

Characteristics of nicotine vaping products used by participants in the 2016 ITC Four Country Smoking and Vaping Survey

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ABSTRACT

Background and Aims The regulatory environment for nicotine vaping products (NVPs) varies widely across countries and this will probably affect the devices used, nicotine content and usage, and hence the ability of NVPs to substitute for cigarettes. We aimed to describe the types of NVPs used by current vapers in four countries with varying regulatory and enforcement approaches toward the marketing and sale of NVPs. **Methods** Data are from wave 1 (July–November 2016) of the ITC Four Country Smoking and Vaping Survey (4CV1), conducted among a cohort of current and former smokers, and current NVP users ($n = 5147$ adults; ≥ 18 years) in Australia (AU), Canada (CA), England (EN) and the United States (US) reporting either current daily, weekly or occasional NVP use. Devices were described by type, brand, voltage variability and refill capacity. Refill solutions were described by flavour and nicotine content. Descriptive statistics and bivariate analyses were conducted on the overall sample and stratified by country. A multinomial logistic regression examined factors associated with device preference across the whole sample. **Results** The types of NVPs used differed by pattern of use and country. Exclusive, daily vapers were more likely to use refillable pen-shaped devices [odds ratio (OR) = 10.0] or refillable box-shaped devices (OR = 5.4) than disposable cigalike devices, when compared with other (non-daily/dual) users. Nearly all respondents reported using flavoured NVPs, fruit (28.3%) being the most common flavour. Refillable devices were the most popular: refillable box-shaped devices were more commonly reported by vapers in AU (36.8%) and US (31.4%), whereas in EN (47.4%) and CA (29.7%), vapers more often reported using refillable pen-style devices. Most users also reported that their products contained nicotine, even in CA (87.8%) and AU (91.2%), where vaping products containing nicotine were technically illegal. **Conclusions** In Australia, Canada, England and the United States in 2016, refillable nicotine vaping products were the most common type of nicotine vaping products used by daily vapers. Most daily vapers reported using flavoured e-liquids/refills (with variance across countries) and most reported using products that contain nicotine, even where vaping products with nicotine were banned.

Keywords Aerosol, delivery, device, e-cigarettes, flavour, nicotine, vaporized nicotine products.

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INTRODUCTION

There are a considerable number of nicotine vaping products (NVPs, also called e-cigarettes or vaporizers) available to consumers, with nicotine-containing liquids used by the vast majority of adult consumers. Nicotine delivery is likely to affect ease of substitution for cigarettes in nicotine

dependent smokers and as a result is likely to affect smoking cessation and patterns of use, such as dual use and long-term use [1–5]. The kind of NVPs people use, levels of overall use and whether they use with nicotine is likely to be affected by the regulatory environment. Further, devices which differ in the way they deliver the product are likely to affect overall use patterns, and potentially

the public health implications. Therefore, understanding the nature of the vaping market, including the diversity of products and how they are used, is important in trying to understand the impacts of differing regulatory environments, as well as the potential implications of different types of devices on usage, and potential harm.

NVPs can be classified roughly into three broad categories: (1) disposable systems, (2) systems with closed, non-refillable disposable cartridges/capsules/pods (typically containing the solution and the heating element) and (3) tank systems where a reservoir is filled with liquid (i.e. 'open' system). Some previously referred to first-, second- and third-generation devices, but while useful for summarizing the evolution of NVPs over time, it fails to clearly distinguish specific design elements that may be critical to nicotine and toxicant exposure, satisfaction and ability to substitute for cigarettes. Closed systems rely on pre-filled liquid reservoirs or cartridges to contain the liquid solution, and while this category began with products designed to closely resemble cigarettes ('cigalikes'), it now has much more heterogeneity not just in appearance, with most no longer resembling cigarettes, but in terms of battery capacity and efficiency in nicotine delivery (e.g. tank systems with capsules such as Logic pro; pods such as JUUL). Among the open systems there are smaller models, with lower-capacity batteries, and modular systems with greater power capability and options for customizability. Some devices, primarily open systems, allow user customization of device temperature or voltage. These features may again be important to some users, enabling them to titrate delivery. Some larger NVP manufacturers, who previously only sold closed-system NVPs in some countries, have introduced open-system NVPs (e.g. NJoy, Vype, Blu), perhaps responding to consumer demands for refillable products.

Several studies have reported that the type of NVP device used can influence nicotine delivery and exposure to toxicants [6,7]. In a convenience sample of experienced US vapers surveyed in 2014, Yingst *et al.* showed that most vapers began with a disposable or 'cigalike' device (59%) and nearly two-thirds transitioned to a refillable device, whereas only 6% of those who began on a refillable device made the reverse move [8]. In a 2014–16 survey of US adolescents and young adults, Barrington-Trimis and colleagues found that 8% used a disposable device, while 77% used cartridge or tank systems [1]. Etter, in a 2012–14 online survey of vapers in multiple countries, showed that the vast majority used refillable products [2]. Harvanko and colleagues showed that factors such as ability to change device voltage, level of coil resistance, amount of liquid consumed, nicotine concentration and milligrams of nicotine used per week were all associated with users' level of nicotine dependence [9]. NVPs that deliver nicotine in a similar fashion to that from a conventional cigarette

appear to be associated with greater levels of cigarette substitution and higher rates of complete abstinence from smoking [10]. However, comprehensive data on the types of NVPs used by vapers are limited, and to our knowledge only one study used consistent terminology allowing cross-country comparisons [2]. This complicates the interpretation of findings from the UK into a US context; for example, with regard to the use of NVP for cessation of smoking versus situational substitution (e.g. dual use). This lack of comparable data makes it difficult to thoroughly examine the positive and negative impacts of NVP use on smoking rates and nicotine dependence, as NVP substitution may be directly tied to the type of device used.

Regulation of NVPs can also shape consumer behaviour by altering the availability of products for purchase. We consider four countries with different regulatory environments. In Australia (AU), NVPs have been effectively banned from retail sale if they contain nicotine, except with special permission [11]. In Canada (CA), where vape shops are the most commonly reported source of NVPs, e-cigarettes containing nicotine have been technically illegal, although enforcement has been weak, and new regulations that will permit the legal retail sale of NVPs are under consideration. The legal restrictions on the sale of NVPs in CA have had the effect of keeping NVP devices (typically closed systems) manufactured by cigarette manufacturers out of retail shops, while NVP devices manufactured by non-cigarette companies (typically open systems) dominate the market [12]. Government regulators are increasingly being asked to develop standards that address the safety, labelling and nicotine delivery of NVPs [13–17]. One of the key components of the European Union (EU) Tobacco Products Directive (TPD), introduced in May 2016, is that NVPs and/or e-liquid bottles/cartridges containing < 20 mg/ml are treated as consumer products, while those with greater nicotine concentrations are subject to regulation as a medicinal product [18]. In EN, from 1 October 2015, a minimum age of sale (18 years) for NVPs was introduced. In August 2016, the US Food and Drug Administration (FDA) was granted regulatory authority over NVPs, which barred the sale of NVPs to minors and prevented distribution of free product samples, although other regulatory conditions were delayed to 2022 [19]. Devices themselves have seen less regulation than have nicotine-containing liquids. In the EU, this has taken the form of limiting refillable tank capacity to 2 mL. Agencies such as the FDA in the US have the authority to set product standards, and setting such standards requires at base an understanding of the state of the market-place—how, in what context and by whom devices are used.

The objective of this paper is to describe the types of NVPs reportedly used by current vapers who were participants in the 2016 ITC 4 Country Smoking and Vaping Survey (4CV1), using consistent measures across the four

countries. As these markets differ in smoking and vaping rates and patterns as well as policies, we also examine the role of these factors with respect to device and liquid preferences.

METHODS

The ITC Four Country Smoking and Vaping Survey (4CV1) is an expansion of the original ITC Four Country Survey infrastructure, conceptual model [20] and methodologies [21], to examine the use and evolution of the NVP market-place and policy environments by surveying adult smokers, recent ex-smokers and NVP-only users in AU, CA, England (EN, not the entire UK) and the US—four countries with similar cigarette smoking rates but divergent policies related to NVPs. Methodological details for each country are available in Thompson *et al.* (this issue) and via the ITC website (<http://www.itcproject.org/methods>). In brief, the wave 1 Survey (4 CE1) sample, accrued between July and November 2016, consisted of the following cohorts: (1) re-contact smokers and quitters who participated in the final wave of the ITC 4C project; (2) newly recruited current smokers and recent quitters (quit smoking in the past 24 months) from country-specific panels; and (3) newly recruited current e-cigarette users (use at least weekly) from country-specific panels. Respondents for the ITC 4CV1 survey were recruited via random-digit-dialling (RDD) sampling frames, or web-based or address-based panels, or a combination of these frames, and were designed to be as representative as possible of smokers, non-smokers and NVP users. These analyses characterized NVPs used by 4CV1 participants; thus, analyses focused on the 5147 respondents who indicated that they were current daily, weekly or occasional NVP users at the time of the survey.

NVP product use was categorized as exclusive daily, exclusive non-daily or one of four types of concurrent use, as defined by crossing daily or non-daily NVP use with daily or non-daily cigarette smoking. Note that questions were not asked about IQOS or similar heated tobacco products, because IQOS have only recently become available for sale from limited sources in England and Canada.

MEASURES

Device characteristics

Device type was characterized by combining two different measures, in order to capture myriad possible variations. First, participants were asked to describe the appearance of the type of NVP currently used most, selecting from the following choices: (1) 'looks like an ordinary cigarette, including shape, size, and colour'; (2) 'looks similar in shape and size to an ordinary cigarette, but is a different colour'; (3) 'looks similar in shape to a pen, but may not

be round, and is pen-sized or larger'; (4) 'looks like a box-shaped battery (that fits in the palm of my hand) with a mouthpiece'; and (5) 'looks different than any of the options described above'. Participants were also asked to describe the type of NVP currently used most, categorizing the device type as: (1) 'disposable' (2), 'cartridge-based' and (3) 'refillable tank-based'. Respondents who reported use of refillable products were asked additional questions about whether the voltage on their NVP could be adjusted, and about the capacity of the e-liquid tank.

Questions about the look of the device as well as device type were combined to create an analytical variable containing the following descriptors: (1) 'cigalikes' (a combination of looks like/similar to an ordinary cigarette and is disposable or cartridge-based); (2) 'pen-style cartridge' (similar in shape to a pen and uses a cartridge-based refill); (3) 'pen-style tank' (similar in shape to a pen and has a refillable tank); (4) 'box tanks' (box-shaped with a mouthpiece and refillable tank); and (5) 'all other combinations'.

Refill solution characteristics

Refill solution flavour was assessed by asking respondents to report the flavour of the e-liquid used. Ten response options were offered as follows: (1) no flavour, (2) tobacco flavour, (3) mix of tobacco and menthol, (4) menthol/mint, (5) fruit flavour, (6) candy/desserts/sweets, (7) chocolate, clove/spice, (8) coffee, (9) non-alcoholic drink and (10) alcoholic drink. Given the response distribution, we further collapsed responses into six categories as follows: (1) unflavoured, (2) tobacco, (3) menthol or tobacco/menthol mix, (4) fruit flavoured, (5) candy/sweets/dessert/chocolate flavoured and (6) some other flavour.

Nicotine content of the refillable e-liquid was assessed using two different questions—one for respondents who reported the nicotine content of their primary e-cigarette in terms of ng/ml and one for respondents who reported the nicotine content of their primary NVP using a verbal descriptor, such as: 'no nicotine, low or light, medium or regular, and high, strong or bold'. The two variables were combined as follows: (1) no nicotine, (2) 1–4 ng/ml and low nicotine, (3) 5–14 ng/ml and medium nicotine and (4) 15 + ng/ml and high nicotine. Additionally, we grouped those who reported numerical values as < 20 mg and 21+ mg to evaluate compliance with the EU TPD.

Data analysis

Analyses were weighted to country-representative samples using a cross-sectional weight for current NVP users. Descriptive statistics and bivariate analyses were conducted on the overall sample and stratified by country, with χ^2 tests used to evaluate descriptive differences. A

multinomial logistic regression (referent was 'cigalike', because it is the format that has been on the market for the longest time) examined factors associated with device preference throughout the whole sample, controlling for country, product use pattern and demographic factors. The referent category was also 'cigalike', because it is the format that has been on the market for the longest time. We examined the odds of choosing each of the other categories (box tank, pen-style tank and all other device types) relative to 'cigalike'. For analytical purposes, the 'pen-style cartridge' category was combined with the 'other devices' category. Missing data were handled as listwise deletions and no imputations were made. An alpha level of 0.05 was used to evaluate statistical significance in the model. All analyses were conducted using SPSS version 21.0 (IBM, Armonk, NY, USA).

Ethics approval

The survey protocols and all materials, including the survey questionnaires, were cleared for ethics by the Research Ethics Office, King's College London, UK; the Office of Research Ethics, University of Waterloo, Canada; and Human Research Ethics, Cancer Council Victoria, Australia. All participants provided consent to participate.

RESULTS

Device characteristics by country

Table 1 shows the results overall and separately for each of the four countries among current vapers. Device type differed by country, with box-shaped tanks more common in the AU and US samples (36.8 and 31.4%, respectively).

Table 1 Device and refill characteristics overall and by country, ITC 4 CE1 survey, 2016.

	Canada (<i>n</i> = 1068)	United States (<i>n</i> = 1073)	England (<i>n</i> = 1284)	Australia (<i>n</i> = 212)	Overall (<i>n</i> = 3637)
Device characteristics					
Type (<i>n</i> = 3637)					
Box-shaped tank	25.7	31.4	20.8	36.8	26.3
Cigalike	22.7	30.7	20.2	22.2	24.1
Pen-style tank	29.7	21.8	47.4	28.8	33.5
Pen-style cartridge	9.3	5.4	7.3	1.9	7.0
All others	12.6	10.7	4.3	10.4	9.0
Adjust temperature/voltage (<i>n</i> = 2975)					
Adjustable	66.5	66.4	44.5	63.2	58.5
Not adjustable	26.1	32.2	53.0	34.6	38.0
Don't know (valid response)	7.4	1.3	2.6	2.2	3.5
Capacity (<i>n</i> = 2961)					
Less than 1 ml	2.8	5.9	2.1	0.5	3.3
1–1.5 ml	18.4	11.6	12.0	13.1	13.8
1.6–2.0 ml	27.6	18.1	27.5	20.2	24.2
2.1–3 ml	16.9	19.0	15.0	20.2	17.1
3.1–4.0 ml	8.3	12.4	9.3	15.3	10.3
Over 4 ml	7.2	7.0	5.3	18.0	7.2
Don't know	18.8	25.8	28.7	12.6	24.1
Refill characteristics					
Flavour (<i>n</i> = 3217)					
Unflavoured	7.4	6.0	2.1	4.8	5.0
Tobacco flavoured	22.8	24.2	35.0	24.9	27.5
Menthol or tobacco/menthol mix	16.6	17.4	27.0	30.2	21.2
Fruit flavoured	30.8	30.5	26.5	15.3	28.3
Candy, sweets, dessert, chocolate	13.4	13.8	5.3	11.6	10.7
Flavoured other	9.0	8.1	4.0	13.2	7.3
Nicotine content (<i>n</i> = 3258)					
No nicotine	12.2	7.1	5.9	8.8	8.3
1–4 ng/ml/low nicotine	23.7	17.6	13.8	17.0	18.0
5–14 ng/ml/medium nicotine	43.3	44.5	42.4	46.4	43.6
15 + ng/ml/high nicotine	17.8	24.4	35.4	23.7	26.2
Don't know (valid response)	3.0	6.3	2.6	4.1	4.0

In EN (47.4%) and CA (29.7%), pen-style devices with a refillable tank were most commonly reported, while cigalikes were most commonly reported among US vapers (30.7%) ($\chi^2_{(12)} = 257.23$, $P < 0.001$). Among vapers who reported using refillable devices at least weekly (92%), 58.5% responded that their device was adjustable, while 3.5% said that they did not know. This differed significantly by country—NVP users in EN were far less likely to report adjustable devices (44.5%) compared to those in CA (66.5%), the US (66.4%) and AU (63.2%) ($\chi^2_{(6)} = 209.11$, $P < 0.001$). The most commonly reported volume or capacity ranged between 1 and 3 ml, although 24.1%

reported that they 'don't know' the volume or capacity of their systems. Those in EN (28.7%) were most likely to report 'don't know' to the size of their tank, and also to report a capacity of 2.0 ml or less ($\chi^2_{(18)} = 153.72$, $P < 0.001$).

Table 2 examines demographic factors associated with device type selection (with 'cigalike' taken as the referent). Exclusive, daily e-cigarette users compared with those who smoke cigarettes were more likely to report using a pen-style device with refillable tank [odds ratio (OR) = 10.04; 95% confidence interval (CI) = 6.24–16.14] or a box-shaped device with a refillable tank (OR = 5.37; 95% CI = 3.41–8.84) over cigalikes.

Table 2 Multinomial logistic regression model comparing characteristics of box-shaped tank users, pen-shaped tank users and users of all other device types to users of cigalike devices ($n = 3380$).

		<i>n</i>	%	<i>P</i> -value	aOR	95% CI		
						Lower bound	Upper bound	
All other device types	Country							
		Australia	26	40.5	0.847	0.949	0.557	1.617
		Canada	233	40.1	0.000	2.136	1.605	2.844
		England	149	25.6	0.161	1.238	0.919	1.667
		United States	173	29.8	Ref			
		E-cig/tobacco use status						
		Exclusive daily e-cig user	150	25.8	0.006	1.840	1.187	2.853
		Exclusive non-daily e-cig user	68	11.7	0.002	0.484	0.303	0.772
		Mixed daily e-cig/non-daily tobacco user	36	6.2	0.279	1.388	0.767	2.514
		Mixed daily tobacco/non-daily e-cig user	138	23.8	0.156	0.739	0.486	1.122
	Mixed daily tobacco/daily e-cig user	120	20.7	0.838	0.956	0.622	1.470	
	Mixed non-daily e-cig/non-daily tobacco user	69	11.9	Ref				
Box-tank	Country							
		Australia	61	5.0	0.020	1.704	1.089	2.668
		Canada	317	26.0	0.000	2.970	2.282	3.866
		England	608	49.8	0.000	2.795	2.177	3.589
		United States	234	19.2	Ref			
		E-cig/tobacco use status						
		Exclusive daily e-cig user	506	41.1	0.000	5.372	3.418	8.442
		Exclusive non-daily e-cig user	106	8.7	0.523	1.169	0.725	1.884
		Mixed daily e-cig/non-daily tobacco user	96	7.9	0.000	3.408	1.940	5.987
		Mixed daily tobacco/non-daily e-cig user	283	23.2	0.091	1.461	0.942	2.265
	Mixed daily tobacco/daily e-cig user	184	15.1	0.108	1.453	0.921	2.292	
	Mixed non-daily e-cig/non-daily tobacco user	46	3.8	Ref				
Pen-style tank	Country							
		Australia	78	8.2	0.150	1.380	0.890	2.140
		Canada	275	28.7	0.000	1.682	1.286	2.200
		England	267	27.9	0.160	.825	0.631	1.079
		United States	337	35.2	Ref			
		E-cig/tobacco use status						
		Exclusive daily e-cig-user	500	52.2	0.000	10.035	6.239	16.141
		Exclusive non-daily e-cig user	110	11.5	0.085	1.545	0.941	2.537
		Mixed daily e-cig/non-daily tobacco user	76	7.9	0.000	4.857	2.695	8.753
		Mixed daily tobacco/non-daily e-cig user	127	13.3	0.782	1.070	0.663	1.725
	Mixed daily tobacco/daily e-cig user	106	11.1	0.347	1.267	0.774	2.073	
	Mixed non-daily e-cig/non-daily tobacco user	38	4.0	Ref				

Referent group for multinomial regression is 'cigalike'. Model is adjusted for age, sex, race/ethnicity, income and education. CI = confidence interval; aOR = adjusted odds ratio.

Refill solution characteristics by country

Nearly all respondents (95%) reported using flavoured NVPs, with fruit (28.3%) being the most commonly reported flavour, followed by tobacco (27.5%), menthol (21.2%), candy/sweets (10.7%), and 'other' (7.3%). Use of candy/sweet flavours were more frequently reported by NVP users in CA (30.8%) and the US (30.5%) when compared to users in EN and AU (Table 3). NVP users in AU and EN were more likely to report using a NVP product with menthol flavour (30.2 and 37.0%, respectively)

compared to their counterparts in the other countries ($\chi^2_{(15)} = 265.67, P < 0.001$). Those using a box-shaped refillable tank device were most likely to report fruit flavours (35.1%).

Overall, 92.0% reported using a nicotine-containing NVP. Products containing nicotine were more commonly reported in US (92.9%) and EN (94.9%). In AU and CA, where nicotine liquid is subject to a greater degree of prohibition, rates of use of nicotine containing liquids were still high, at 91.2 and 87.8%, respectively ($\chi^2_{(12)} = 140.56, P < 0.001$). Vaporized products without nicotine were

Table 3 Flavour preference as a function of device type.

	<i>Canada</i> $\chi^2_{(20)} = 102.210,$ $P < 0.001$	<i>United States</i> $\chi^2_{(20)} = 280.524,$ $P < 0.001$	<i>England</i> $\chi^2_{(20)} = 147.168,$ $P < 0.001$	<i>Australia</i> $\chi^2_{(20)} = 47.205,$ $P = 0.001$	<i>Overall</i> $\chi^2_{(20)} = 402.151,$ $P < 0.001$
Cigalike	<i>n</i> = 215	<i>n</i> = 296	<i>n</i> = 203	<i>n</i> = 42	<i>n</i> = 756
Unflavoured	9.8%	7.8%	7.4%	2.4%	7.9%
Tobacco flavoured	26.0%	43.9%	53.2%	23.8%	40.2%
Menthol or tobacco	22.3%	28.0%	27.1%	23.8%	25.9%
Flavour/menthol mix					
Fruit flavoured	26.0%	6.8%	4.4%	23.8%	12.6%
Candy/sweets flavoured	8.4%	5.7%	4.9%	11.9%	6.6%
Other flavour	7.4%	7.8%	3.0%	14.3%	6.7%
Box-tank	<i>n</i> = 243	<i>n</i> = 316	<i>n</i> = 240	<i>n</i> = 74	<i>n</i> = 873
Unflavoured	5.8%	3.8%	0.4%	8.1%	3.8%
Tobacco flavoured	12.8%	10.1%	25.0%	18.9%	15.7%
Menthol or tobacco	8.6%	9.5%	27.9%	16.2%	14.9%
Flavour/menthol mix					
Fruit flavoured	39.9%	39.9%	30.4%	16.2%	35.3%
Candy/sweets flavoured	24.3%	27.2%	12.1%	23.0%	21.9%
Other flavour	8.6%	9.5%	4.2%	17.6%	8.5%
Pen-style tank	<i>n</i> = 273	<i>n</i> = 210	<i>n</i> = 532	<i>n</i> = 52	<i>n</i> = 1067
Unflavoured	3.7%	5.2%	80.0%	3.8%	2.5%
Tobacco flavoured	30.8%	18.6%	33.1%	36.5%	29.8%
Menthol or tobacco	18.7%	16.7%	27.6%	42.3%	23.9%
Flavour/menthol mix					
Fruit flavoured	26.4%	40.0%	32.1%	7.7%	31.0%
Candy/sweets flavoured	11.0%	9.5%	2.1%	0.0%	5.7%
Other flavour	9.5%	10.0%	4.3%	9.6%	7.0%
Pen-style cartridge	<i>n</i> = 89	<i>n</i> = 55	<i>n</i> = 75	<i>n</i> = 3	<i>n</i> = 222
Unflavoured	16.9%	1.8%	1.3%	0.0%	7.7%
Tobacco flavoured	19.1%	36.4%	33.3%	33.3%	28.4%
Menthol or tobacco	13.5%	20.0%	26.7%	33.3%	19.8%
Flavour/menthol mix					
Fruit flavoured	32.6%	32.7%	30.7%	0.0%	31.5%
Candy/sweets flavoured	3.4%	7.3%	4.0%	33.3%	5.0%
Other flavour	14.6%	1.8%	4.0%	0.0%	7.7%
All other devices	<i>n</i> = 112	<i>n</i> = 112	<i>n</i> = 40	<i>n</i> = 19	<i>n</i> = 293
Unflavoured	6.6%	11.6%	2.5%	0.0%	7.5%
Tobacco flavoured	22.1%	17.0%	32.5%	15.8%	21.2%
Menthol or tobacco	20.5%	11.6%	15.0%	63.2%	19.1%
Flavour/menthol mix					
Fruit flavoured	30.3%	49.1%	32.5%	15.8%	36.9%
Candy/sweets flavoured	12.3%	6.3%	10.0%	0.0%	8.9%
Other flavour	8.2%	4.5%	7.5%	5.3%	6.5%

Table 4 Nicotine level in e-liquid as a function of device type and country.

	<i>Canada</i> $\chi^2_{(8)} = 28.796,$ $P < 0.001$	<i>United States</i> $\chi^2_{(8)} = 72.513,$ $P < 0.001$	<i>England</i> $\chi^2_{(8)} = 36.407,$ $P < 0.001$	<i>Australia</i> $\chi^2_{(8)} = 15.234,$ $P = 0.055$	<i>Overall</i> $\chi^2_{(8)} = 97.893,$ $P < 0.001$
Cigalike	<i>n</i> = 212	<i>n</i> = 303	<i>n</i> = 209	<i>n</i> = 41	<i>n</i> = 765
20 mg or less	93.9%	71.0%	81.3%	82.9%	80.8%
21 mg or greater	1.4%	15.2%	11.5%	12.2%	10.2%
Don't know	4.7%	13.9%	7.2%	4.9%	9.0%
Box tank	<i>n</i> = 245	<i>n</i> = 318	<i>n</i> = 240	<i>n</i> = 77	<i>n</i> = 880
20 mg or less	95.9%	91.8%	92.1%	94.8%	93.3%
21 mg or greater	2.4%	5.7%	7.9%	2.6%	5.1%
Don't know	1.6%	25.0%	0.0%	2.6%	1.6%
Pen-style tank	<i>n</i> = 276	<i>n</i> = 212	<i>n</i> = 537	<i>n</i> = 53	<i>n</i> = 1078
20 mg or less	89.1%	83.5%	90.7%	88.7%	88.8%
21 mg or greater	8.3%	13.2%	7.4%	5.7%	8.7%
Don't know	2.5%	3.3%	1.9%	5.7%	2.5%
Pen-style cartridge	<i>n</i> = 90	<i>n</i> = 55	<i>n</i> = 74	<i>n</i> = 4	<i>n</i> = 223
20 mg or less	91.1%	83.6%	95.9%	50.0%	90.1%
21 mg or greater	2.2%	14.5%	2.7%	25.0%	5.8%
Don't know	6.7%	1.8%	1.4%	25.0%	4.0%
All other devices	<i>n</i> = 123	<i>n</i> = 114	<i>n</i> = 42	<i>n</i> = 19	<i>n</i> = 298
20 mg or less	92.7%	93.0%	88.1%	100.0%	92.6%
21 mg or greater	6.5%	3.5%	4.8%	0.0%	4.7%
Don't know	0.8%	3.5%	7.1%	0.0%	2.7%

reported by similar proportions of users across device type. The most commonly reported nicotine strength throughout countries was 20 mg or less (Table 4). Use of nicotine levels > 21 mg/ml was more common among those using cigalikes (10.2%).

DISCUSSION

This study is the first to describe key characteristics of NVPs reported by adult current regular (daily and/or weekly) vapers throughout countries that vary substantially in their regulatory and enforcement approaches toward NVPs. Refillable devices were the most common among exclusive daily vapers compared to other users, with differences in the choices of pen- or box-shaped devices by country. In all countries except EN, temperature adjustable devices were more common than other styles. Nearly 90% of users' products contained nicotine despite differing regulatory policies across countries and 95% reported using flavours.

The findings demonstrate the dominance of refillable NVP devices in all four countries. Such devices have emerged as rivals to cigarettes in terms of nicotine delivery [22,23], thereby increasing their acceptability as substitutes for cigarettes [24,25]. Indeed, refillable use was particularly common among daily vapers and former cigarette smokers. Most respondents using refillable systems were able to report whether their device was adjustable in terms of temperature or voltage, although we did

not ask respondents to specifically report device power, which has been identified as often inaccurate by other research groups [26]. Nearly a quarter of users were unable to report the capacity of their cartridge or refillable tank, even when given a range of values, suggesting that this may not be a particularly salient feature for many vapers. In all countries except EN, temperature adjustable devices were more common than other styles. Cartridge-based (closed) systems, typically marketed by tobacco companies, were more common among US and EN respondents. This is unsurprising, given that such products (if they contained nicotine) could not, at the time of survey, be legally sold in AU. In CA, enforcement of this law is weak, and products containing nicotine are available in vape shops. Use of disposable products was uncommon in this sample, but was relatively more common among non-daily vapers in the US. Countries also differed in their specific flavour preferences.

The clear majority of users throughout countries used flavoured e-liquids/refills, although the popularity of specific flavour types varied across countries. Tobacco and menthol flavours were commonly reported, particularly for disposable and cartridge products. This is consistent with the development of the closed-system market, dominated by cigarette manufacturers, who initially only introduced tobacco and menthol variants, and later on introduced additional flavours, perhaps to compete more effectively with the more popular refillable open-system devices. Our finding that most users preferred flavoured

e-liquids is important, given that the US FDA is considering a ban on these flavours. Most users also reported that their products contained nicotine, and nicotine use was high, even in the two countries where nicotine containing NVPs were (at least nominally) prohibited (87.8% in CA; 91.2% in AU). The high percentage of nicotine use in those two countries reflects the central importance of nicotine for vapers and the lack of strong enforcement and/or the availability of nicotine from the internet and other sources in both countries.

The variability in the strictness of the regulatory approach and enforcement was hypothesized to have implications for the characteristics of NVPs used in each country. A recent study reported that the prevalence of current VNP use in 14 ITC project countries varied by the level and strength of national regulations governing EC sales [5]. We found key differences across countries, which may be driven by policy differences, with EN and the US having, at the time of the data collection in 2016, the least restrictive, and CA and AU having the most restrictive NVP laws. CA differs from AU, however, as the law that prohibits the sale of NVPs with nicotine was not consistently enforced.

This study was conducted among a large sample of NVP users among four countries with varying policy approaches. However, the study was limited by the pace at which the NVP market has evolved. Thus, the data reported here are a reflection of the devices reportedly used by vapers at a particular point in time. The survey did not capture reported use of JUUL and other products that have emerged relatively recently. Additionally, although the survey questions were designed to collect comprehensive data about the multiple points of variation between products, the questions have not been compared against other questions or methods.

Ensuring product safety and minimizing delivery of toxins should be directly addressed via regulation, and more detailed research is needed with components and use patterns to understand more clearly the most health-relevant factors to target for regulation. The degree to which products are satisfying to smokers in terms of nicotine intake and subjective effects maximizes the likelihood of complete switching or of substantial harm reduction via lower toxin exposure. A competitive, innovative market-place with many product options may have helped NVPs become substitutes for cigarettes for some consumers (Levy *et al.*, in review). However, emerging regulatory requirements could create unintended, negative impacts on public health by disadvantaging NVPs or inhibiting switching. The observed commonalities across markets outnumbered the differences, despite divergent regulatory schemes, suggesting that consumers can access desired products.

The market effects of regulation in the US and CA, only recently in force, will begin to manifest in the coming

years. In England, the Trading Standards Institute showed a fair degree of non-compliance with TPD (22%) in vape shops for a variety of reasons, pointing to a need for continued monitoring and enforcement [27]. As long as the end user has the capability to add a nicotine-containing liquid to their device, the regulations related to nicotine content in a liquid can be easily circumvented via online purchase and other methods, as in Australia (D. Braak, unpublished analysis). The recent emergence of JUUL as the dominant product in US retail sales (although subsequent to our data collection) suggests an ongoing dynamism in the market. Notably, JUUL, as sold in the US, would be banned in EN due to its high nicotine content (50 mg/ml), unless it was licensed as a medicinal product. In this regard, it is important to note that recent evidence suggests that lower nicotine concentrations may promote compensatory behaviours, leading to greater intake of the constituents in an attempt to equalize nicotine doses, thus potentially increasing health risks [28]. This underscores the importance of regularly tracking the types and brands of products used by consumers as a step towards understanding their association with nicotine dependence and health outcomes.

Declaration of interests

K.M.C. has received grant funding from the Pfizer, Inc. to study the impact of a hospital-based tobacco cessation intervention. K.M.C. also receives funding as an expert witness in litigation filed against the tobacco industry. M.L.G. revived a research grant from Pfizer Inc. and served as a member of advisory board to Johnson & Johnson, manufacturers of smoking cessation medications. D.H. and G.T.F. have served as expert witnesses on behalf of governments in litigation involving the cigarette industry. All other authors have no conflicts of interest to declare.

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