of respondents reported being aware of HTPs (CA=30.4%; EN=31.0%; US=30.2%; AU=27.4%; p=0.346), 2.4% had ever tried HTPs (CA=3.3%; EN=2.4%; US=2.0%; AU=0.9%; p=0.001) and 0.9% currently used HTPs at least monthly (CA=0.8%; EN=1.2%; US=0.7%; AU=0.2%; p<0.001). Trial and current use were higher among those who concurrently smoked and vaped (at least monthly) versus other nicotine use categories (trial: 10.9% v. 1.2%–2.0%, p<0.001; current use: 8.4% v. 0.1%–1.0%, p<0.001). In multivariable analyses, HTP awareness did not differ across countries, whereas odds of trial and current use were lower where HTPs were unavailable. Odds of HTP trial did not differ by regulatory environment when restricting analysis to HTP-aware concurrent smokers–vapers.

Conclusion Approximately one third of respondents were aware of HTPs, even in the USA and Australia, where contemporary HTPs were not yet on the market. Trial and use were uncommon, except among concurrent smokers–vapers. Restrictions on availability may have limited HTP use generally, but less so for concurrent smokers–vapers.

INTRODUCTION

Heated tobacco products (HTPs) are an expanding category within the novel tobacco product marketplace. They differ from conventional cigarettes in that they heat rather than burn tobacco, as well as from nicotine vaping products (NVPs; also known as e-cigarettes), which heat e-liquid (ie, mainly nicotine, propylene glycol, vegetable glycerine and flavourings). Although HTPs are not strictly new

products,¹ a plethora of contemporary HTP brands have been launched in select metropolitan areas of more than 50 countries since 2014,² leading to an international HTP market valued in 2018 at US\$6.3 billion.³ Substantial market growth is forecast through 2022.⁴ HTPs have attained a significant share of the Japanese tobacco market in particular, where tobacco inserts for Philip Morris International's (PMI) HTP brand IQOS comprised 17% of all tobacco sales from July to September 2019.⁵ HTPs are also gaining traction elsewhere: British American Tobacco (BAT) reported its HTP brand (glo) maintained at least a 5% share of national tobacco markets in Romania, Serbia and Poland as of June 2019.⁶

IQOS has been retailed online and in storefronts in parts of England since December 2016⁷ and Canada since April 2017,⁸ whereas BAT launched glo in Canada in May 2017.⁹ In both countries, awareness of HTPs was limited and uptake negligible 3–6 months after HTPs entered the market,^{7,8} to the extent that Canadian glo sales were terminated in September 2019.¹⁰ Still, from 2018 to 2019, PMI reported 92.5% and 44.2% revenue increases from their 'reduced risk' product line (including IQOS) in market regions encompassing England and Canada, respectively.⁵

In stark contrast with these countries, the sale of contemporary HTPs is effectively barred in Australia,¹¹ and earlier generation HTPs were never widely marketed, although PMI did trial their product HeatBar in 2007 for a brief period.¹² Likewise, no contemporary HTP brands were authorised for sale in the USA until PMI's IQOS in April 2019. IQOS has been regulated stringently since the Food and Drug Administration (FDA) approved sales, and similar to policies in Canada and England, PMI is prohibited from making claims of reduced risk.¹³ On 7 July 2020, the FDA ruled that PMI could make claims of modified exposure when marketing IQOS (eg, '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').¹⁴ Earlier generation HTPs have previously been marketed in the USA, including RJ Reynolds's brand Eclipse, which was



© Author(s) (or their employer(s)) 2020. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

To cite: Miller CR, Sutanto E, Smith DM, et al. *Tob Control* Epub ahead of print: [please include Day Month Year]. doi:10.1136/tobaccocontrol-2020-055985

formally marketed between 2003 and 2007 and could still be found sparingly as of 2017.¹⁵ However, a number of early generation HTP brands were rescinded following a test market period, and the few that made it to market had limited distribution and advertising support.¹⁶

As with any novel tobacco/nicotine product, evaluating patterns of awareness and use in populations of interest is necessary for understanding the public health implications of HTPs. Additionally, comparisons between countries with divergent regulatory environments may clarify the impact that policy decisions have on HTP awareness and use. Few studies to date have conducted cross-national examinations of HTP awareness or use among adults, and most publications have used data from 2016 and 2017.^{7 8 17–19} Moreover, no studies have directly compared HTP awareness and use between countries that permit HTP sales and those that explicitly or implicitly restrict them. The present study used data from 2018 to assess prevalence and characteristics associated with awareness, trial and current use of HTPs among adult smokers and vaping product users in two countries that permitted contemporary HTP sales (Canada and England) and two countries where contemporary HTPs were unavailable (USA and Australia).

METHODS

Study design and sample

Data originated from the International Tobacco Control (ITC) Four Country Smoking and Vaping Wave 2 (4CV2) Survey conducted in Canada (CA), England (EN), USA (US) and Australia (AU) in 2018. Data collection took place from February 2018 through July 2018. Methodological details are available on the ITC website (https://itcproject.s3.amazonaws.com/uploads/documents/4CV2_Technical_Report_15Jan202.pdf). The 4CV2 main sample comprised the following subsamples of adults (aged 18+): (1) recontact smokers and former smokers who had participated in the previous wave of the ITC 4CV Project (ie, 4CV1)²⁰, (2) newly recruited current and former smokers (quit smoking in the previous 24 months) from country-specific panels, regardless of vaping status, (3) recontact vapers who had participated in 4CV1 and (4) newly recruited vapers (using a vaping device at least weekly) from country-specific panels, regardless of smoking status. The newly recruited smoker and vaper samples in each country were designed to be representative of smokers and at-least-weekly vapers respectively, using either probability-based sampling frames or non-probability opt-in sampling frames, or a combination of these methods. Survey weights were designed to ensure sample generalisability to smokers, recent quitters and vapers in each country. The present study included data for the 12 987 respondents that comprise the main ITC 4CV2 sample (CA: n=3778; EN: n=4848; US: n=2846; AU: n=1515).

Measures

HTP awareness, trial and use

Awareness, trial and current use of HTPs were assessed with the following questions: (1) awareness: *'Have you heard about new electronic products that heat tobacco instead of burning it? These products use battery power to heat capsules, pods, or cigarette-like sticks that contain tobacco. These include products such as iQOS'* (yes | no | don't know); (2) trial (asked only to those who responded 'yes' to HTP awareness question): *'Have you ever used one of these 'heat-not-burn' products, even one time?'* (yes | no | don't know); and (3) current use (asked only to those who responded 'yes' to the HTP trial question): *'How often, if at all, do you CURRENTLY use heat-not-burn products?'* (daily less

than daily, but at least once a week | less than weekly, but at least once a month | less than once a month, but occasionally | I have only tried a heat-not-burn product a few times, but more than once | I have only ever tried a heat-not-burn product once | do not know). HTP awareness and trial were categorised dichotomously (yes vs no/do not know), whereas current HTP use was defined as at least once a month.

Respondents who reported ever using HTPs were also asked to identify which HTP brand(s) they had used. As previous research⁷ indicates that survey respondents may struggle to distinguish the use of HTPs from other modalities (eg, NVPs) and substances (eg, cannabis), only those self-reported HTP users who identified a known HTP brand were considered as 'ever' or 'current' HTP users, respectively. Briefly, 23.6% of those who supposedly had ever used HTPs selected 'do not know' and 5.3% selected 'other', whereas 6.1% of current HTP users selected 'do not know' and 6.3% selected 'other' (reported in text only; percentages unweighted). These respondents were reclassified accordingly (see the online supplemental figures S1–S3 for additional details).

Other nicotine use status

Using monthly use as our threshold for current product use, we categorised participants into four mutually exclusive groups: (1) 'exclusive' smokers; (2) 'exclusive' vapers; (3) concurrent smoker-vapers; (4) non-current smoker/vapers. The classification used to derive each of the four groups and details regarding the composition of the non-current smoker/vaper category can be found in the online supplemental tables 1 and 2. Participants who reported using e-cigarettes or vaping devices but indicated they exclusively used products that did not contain nicotine were reclassified as non-vapers. This altered the categorisation of 119 participants, 66 of which were reclassified from the concurrent smoker-vaper group into the 'exclusive' smoker group and 53 from the 'exclusive' vaper group into the non-current smoker/vaper group.

Sociodemographic measures

Sociodemographic measures included age (18–24, 25–39, 40–54, and 55 and older), sex (male and female individuals), socioeconomic status (SES) and ethnicity. SES was derived from three-level education and income variables (low, moderate and high) that accounted for country-specific differences in currency and education systems.²¹ Respondents in the 'high' category for either education or income were classified as having 'high' SES; remaining respondents in the 'low' category for either education or income were classified as having 'low' SES, and the rest were classified as having 'moderate' SES (those who responded 'do not know' or 'refused' for both variables were coded as missing). Ethnicity was dichotomised as 'majority' (CA/US/EN=white; AU=English speaking) or 'minority'.

Statistical analyses

Descriptive characteristics were presented as unweighted frequencies and percentages. For HTP prevalence measures (awareness, trial and current use), cross-sectional sampling weights for the 4CV2 sample were used to generate population estimates. HTP prevalence measures were estimated for the overall sample, by country of residence and by nicotine use status. The χ^2 tests were used to assess bivariate associations of categorical variables. Where post hoc pairwise comparisons were conducted, the Bonferroni correction was used.

Adjusted ORs and 95% CIs from multivariable logistic regression models were used to examine independent correlates of the three HTP prevalence measures. All multivariable regression analyses applied cross-sectional sampling weights for the 4CV2 sample. For models predicting HTP awareness, the full analytic sample was analysed. For models predicting the HTP trial, separate analyses were conducted among (a) the full analytic sample and (b) only HTP-aware respondents. For models predicting the HTP current use, separate analyses were conducted among (a) the full analytic sample and (b) among HTP ever users. The following covariates were evaluated in regression models: age, sex, ethnicity, SES, country of residence and other nicotine use status.

Additionally, to further explore differences according to HTP regulatory environments, we classified the four countries according to the market availability of HTPs. Respondents from CA and EN comprised the HTP-available category (where contemporary HTP sales were permitted at the time of the survey (2018)), and those from the US and AU comprised the HTP-unavailable category (where contemporary HTPs were unavailable at the time of the survey). After substituting the 'HTP-availability' variable for the 'country of residence' variable, the logistic regression models were repeated. For HTP trial and current use, there was some evidence of interaction between other nicotine use status and HTP availability (interaction $p < 0.05$). Therefore, we conducted additional regression analyses within each nicotine use category, controlling for age, sex, ethnicity, SES and HTP availability (only results for concurrent smoker-vapers are shown). Finally, given the many ways in which one can classify current product use, we repeated the analyses for current weekly HTP use (results can be found in the online supplemental files). All analyses were conducted in SAS V.9.4 (SAS Institute), and an alpha of 0.05 was used to determine statistical significance. In multivariable analyses, missing data were handled as listwise deletions.

RESULTS

Prevalence of HTP awareness, trial and current use

Table 1 presents descriptive characteristics and HTP prevalence measures for the overall sample. An estimated 30.2% of the sample reported that they had heard of HTPs, 2.4% had ever tried HTPs and 0.9% currently used HTPs at least monthly. Bonferroni-adjusted pairwise comparisons showed no significant differences in the awareness of HTPs between countries. Compared with CA (3.3%) and EN (2.4%), the trial of HTPs was significantly lower in AU (0.9%) and the trial was lower in the US (2.0%) compared with CA. Current HTP use was significantly lower in the US (0.7%) compared with EN (1.2%) and was lower in AU (0.2%) compared with each of the other countries (CA=0.8%).

Table 2 displays HTP prevalence measures according to other nicotine use status, both overall and according to the country of residence. Significant differences across nicotine use categories were observed for all three measures (all $\chi^2 p < 0.001$), each of which was highest among concurrent smoker-vapers: 40.5% reported that they had heard of HTPs, 10.9% had ever tried HTPs and 8.4% currently used HTPs at least monthly. Altogether, 89.8% of current HTP users were concurrent smoker-vapers, 5.4% 'exclusive' smokers, 4.3% 'exclusive' vapers and 0.5% non-current smoker/vapers (reported in text only; unweighted percentages). Patterns observed in the overall sample were generally consistent within all four countries, though no significant differences in HTP awareness were

seen across nicotine use categories within the US subsample ($\chi^2 p = 0.403$).

Correlates of HTP awareness, trial and current use

In multivariable analyses of the overall sample (table 3), higher odds of HTP awareness, trial and current use were seen for younger age groups and male individuals. Minority ethnicity was associated with HTP awareness and trial, and higher SES was associated with trial and current use of HTPs. Compared with respondents from CA, those from the US and AU were less likely to have ever tried or currently use HTPs, and EN respondents were less likely to have ever tried HTPs. 'Exclusive' vapers, 'exclusive' smokers and concurrent smoker-vapers were each more likely than non-current smoker/vapers to be aware of HTPs. Concurrent smoker-vapers had higher odds of HTP trial than non-current smoker/vapers, and 'exclusive' vapers and concurrent smoker-vapers were more likely than 'exclusive' smokers to be current HTP users. After limiting the analysis to HTP-aware respondents, the associations of younger age, minority ethnicity and high SES with HTP trial remained statistically significant, as did the associations for the country of residence and nicotine use status.

In multivariable analyses modelling HTP availability in place of country of residence (table 4), respondents from HTP-available countries were more likely to have ever tried HTPs, even after limiting the analysis to HTP-aware respondents. Respondents from HTP-available countries also had higher odds of current HTP use overall; this association attenuated and was not statistically significant when limiting the analysis to HTP ever users. When restricting the analysis to concurrent smoker-vapers who were aware of HTPs (table 4), there was no significant difference in the odds of HTP trial according to HTP availability.

DISCUSSION

In this study of adult smokers and vaping product users in CA, EN, US and AU, approximately one in three respondents self-reported awareness of HTPs in 2018. Trial and current use of HTPs were uncommon, even in countries where HTPs had been available on the market. As seen in 2017 data from the US,¹⁷ current HTP use was negligible among 2018 ITC 4CV2 respondents who were neither current users of cigarettes nor NVPs. Although our data lack generalisability to nicotine-naïve adults, limited uptake among these former and less-than-monthly nicotine users is encouraging from a public health perspective. Still, there were patterns observed in the data that may cause concern. Specifically, trial and current use of HTPs were higher among concurrent smoker-vapers than other groups. Though a minority of study respondents were considered concurrent smoker-vapers, they made up over half of the current HTP users. Current HTP use was also higher among 'exclusive' vapers than 'exclusive' smokers, highlighting NVPs as a common denominator for the majority of current HTP use.

HTP uptake alongside NVPs may reflect similarities between the two products: both are promoted as potentially modified risk products, with an emphasis on sleek, 'high tech' product designs.^{22 23} Higher odds of HTP trial and use among 18–24 year olds—a demographic group where NVP use is pervasive²⁴—further supports this premise. These patterns suggest that early adopters of HTPs are more likely to be users of multiple nicotine products and in an age range prone to experimentation.²⁵ However, the cross-sectional study design limits the understanding of product use patterns over time. Alternatively, the high prevalence of HTP use among concurrent

Table 1 Descriptive characteristics and HTP prevalence measures for the overall analytic sample and according to country of residence

Variables	Overall (N=12 987)	Canada (N=3778)	England (N=4848)	USA (N=2846)	Australia (N=1515)	χ^2 p value
Descriptive characteristics*						
Age (years)						
18–24	2562 (19.7)	804 (21.3)	1118 (23.1)	617 (21.7)	23 (1.5)	<0.001
25–39	2857 (22.0)	995 (26.3)	1105 (22.8)	516 (18.1)	241 (15.9)	
40–54	3322 (25.6)	1030 (27.3)	1220 (25.2)	567 (19.9)	505 (33.3)	
55+	4246 (32.7)	949 (25.1)	1405 (29.0)	1146 (40.3)	746 (49.2)	
Sex						
Male	6322 (48.7)	1785 (47.3)	2436 (50.3)	1318 (46.3)	783 (51.7)	<0.001
Female	6663 (51.3)	1992 (52.7)	2411 (49.7)	1528 (53.7)	732 (48.3)	
Ethnicity						
Majority	10 770 (84.4)	2951 (79.5)	4351 (90.7)	2094 (76.2)	1374 (90.8)	<0.001
Minority	1998 (15.7)	759 (20.5)	446 (9.3)	654 (23.8)	139 (9.2)	
SES						
Low	4380 (33.9)	1147 (30.5)	1550 (32.2)	1202 (42.2)	481 (31.8)	<0.001
Moderate	1989 (15.4)	642 (17.1)	744 (15.5)	399 (14.0)	204 (13.5)	
High	6568 (50.8)	1976 (52.5)	2519 (52.3)	1245 (43.8)	828 (54.7)	
Other nicotine use status†						
Non-current smoker/vaper	1619 (12.5)	705 (18.7)	301 (6.2)	422 (14.8)	191 (12.6)	<0.001
'Exclusive' vaper	1087 (8.4)	251 (6.6)	398 (8.2)	358 (12.6)	80 (5.3)	
'Exclusive' smoker	6753 (52.0)	1948 (51.6)	2358 (48.6)	1361 (47.8)	1086 (71.7)	
Concurrent smoker–vaper	3528 (27.2)	874 (23.1)	1791 (36.9)	705 (24.8)	158 (10.4)	
HTP prevalence measures‡						
Aware of HTPs						
Yes	30.2 (29.1–31.4)§	30.4 (28.5–32.4)	31.0 (28.9–33.2)	30.2 (27.8–32.6)	27.4 (24.1–34.8)	0.346
No	69.8 (68.6–70.9)	69.6 (67.6–71.5)	69.0 (66.8–71.1)	69.8 (67.4–72.2)	72.6 (69.2–75.9)	
Ever tried HTPs						
Yes	2.4 (2.1–2.8)¶	3.3 (2.6–4.4)	2.4 (1.9–3.2)	2.0 (1.3–2.8)	0.9 (0.2–1.7)	0.001 ^{b,c,e}
No	97.6 (97.2–97.9)	96.6 (96.0–97.4)	97.5 (97.8–98.1)	98.0 (97.2–98.7)	99.1 (98.3–99.8)	
Current HTP user						
Yes	0.9 (0.7–1.0)**	0.8 (0.6–1.1)	1.2 (0.9–1.6)	0.7 (0.4–0.9)	0.2 (0.0–0.4)	<0.001 ^{c,d,e,f}
No	99.1 (99.0–99.3)	99.2 (98.9–99.4)	98.8 (98.4–99.1)	99.3 (99.1–99.6)	99.8 (99.6–100.0)	

Some n's may not add to column totals due to missing data: sex (n=2), ethnicity (n=219), SES (n=50), aware of HTPs (n=12), ever tried HTPs (n=14) and current HTP user (n=18).

Six post hoc analyses with Bonferroni correction were performed for the HTP prevalence measures, with $p < 0.0083$ considered statistically significant; ^aCanada vs England, ^bCanada vs USA, ^cCanada vs Australia, ^dEngland vs USA, ^eEngland vs Australia, ^fUSA vs Australia.

*Values are unweighted and represent n (column %); χ^2 p values are from Pearson χ^2 tests.

†For details of the 'other nicotine use status' classification strategy, please refer to online supplemental table S1.

‡Values are weighted and represent column % (95% CI); χ^2 p values are from Rao-Scott adjusted χ^2 tests.

§n=4252.

¶n=697.

**n=443.

HTP, heated tobacco product; SES, socioeconomic status.

users could be driven by those concurrent smoker–vapors that are actively exploring additional alternatives to conventional tobacco smoking. Continued surveillance efforts of awareness, trial and use of HTPs according to the use of other nicotine-containing products will be important to monitor public health implications of permitting the sale of HTPs. Additionally, studies examining HTP initiation, transitions with the use of other nicotine-containing products and polyproduct use will constitute important directions for future research as marketing and availability of HTPs continues to grow across jurisdictions.

Regulatory environment and HTPs

Although HTP trial and current use were generally uncommon in all four countries, multivariable results indicated a higher likelihood of trial and current use of HTPs where the products were readily accessible (ie, no sales restrictions). For HTP trial, this remained true when limiting the analysis to HTP-aware

respondents, suggesting that lower odds of trial in HTP-unavailable countries were somewhat independent of levels of awareness. This likely reflects logistical obstacles that prospective HTP users face where sales are restricted: even if someone has heard of HTPs, obtaining the product is more difficult if local retailers do not sell HTP devices or tobacco inserts. Regardless, the absolute differences in use between HTP-available and HTP-unavailable countries were quite small. Given the novelty of contemporary HTPs in 2018 and the expanding international market (now including sales in the US), it is likely that awareness could increase over time. Continued monitoring of these patterns is warranted to track the implications of regulatory decisions on patterns of use as awareness changes.

Whereas trial and current use of HTPs were relatively less common where availability was restricted (US and AU), self-reported awareness was similar across all countries. This contrasts with cross-national patterns of initial NVP awareness,

Table 2 Awareness, trial and current use of HTPs, according to other nicotine use status

Outcome of interest	Non-current smoker/vaper	'Exclusive' vaper	'Exclusive' smoker	Concurrent smoker-vaper	Rao-Scott χ^2 p value
Overall sample (n=12 987)	n=1619	n=1087	n=6753	n=3528	
Aware of HTPs	25.7 (22.8–28.6)	34.5 (29.4–39.5)	30.4 (29.0–31.7)	40.5 (38.2–42.7)	<0.001
Ever tried HTPs	1.2 (0.6–1.8)	2.0 (0.9–3.1)	2.0 (1.6–2.5)	10.9 (9.6–12.2)	<0.001
Current HTP user	0.1 (0.0–0.1)	1.0 (0.3–1.8)	0.3 (0.2–0.5)	8.4 (7.3–9.6)	<0.001*
CA respondents (n=3778)	n=705	n=251	n=1948	n=874	
Aware of HTPs	28.3 (24.0–32.6)	27.1 (17.3–36.9)	30.8 (28.6–33.0)	39.9 (35.5–44.3)	0.044
Ever tried HTPs	2.5 (1.1–3.9)	5.6 (0.0–11.2)	2.8 (1.9–3.6)	13.9 (10.7–17.0)	<0.001
Current HTP user	0.2 (0.0–0.4)	2.4 (0.0–5.2)	0.4 (0.1–0.7)	9.0 (6.3–11.7)	<0.001*
EN respondents (n=4848)	n=301	n=398	n=2358	n=1791	
Aware of HTPs	20.8 (14.8–26.8)	35.7 (28.0–43.4)	32.0 (29.7–34.3)	42.7 (39.6–45.9)	<0.001
Ever tried HTPs	0.5 (0.0–1.3)	1.6 (0.2–3.1)	1.9 (1.1–2.7)	10.8 (9.1–12.6)	<0.001*
Current HTP user	0.0 (0.0–0.0)	0.7 (0.0–1.7)	0.5 (0.1–0.9)	9.1 (7.5–10.8)	<0.001*
US respondents (n=2846)	n=422	n=358	n=1361	n=705	
Aware of HTPs	29.9 (24.5–35.2)	27.7 (21.6–33.8)	29.9 (26.8–33.0)	36.3 (31.4–41.2)	0.403
Ever tried HTPs	0.5 (0.0–1.1)	2.7 (0.5–4.9)	2.0 (0.9–3.1)	7.8 (5.3–10.2)	<0.001*
Current HTP user	0.0 (0.0–0.0)	2.0 (0.0–4.1)	0.2 (0.0–0.4)	6.3 (4.0–8.5)	0.027†
AU respondents (n=1515)	n=191	n=80	n=1086	n=158	
Aware of HTPs	23.5 (15.9–31.1)	44.0 (29.7–58.2)	25.8 (22.1–29.6)	34.8 (23.4–46.2)	0.005
Ever tried HTPs	0.9 (0.0–2.8)	0.0 (0.0–0.0)	0.8 (0.0–1.6)	11.4 (2.7–20.1)	N/A
Current HTP user	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.1)	7.3 (0.4–14.1)	N/A

Values represent weighted % (95% CI) unless otherwise indicated.

*Due to limited cell sizes (n<5), non-current smoker-vaper category excluded from the χ^2 test.

†Due to limited cell sizes (n<5), non-current smoker-vaper and 'exclusive' smoker categories excluded from the χ^2 test.

HTP, heated tobacco product.

which was substantially higher among ITC Four Country Study respondents in NVP-available environments (US and EN) than in NVP-unavailable environments (CA and AU) in 2010–2011.²⁶ Two potential contributors to this difference are worth highlighting: first, contemporary HTPs are being unveiled during a time period of heightened media accessibility, in which the growing popularity of social media platforms²⁷ has increased exposure to international promotional materials.^{28,29} Second, in comparison with initial NVP advertisement regulations in the US and EN,^{30,31} HTP advertisement restrictions in CA and EN were more stringent in 2018.^{32,33} Taken together, these distinctions may have contributed to similar awareness in HTP-unavailable and HTP-available countries in 2018.

Even still, many factors likely influence awareness of HTPs, as evidenced by the 2018 EUREST-PLUS ITC Survey conducted in six HTP-available countries in the European Union. Using the same survey item as ITC 4CV2, self-reported awareness of HTPs among current and former smokers in Spain, Romania, Hungary and Poland ranged from 7.8% to 17.2%,³⁴ substantially less than all four of our country-specific estimates in ITC 4CV2. By contrast, awareness in Germany and Greece appeared more similar to ITC 4CV2 results. These cross-national patterns highlight the interplay between market availability and the many other determinants of novel nicotine product awareness and uptake, including social norms, harm perceptions, prevalence of smoking/vaping and many others.

Notably, in our multivariable analyses restricted to concurrent smoker-vapers, odds of the trial were lower in HTP-unavailable than HTP-available countries, but no significant differences were seen when further restricting the analysis to only concurrent smoker-vapers who were aware of HTPs. It may be that interested concurrent smoker-vapers are more willing and able to obtain HTPs than other tobacco users, regardless of local

sales restrictions: compared with those who have tried or are currently using some alternative product, exclusive smokers are generally less interested as a whole.³⁵ With respect to HTPs, this might be true for exclusive vapers as well, given they are abstaining from smoking already and may find NVPs to suffice as an alternative product. This likely contrasts with the subgroup of concurrent smoker-vapers who are actively exploring alternatives to tobacco smoking outside of, or in addition to, NVPs.

Strengths and limitations

Although our findings provide important insight into HTP awareness and use across different regulatory environments, our results should be interpreted judiciously. Whereas prior research has evaluated HTP awareness and use in general population surveys,^{17,18} all respondents in ITC 4CV2 were current or former users of cigarettes and/or vaping devices, making the results of this study inapplicable to tobacco-naïve adults. Additionally, both the non-current smoker/vaper and the 'exclusive' vaper categories contained individuals with a mixture of lifetime smoking patterns, including a small number of never smokers, long-term quitters, recent quitters and current less-than-monthly smokers. Stratification across these groups suggested that HTP awareness corresponded with the recency of smoking (online supplemental table S8).

Misreported HTP prevalence measures are also of concern, as HTPs are new to the market and might be confused with other products, including NVPs and cannabis vaporisers or vape pens (eg, the HTP brand PAX, which heats loose-leaf tobacco, is marketed primarily for the consumption of cannabis). Although the ITC 4CV2 survey attempted to clearly differentiate HTPs, we found some evidence of misreporting: 5.6% of respondents who self-reported ever trying HTPs reported a product brand

Table 3 Multivariable logistic regression of awareness, trial and current use of HTPs in the overall sample

Characteristics	Aware of HTPs	Ever tried HTPs		Current HTP user	
	(n=12 987)*	(n=12 987)*	(n=4252)†	(n=12 987)*	(n=697)‡
Age (years)					
55+	REF	REF	REF	REF	REF
40–54	1.32 (1.15–1.52)	3.18 (1.69–5.98)	2.82 (1.48–5.37)	3.41 (1.67–6.99)	1.60 (0.41–6.20)
25–39	1.39 (1.20–1.62)	5.83 (3.15–10.81)	4.93 (2.62–9.25)	4.91 (2.47–9.76)	1.05 (0.29–3.85)
18–24	1.26 (1.05–1.50)	7.13 (3.83–13.28)	6.61 (3.49–12.51)	7.47 (3.76–14.82)	1.31 (0.33–5.15)
Sex					
Female	REF	REF	REF	REF	REF
Male	1.74 (1.56–1.95)	1.68 (1.25–2.26)	1.27 (0.92–1.74)	1.50 (1.04–2.17)	0.64 (0.31–1.34)
Ethnicity					
Majority	REF	REF	REF	REF	REF
Minority	1.20 (1.02–1.42)	1.80 (1.27–2.55)	1.61 (1.10–2.37)	1.36 (0.94–1.97)	0.79 (0.39–1.58)
Socioeconomic status					
Low	REF	REF	REF	REF	REF
Moderate	0.81 (0.68–0.96)	0.98 (0.62–1.55)	1.15 (0.71–1.88)	0.77 (0.45–1.32)	0.60 (0.25–1.43)
High	0.94 (0.82–1.07)	1.70 (1.21–2.41)	1.79 (1.24–2.57)	1.73 (1.14–2.63)	1.38 (0.67–2.85)
Country of residence					
Canada	REF	REF	REF	REF	REF
England	0.98 (0.86–1.13)	0.57 (0.41–0.79)	0.56 (0.39–0.81)	0.96 (0.61–1.49)	2.13 (0.96–4.73)
USA	0.95 (0.82–1.11)	0.57 (0.36–0.90)	0.58 (0.36–0.95)	0.62 (0.38–0.97)	1.33 (0.58–3.04)
Australia	0.83 (0.68–1.01)	0.26 (0.12–0.60)	0.30 (0.13–0.70)	0.25 (0.09–0.68)	0.67 (0.16–2.74)
Other nicotine use status					
Non-current smoker/vaper	REF	REF	REF	0.15 (0.03–0.69)	0.23 (0.04–1.34)
'Exclusive' vaper	1.53 (1.16–2.02)	1.65 (0.77–3.56)	1.36 (0.60–3.09)	2.22 (0.84–5.85)	4.07 (1.19–13.91)
'Exclusive' smoker	1.30 (1.10–1.54)	1.27 (0.85–1.82)	1.59 (0.88–2.87)	REF	REF
Concurrent smoker–vaper	1.94 (1.61–2.34)	10.56 (6.29–17.73)	7.87 (4.47–13.84)	21.75 (12.38–38.19)	16.40 (8.37–32.13)

Values represent aOR (95% CI) unless otherwise indicated. Bold values indicate the 95% CI does not include the null value.

aORs represent results of multivariable logistic regression analysis adjusted for all variables in the table.

*All respondents (n=12 987) included in analytic sample.

†Only HTP-aware respondents (n=4252) included in analytic sample.

‡Only HTP ever users (n=697) included in analytic sample.

aOR, adjusted odds ratio; HTP, heated tobacco product; REF, reference value.

that was an NVP or cannabis vaporiser or vape pen, whereas 23.6% could not recall the HTP brand they had tried (percentages are unweighted).

Given there was just one measure used to assess HTP awareness, this outcome was susceptible to misclassification, likely as an overestimate. Indeed, a 2018 study in England found a higher prevalence of self-reported HTP awareness among respondents whose questionnaire item read 'heat-not-burn tobacco products use a technology whereby tobacco is being heated as opposed to being burnt...' versus those whose questionnaire item further included '...some of the popular brands of heat-not-burn tobacco products include Ploom and iQos...'.⁷ Notably, the ITC 4CV2 HTP awareness item included not only brand examples, but also a country-specific photo of a contemporary HTP brand. Nevertheless, the potential for misclassification remains, and our results for HTP awareness should be interpreted with some caution. Future studies should incorporate additional measures to clarify awareness, trial and use of early generation and contemporary HTP devices from other forms of nicotine delivery, or from devices intended for use with other substances. Additionally, the ITC 4CV2 HTP awareness questionnaire item describes HTPs as using '...battery power to heat capsules, pods, or cigarette-like sticks that contain tobacco'. Although true for the majority of contemporary HTP brands, this definition excludes those HTP brands that use carbon tip technology. The most notable of these is the early generation HTP brand Eclipse,

however there are also some contemporary HTP brands that rely on carbon tip technology, including PMI's TEEPS (thus far only released in test markets).³⁶

In contrast with HTP awareness, we developed more rigorous definitions for HTP trial and current use according to brand responses. If someone who currently used HTPs on a monthly basis was able to identify the brand(s) used, then this definition would more accurately capture current HTP use versus relying on a single questionnaire item. However, it is plausible that those who reported trying HTPs once or only a handful of times truly did not know what HTP brand they tried, particularly if they used someone else's HTP. We elected to reclassify 'do not know' responses, as misreporting sporadic use of NVPs as HTPs is possible, and self-reported ever use of NVPs was substantially higher than HTPs in ITC 4CV2.³⁷ Still, this ambiguity means HTP trial may be underestimated, though the extent to which treating 'do not know' brand responses as HTP ever users alters the interpretation of results appears minimal (online supplemental table S9).

CONCLUSION

Our study found that in 2018, similar proportions of respondents in CA, EN, the US and AU self-reported awareness of HTPs, regardless of country-specific market availability. Although HTP use was uncommon among former product users,

Table 4 Multivariable associations of HTP regulatory environment with awareness, trial and current use of HTPs, within the overall sample and among concurrent smokers–vapers

Outcome variable & HTP regulatory environment	aOR (95% CI)	
	Overall sample*	Concurrent smoker–vapers†
Aware of HTPs‡	n=12 987	n=3528
HTP-unavailable countries	REF	REF
HTP-available countries	1.10 (0.96–1.24)	1.42 (1.13–1.79)
Ever tried HTPs‡	n=12 987	n=3528
HTP-unavailable countries	REF	REF
HTP-available countries	1.61 (1.11–2.35)	1.68 (1.18–2.41)
Ever tried HTPs§	n=4252	n=1589
HTP-unavailable countries	REF	REF
HTP-available countries	1.54 (1.05–2.30)	1.21 (0.77–1.92)
Current HTP user‡	n=12 987	n=3528
HTP-unavailable countries	REF	REF
HTP-available countries	1.79 (1.16–2.76)	1.68 (1.12–2.53)
Current HTP user¶	n=697	n=527
HTP-unavailable countries	REF	REF
HTP-available countries	1.25 (0.62–2.50)	1.09 (0.50–2.39)

Bold values indicate the 95% CI does not include the null value.

*Adjusted for age, sex, ethnicity, SES and other nicotine use status.

†Adjusted for age, sex, ethnicity and SES.

‡All respondents included in analysis.

§Only HTP-aware respondents included in analysis.

¶Only HTP ever users included in analysis.

aOR, adjusted odds ratio; HTP, heated tobacco product; HTP-available, respondents from CA or EN; HTP-unavailable, respondents from the US or AU; REF, reference value; SES, socioeconomic status.

experimental product users and smokers who did not use NVPs, trial and current use were higher for concurrent users of NVPs and cigarettes. Comparisons between countries with divergent regulatory environments suggest that sales restrictions may have impacted overall levels of HTP use, but not necessarily among concurrent smoker–vapers.

What this paper adds

- ▶ Heated tobacco products (HTPs) are sold in over 50 countries worldwide, often as potentially modified risk tobacco products.
- ▶ Research on awareness and use of HTPs in newly established markets is lacking, and no studies have compared awareness and use between countries that actively permit HTP sales and those that restrict HTP sales.
- ▶ In this 2018 cross-national study of adult smokers and vaping product users, awareness of HTPs was similar between countries that actively permitted the sale of contemporary HTPs (Canada and England) and countries that did not (USA and Australia).
- ▶ Although HTP use was negligible overall (particularly where sales were restricted), trial and current use were more common among those who concurrently smoked and vaped, regardless of country-specific regulations on HTP sales.

Author affiliations

¹Department of Health Behavior, Roswell Park Comprehensive Cancer Center, Buffalo, New York, USA

²Department of Addictions, Institute of Psychiatry, Psychology & Neuroscience, King's College London, London, UK

³Department of Psychology, University of Waterloo, Waterloo, Ontario, Canada

⁴School of Psychology, Deakin University, Geelong, Victoria, Australia

⁵School of Psychological Sciences, University of Melbourne, Melbourne, Victoria, Australia

⁶Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina, Charleston, South Carolina, USA

⁷Ontario Institute for Cancer Research, Toronto, Ontario, Canada

Twitter Geoffrey T Fong @gfgong570

Acknowledgements The authors would like to acknowledge and thank all those that contributed to the International Tobacco Control Four Country Smoking and Vaping (ITC 4CV) Survey: all study investigators and collaborators, and the project staff at their respective institutions.

Contributors All authors have made substantial contributions to this paper. MLG, CRM and DMS conceptualised the study. CRM carried out the analysis and along with ES, DMS and MLG interpreted the results. CRM drafted the paper with critical review and significant comments from all other authors.

Funding This study was supported by grants from the US National Cancer Institute (P01 CA200512), the Canadian Institutes of Health Research (FDN-148477), and by the National Health and Medical Research Council of Australia (APP 1106451). GTF was supported by a Senior Investigator Grant from the Ontario Institute for Cancer Research. CRM, DS, RO, AH and MLG were supported by a Tobacco Centers of Regulatory Science US National Cancer Institute grant (U54CA238110).

Competing interests KMC has received payment as a consultant to Pfizer for service on an external advisory panel to assess ways to improve smoking cessation delivery in health care settings. KMC also has served as paid expert witness in litigation filed against the tobacco industry. GTF has served as expert witnesses on behalf of governments in litigation involving the tobacco industry. MLG received research grant from Pfizer and served as a member of scientific advisory board to Johnson&Johnson.

Patient consent for publication Not required.

Ethics approval Study questionnaires and materials were reviewed and provided clearance by Research Ethics Committees at the following institutions: University of Waterloo (Canada, ORE#20803/30570, ORE#21609/30878), King's College London, UK (RESCM-17/18-2240), Cancer Council Victoria, Australia (HREC1603), University of Queensland, Australia (2016000330/HREC1603); and Medical University of South Carolina (waived due to minimal risk). All participants provided consent to participate.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iDs

Connor R Miller <http://orcid.org/0000-0002-4810-4816>

Edward Sutanto <http://orcid.org/0000-0002-8852-5770>

Danielle M Smith <http://orcid.org/0000-0002-1637-0992>

Sara C Hitchman <http://orcid.org/0000-0001-6155-6916>

Hua H Yong <http://orcid.org/0000-0001-8167-6173>

K Michael Cummings <http://orcid.org/0000-0002-7103-7017>

Maciej L Goniewicz <http://orcid.org/0000-0001-6748-3068>

REFERENCES

- 1 Caputi TL. Industry watch: heat-not-burn tobacco products are about to reach their boiling point. *Tob Control* 2017;26:609–10.
- 2 Bialous SA, Glantz SA. Heated tobacco products: another tobacco industry global strategy to slow progress in tobacco control. *Tob Control* 2018;27:s111–7.
- 3 Uranaka T, Ando R. Philip Morris aims to revive Japan sales with cheaper heat-not-burn tobacco, 2018. Available: <https://uk.reuters.com/article/us-pmi-japan/philip-morris-aims-to-revive-japan-sales-with-cheaper-heat-not-burn-tobacco-idUKKCN1MX06E> [Accessed 26 Nov 2019].
- 4 Technavio. Global Heat-Not-Burn tobacco products market, 2018–2022, 2018. Available: https://www.technavio.com/report/global-heat-not-burn-cigarettes-market-analysis-share-2018?utm_source=t9discount&utm_medium=bw_wk33&utm_campaign=businesswire [Accessed 26 Nov 2019].
- 5 Philip Morris International. 2019 Third-Quarter results, 2019. Available: <https://philipmorrisinternational.gcs-web.com/static-files/a5f2050f-4fda-4713-9278-d9e39b4b38f7> [Accessed 19 Oct 2019].

- 6 British American Tobacco. Half-year report for the six months to 30 June 2019, 2019. Available: [https://www.bat.com/group/sites/uk__9d9kcy.nsf/vwPagesWebLive/DO72TJQU/\\$FILE/medMDBEMBMN.pdf?openelement](https://www.bat.com/group/sites/uk__9d9kcy.nsf/vwPagesWebLive/DO72TJQU/$FILE/medMDBEMBMN.pdf?openelement) [Accessed 25 Nov 2019].
- 7 Brose LS, Simonavicius E, Cheeseman H. Awareness and Use of 'Heat-not-burn' Tobacco Products in Great Britain. *Tob Regul Sci* 2018;4:44–50.
- 8 Fung MDT, Diemert LM, Zhang B, et al. Awareness and perceived risk of heated tobacco products. *Tob Regul Sci* 2020;6:15–19.
- 9 Non-Smokers' Rights Association, Smoking and Health Action Foundation. Next generation products in Canada: an update on heated tobacco, 2017. Available: <https://nsra-adnf.ca/wp-content/uploads/2018/03/12-dec-2017-heated-tobacco-update2-final-1.pdf> [Accessed 28 Oct 2019].
- 10 British American Tobacco. glo is being discontinued. Available: <https://glo.ca/sunset-faq/> [Accessed 25 Nov 2019].
- 11 Greenhalgh E. Heated tobacco ('heat-not-burn') products. In: *Tobacco in Australia: facts and issues*. Melbourne: Cancer Council Victoria, 2018. www.TobaccoInAustralia.org.au
- 12 Freeman B, Haslam I, Tumini V. Tobacco advertising and promotion. In: *Tobacco in Australia: facts and issues*. Melbourne: Cancer Council Victoria, 2012. http://tobacco.clearhear.org.hk/wp-content/uploads/2016/01/Ch11_Advertising.pdf
- 13 Food and Drug Administration. Fda permits sale of IQOS tobacco heating system through premarket tobacco product application pathway, 2019. Available: <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway> [Accessed 25 Nov 2019].
- 14 Food and Drug Administration. FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information, 2020. Available: <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information> [Accessed 20 Jul 2020].
- 15 Richard Craver. Reynolds pursues another restart with revamped heat-not-burn cigarette eclipse, 2017. Available: https://www.journalnow.com/business/reynolds-pursues-another-restart-with-revamped-heat-not-burn-cigarette/article_2be640ec-f0e8-517e-a9ff-8bee3b0fdf07.html [Accessed 3 Jun 2020].
- 16 Jackler RK, Ramamurthi D, Axelrod AK, et al. Global Marketing of IQOS The Philip Morris Campaign to Popularize "Heat Not Burn" Tobacco, 2020. Available: <http://tobacco.stanford.edu/iqosanalysis>
- 17 Nyman AL, Weaver SR, Popova L, et al. Awareness and use of heated tobacco products among US adults, 2016-2017. *Tob Control* 2018;27:s55–61.
- 18 Marynak KL, Wang TW, King BA, et al. Awareness and Ever Use of "Heat-Not-Burn" Tobacco Products Among U.S. Adults, 2017. *Am J Prev Med* 2018;55:551–4.
- 19 McNeill A, Brose LS, Calder R, et al. *Evidence review of e-cigarettes and heated tobacco products 2018: a report commissioned by public health England*. London: Public Health England, 2018.
- 20 Thompson ME, Fong GT, Boudreau C, et al. Methods of the ITC four country smoking and Vaping survey, wave 1 (2016). *Addiction* 2019;114 Suppl 1:6–14.
- 21 Li L, Borland R, O'Connor RJ, et al. How are self-reported physical and mental health conditions related to Vaping activities among smokers and quitters: findings from the ITC four country smoking and Vaping wave 1 survey. *Int J Environ Res Public Health* 2019;16:1–13.
- 22 McKelvey K, Popova L, Kim M, et al. Heated tobacco products likely appeal to adolescents and young adults. *Tob Control* 2018;27:s41–7.
- 23 Nardone N, Helen GS, Addo N, et al. JUUL electronic cigarettes: nicotine exposure and the user experience. *Drug Alcohol Depend* 2019;203:83–7.
- 24 Dai H, Leventhal AM. Prevalence of e-cigarette use among adults in the United States, 2014-2018. *JAMA* 2019;322:1824–7.
- 25 Villanti AC, Niaura RS, Abrams DB, et al. Preventing smoking progression in young adults: the concept of preescalation. *Prev Sci* 2019;20:377–84.
- 26 Adkison SE, O'Connor RJ, Bansal-Travers M, et al. Electronic nicotine delivery systems: international tobacco control four-country survey. *Am J Prev Med* 2013;44:207–15.
- 27 Perrin A. Social networking usage: 2005-2015. Pew research center 2015. Available: <https://www.pewresearch.org/internet/2015/10/08/social-networking-usage-2005-2015/> [Accessed 21 Dec 2019].
- 28 Berthon PR, Pitt LF, Plangger K, et al. Marketing meets web 2.0, social media, and creative consumers: implications for international marketing strategy. *Bus Horiz* 2012;55:261–71.
- 29 Dagli E, Guner M, Sonmez U, et al. Heated tobacco product marketing: Internet platforms undermine regulations. *Eur Respir J* 2019;54:PA1693.
- 30 Bauld L, Angus K, De Andrade M. *E-Cigarette uptake and marketing: a report commissioned by public health England*, 2014.
- 31 Noel JK, Rees VW, Connolly GN. Electronic cigarettes: a new 'tobacco' industry? *Tob Control* 2011;20:81.
- 32 Mathers A, Schwartz R, O'Connor S, et al. Marketing IQOS in a dark market. *Tob Control* 2019;28:237–8.
- 33 Tompkins CNE, Burnley A, McNeill A, et al. Factors that influence smokers' and ex-smokers' use of IQOS: a qualitative study of IQOS users and ex-users in the UK. *Tob Control* 2020. doi:10.1136/tobaccocontrol-2019-055306. [Epub ahead of print: 15 Jan 2020].
- 34 Lotrean LM, Trofor A, Radu-Loghin C, et al. Awareness and use of heated tobacco products among adult smokers in six European countries: findings from the EUREST-PLUS ITC Europe surveys. *Eur J Public Health* 2019.
- 35 Taylor KA, Sharma E, Edwards KC, et al. Longitudinal pathways of exclusive and polytobacco cigarette use among youth, young adults and adults in the USA: findings from the path study waves 1-3 (2013-2016). *Tob Control* 2020;29:s139–46.
- 36 Philip Morris International. Carbon-heated tobacco product: TEEPS. Available: <https://www.pmi.com/smoke-free-products/teeps-carbon-heated-tobacco-product> [Accessed 20 Jul 2020].
- 37 Gravely S, Driezen P, Ouimet J, et al. Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among adult current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross-sectional findings from the ITC project. *Addiction* 2019;114:1060–73.