FISEVIER

Contents lists available at ScienceDirect

International Journal of Drug Policy

journal homepage: www.elsevier.com/locate/drugpo



Short Report

E-cigarette nicotine content and labelling practices in a restricted market: Findings from Ontario, Canada



Christine D. Czoli^a, Maciej L. Goniewicz^b, Mary Palumbo^b, Christine M. White^a, David Hammond^{a,*}

- a School of Public Health & Health Systems, University of Waterloo, 200 University Avenue West, Waterloo, Ontario N2L 3G1, Canada
- b Department of Health Behavior, Division of Cancer Prevention and Population Sciences, Roswell Park Cancer Institute, Carlton House A320, Elm & Carlton Streets, Buffalo, New York 14263, USA

Introduction

Electronic cigarettes (e-cigarettes) are devices that deliver nicotine via an aerosol. The aerosol is produced by heating an enclosed solution which typically contains nicotine and flavouring chemicals dissolved in propylene glycol and/or glycerin (Breland et al., 2017). Although ecigarettes are likely to pose fewer health risks than combustible tobacco cigarettes – given that they do not contain tobacco and do not combust to produce tobacco smoke (NASEM, 2018) – their overall potential impact on public health remains unclear (Breland et al., 2017).

According to the Institute for Global Tobacco Control (Kennedy, Awopegba, De Leon, & Cohen, 2017), 79 countries have national laws regulating e-cigarettes. In several countries, regulations restrict the amount of nicotine in e-liquids and/or the quality of nicotine or other ingredients used to manufacture e-liquids. The sale of e-cigarettes containing nicotine is prohibited or requires pre-market approval in several countries, including Australia, Canada, Costa Rica, Jamaica, Japan, Malaysia, Mexico, New Zealand and Switzerland (Institute for Global Tobacco Control, 2017).

In Canada, nicotine-containing e-cigarettes require market approval, whereas non-nicotine containing e-cigarettes can be sold without this requirement (Health Canada, 2009). To date, no nicotinecontaining e-cigarettes have received approval. While many conventional retail outlets, such as grocery and convenience store chains, typically sell e-cigarettes without nicotine in compliance with federal regulations, e-cigarettes with nicotine are widely available at vape shops (Hammond et al., 2015) and many Canadians report using nicotine-containing e-cigarettes (Hamilton et al., 2015; Reid et al., 2017), similar to consumers in jurisdictions in which e-cigarettes are permitted for sale (Gravely et al., 2014). To date, there is little empirical evidence examining the presence of nicotine or the accuracy of nicotine labelling in markets that restrict or prohibit sales of e-cigarette products. Unpublished data from testing conducted on behalf of Health Canada in spring 2014 indicated that almost half of the 91 e-cigarettes tested contained nicotine (Standing Committee on Health, 2015). However, it is unclear whether the purchasing and testing of these products was conducted systematically, with respect to the range of retail outlets from which the e-cigarettes were sourced and the types of products included

Given that labelled concentrations of nicotine in e-cigarette products often suffer from inaccuracies (Buettner-Schmidt, Miller, & Balasubramanina, 2016; Goniewicz, Kuma, Gawron, Knysak, & Kosmider, 2013; Kim, Goniewicz, Yu, Kim, & Gupta, 2015), product testing methods can help determine whether, and the extent to which, nicotine is present in Canadian e-cigarette products, as well as provide contextual understanding of the presence of such products in a restricted market. Thus, the current study aimed to examine the nicotine content of e-cigarette products on the Canadian market, with a focus on the province of Ontario.

Materials and methods

Products

E-cigarette products were purchased by a trained research assistant using a systematic protocol at retail outlets across four Ontario cities (Toronto, Ottawa, Kitchener-Waterloo, Thunder Bay) in January and February 2015. A total of 80 retail outlets were visited, including five of each of the following types: vape shops, supermarkets, convenience stores, and gas station convenience stores. At each retail outlet, a research assistant was asked to purchase: two flavours of the most popular three brands of disposable products without nicotine; two flavours for any brands of disposable products with nicotine; two flavours for the most popular three brands of e-liquid with nicotine; and two flavours for the most popular three brands of cartomizers/cartridges. 'Popular' brands were established by prior inquiries to retail outlets. Whenever possible, the research assistant selected tobacco- and menthol-flavoured products. Finally, when purchasing e-liquids with nicotine, the research assistant was instructed to purchase e-liquids with a 'medium' concentration of nicotine, based on the available concentration levels.

E-mail address: dhammond@uwaterloo.ca (D. Hammond).

^{*} Corresponding author.

Table 1 Characteristics of tested products, overall and by product label (n = 166).

	Overall (n = 166)		'Without nicotine' (n = 68)		'With nicotine' (n = 73)		Unlabelled $(n = 25)$	
					% (n)			
City ¹								
Toronto	40.0	(66)	29.4	(20)	43.8	(32)	56.0	(14)
Ottawa	18.8	(31)	22.1	(15)	21.9	(16)	0.0	(0)
Kitchener-Waterloo	21.8	(36)	23.5	(16)	16.4	(12)	32.0	(8)
Thunder Bay	19.4	(32)	25.0	(17)	17.8	(13)	8.0	(2)
Retail outlet type ¹								
Vape shop	53.3	(88)	23.5	(16)	93.2	(68)	16.0	(4)
Supermarket	13.3	(22)	22.1	(15)	2.7	(2)	20.0	(5)
Convenience store	27.3	(45)	42.6	(29)	4.1	(3)	52.0	(13)
Gas station convenience store	6.1	(10)	11.8	(8)	0.0	(0)	8.0	(2)
Product type								
Cartridge/cartomizer refill	13.9	(23)	17.6	(12)	2.7	(2)	36.0	(9)
Disposable	33.1	(55)	60.3	(41)	0.0	(0)	56.0	(14)
E-liquid	53.0	(88)	22.1	(15)	97.3	(71)	8.0	(2)
Nicotine detected								
No	52.4	(87)	92.6	(63)	2.7	(2)	88.0	(22)
Yes	47.6	(79)	7.4	(5)	97.3	(71)	12.0	(3)

Note: 1 One product had missing information for city and retail outlet type of purchase. This product was 'unlabelled'.

Product testing

The purchased products were sent to the Tobacco Product Laboratory in Roswell Park Cancer Institute, Buffalo, USA for testing. After arrival to the laboratory, each product was catalogued and assigned a unique sample number. All samples were stored in their original containers in a dark space at room temperature prior to analysis, in order to minimize the risk of nicotine degradation. Laboratory technicians were blinded to the labelled nicotine levels and to the product names, until the determined levels were obtained. Aliquotes of 100 µL of each product were collected from each original container using the reverse pipetting technique. The samples were diluted with 10 mL methanol, and an internal standard (100 µL quinoline solution 50 mg/mL in methanol) was added. The samples were then vigorously shaken for 10 min and subsequently analysed as described below. Each sample was prepared in triplicates in order to validate the results, and the calibration/control solutions were prepared in multiplicity as well. Nicotine concentrations were measured using gas chromatography with a nitrogen-phosphorous detector (GC-NPD, Agilent, USA) as described previously (Goniewicz et al., 2013). The method was validated as per the International Conference on Harmonization guideline Q2 (International Conference on Harmonization, 2005). A calibration curve was generated to cover the range of nicotine concentration from 0 to 100 mg/mL. To ensure accurate results for the samples each calibration curves had linear coefficients of 0.99 ($R^2 \ge 0.99$) or above. The average nicotine recovery was 102% and the lower quantitation limit was 0.05 mg/mL.

Statistical analysis

Product characteristics and the accuracy of nicotine labelling were examined using descriptive statistics. The accuracy of nicotine labelling was examined in two ways: first, with respect to the presence/absence of nicotine; and second, with respect to a 10% threshold of the labelled

nicotine content. Analyses were conducted using SPSS v.24.

Results

A total of 166 e-cigarette products were purchased, including disposable products (33.1%), refillable products (13.9%), and e-liquids (53.0%) (see Table 1). Overall, approximately equal proportions of products were labelled as 'without nicotine' (41.0%), and 'with nicotine' (44.0%), while 15.1% of products were unlabelled.

Gas chromatography revealed that almost half of the products (47.6%) contained nicotine (see Table 1). Nicotine-containing products had an average nicotine concentration of 10.9 (SD = 4.2) mg/mL.

When examining the accuracy of nicotine labelling with respect to the presence/absence of nicotine, a total of 10 products (6%) were mislabelled: 5 products labelled as 'without nicotine' had nicotine present, 2 products labelled as 'with nicotine' did not contain nicotine, and 3 unlabelled products had nicotine present.

When examining nicotine labelling accuracy with respect to a 10% tolerance in nicotine concentration, a total of 25 products (15%) were mislabelled: 2 products labelled as 'without nicotine' had nicotine present, 3 unlabelled products had nicotine present, and 20 products labelled as 'with nicotine' had mislabelled concentrations.

Among the products tested in the current study, 73 were labelled as containing nicotine. According to product labels, the mean nicotine content of these products was $14.3\,\mathrm{mg/mL}$ (SD = 14.5; range: 3.0 to 24.0). Product testing indicated that the mean nicotine content was in fact $11.4\,\mathrm{mg/mL}$ (SD = 3.7; range: 2.8 to 23.3). Among this subsample of products (n = 73), slightly over one-quarter (27.4%) fell outside 10% of their labelled concentration. Among these mislabelled products (n = 20), most contained lower amounts of nicotine than indicated on the label (85%). All of these mislabelled products were e-liquids (100%), the vast majority of which were sold in vape shops (90%), and were found in each of the four cities.

Discussion

The findings confirm that nicotine-containing e-cigarettes are available and sold in Ontario across various retail outlet types, despite Canada's prohibition on the sale of these products. Product testing indicated that approximately one-quarter of products labelled as containing nicotine fell outside a 10% threshold of their labelled concentration. The proportion of products with discrepant nicotine labelling and content was lower than that of other markets, including the United States, the United Kingdom, Poland, France, Switzerland, Greece, and South Korea (Buettner-Schmidt et al., 2016; Etter, Zather, & Svensson, 2013; Goniewicz et al., 2013; Kayvalakis et al., 2015; Kim et al., 2015; Peace et al., 2016). Inaccurate labelling among the Canadian products was particularly high for nicotine-containing e-liquids sold in vape shops. Such inaccuracies are concerning, due to the fact that they can mislead consumers (Etter, Bullen, Flouris, Laugesen, & Eissenberg, 2011). In addition, inaccurate labelling of nicotine may have implications for consumers who wish to use these products to quit smoking and seek to titrate their nicotine intake. Although the sample of products tested in the current study was not necessarily representative of the Ontario or Canadian market, it is nonetheless geographically diverse and large, particularly in comparison to other published studies (Buettner-Schmidt et al., 2016; Etter et al., 2013; Goniewicz et al., 2013; Kim et al., 2015; Etter, Zather, & Svensson, 2013).

Findings from the current study provide empirical evidence regarding the presence of nicotine in e-cigarettes available in Canada, supporting research indicating that such products are accessible and used by Canadians (Hamilton et al., 2015; Hammond et al., 2015; Reid et al., 2017). The widespread availability of nicotine-containing e-cigarettes in Canada may reflect the lack of enforcement activities, particularly in recent years (Standing Committee on Health, 2015). It is unclear whether the lack of enforcement reflects a 'softened' government stance on e-cigarettes or simply reflects the practical challenges of enforcement, particularly given Canada's proximity to the US market. Future research may compare the effectiveness of restrictions and/or prohibitions on the sale of nicotine-containing e-cigarettes, or indeed regulations addressing other policy domains, in jurisdictions that may face similar cross-border issues (e.g., Mexico) versus those that are more geographically isolated (e.g., Australia). Future research should also examine the impact of Canada's new regulatory framework for ecigarettes, which will remove the requirement for pre-market approval while applying product standards with respect to testing, reporting and labelling of e-liquids (Parliament of Canada, 2016). In particular, research should examine changes in nicotine content and the accuracy of nicotine labelling as the market transitions from a 'prohibited' to a 'regulated' framework.

Conclusion

The study findings indicate that nicotine-containing e-cigarettes are sold in Ontario across various retail outlet types, despite Canada's prohibition of such products. While many e-cigarettes were correctly labelled, inaccuracies were common, particularly among nicotine-containing products sold in vape shops. The findings reflect limitations regarding the design and enforcement of the current regulatory framework for e-cigarettes. These limitations should be addressed by regulators as they develop a new framework encompassing all vaping products regardless of nicotine content, with clear product standards and labelling practices.

Declaration of interests

DH has provided paid testimony in tobacco litigation on behalf of governments and class-action plaintiffs on issues related to tobacco product science and regulation. MLG reports grants from and served as an advisory board member to pharmaceutical companies that manufacture smoking cessation drugs. The other authors have no competing interests to declare.

Funding

This research was supported by an Ontario Ministry of Health & Long Term Care Health Systems Research Fund grant (#06697; awarded to DH). Additional support was provided by a Canadian Institutes of Health Research (CIHR) Vanier Canada Graduate Scholarship (CDC), a National Cancer Institute Award (Number P30 CA016056; MLG), as well as a CIHR New Investigator Award (DH), and a CIHR PHAC Chair in Applied Public Health (DH).

Acknowledgements

The authors would like to thank Christina Martin for her assistance conducting the product purchases.

References

- Breland, A., Soule, E., Lopez, A., Ramoa, C., El-Hellani, A., & Eissenberg, T. (2017). Electronic cigarettes: What are they and what do they do? Annals of the New York Academy of Sciences, 1394, 5–30.
- Buettner-Schmidt, K., Miller, D. R., & Balasubramaninan, N. (2016). Electronic cigarette refill liquids: Child-resistant packaging, nicotine content and sales to minors. *Pediatric Nursing*, 31, 373–379.
- Etter, J.-F., Bullen, C., Flouris, A. D., Laugesen, M., & Eissenberg, T. (2011). Electronic nicotine delivery systems: A research agenda. *Tobacco Control*, 20, 243–248.
- Etter, J.-F., Zather, E., & Svensson, S. (2013). Analysis of refill liquids for electronic cigarettes. Addiction, 108, 1671–1679.
- Goniewicz, M. L., Kuma, T., Gawron, M., Knysak, J., & Kosmider, L. (2013). Nicotine levels in electronic cigarettes. Nicotine and Tobacco Research, 15, 158–166.
- Gravely, S., Fong, G. T., Cummings, K. M., Yan, M., Quah, A. C. K., Borland, R., et al. (2014). Awareness, trial, and current use of electronic cigarettes in 10 countries: Findings from the ITC Project. *International Journal of Environmental Research and Public Health*, 11, 11691–11704.
- Hamilton, H. A., Ferrence, R., Boak, A., Schwartz, R., Mann, R. E., O'Connor, S., et al. (2015). Ever use of nicotine and non-nicotine electronic cigarettes among high school students in Ontario, Canada. *Nicotine and Tobacco Research*, 17, 1212–1218.
- Hammond, D., White, C. M., Czoli, C. D., Martin, C. L., Magennis, P., & Shiplo, S. (2015).
 Retail availability and marketing of electronic cigarettes in Canada. *Canadian Journal of Public Health*, 106, e408–e412.
- Health Canada (2009). Notice —To all persons interested in importing, advertising or selling electronic smoking products in Canada. Retrieved from http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/notice_avis_e-cig-eng.php.
- Institute for Global Tobacco Control (2017). Country laws regulating e-cigarettes: A policy scan. Retrieved from http://globaltobaccocontrol.org/node/14052.
- International Conference on Harmonization (2005). Technical requirements for registration of pharmaceuticals for human use, Topic Q2 (R1): Validation of analytical procedures:

 Text and Methodology. Retrieved from https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q2_R1/Step4/Q2_R1_Guideline.pdf.
- Kavvalakis, M. P., Stivaktakis, P. D., Tzatzarakis, M. N., Kouretas, D., Liesivuori, J., Alegakis, A. K., et al. (2015). Multicomponent analysis of replacement liquids of electronic cigarettes using chromatographic techniques. *Journal of Analytical Toxicology*, 39, 262–269.
- Kennedy, R. D., Awopegba, A., De Leon, E., & Cohen, J. E. (2017). Global approaches to regulating electronic cigarettes. *Tobacco Control*, 26, 440–445.
- Kim, S., Goniewicz, M. L., Yu, S., Kim, B., & Gupta, R. (2015). Variations in label information and nicotine levels in electronic cigarette refill liquids in South Korea: Regulation challenges. *International Journal of Environmental Research and Public Health*, 12, 4859–4868.
- National Academies of Sciences, Engineering, and Medicine (2018). *Public health consequences of e-cigarettes*. Retrieved from: http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx.
- Parliament of Canada (2016). Bill S-5, An Act to amend the Tobacco Act and the Non-

- $smokers' Health\ Act\ and\ to\ make\ consequential\ amendments\ to\ other\ Acts.\ Retrieved\ from\ http://www.parl.gc.ca/HousePublications/Publication.aspx?Language = E\&Mode = 1\&DocId = 8616193.$
- Peace, M. R., Baird, T. R., Smith, N., Wolf, C. E., Poklis, J. L., & Poklis, A. (2016). Concentration of nicotine and glycols in 27 electronic cigarette formulations. *Journal of Analytical Toxicology*, 40, 403–407.
- Reid, J. L., Hammond, D., Rynard, V. L., Madill, C. L., & Burkhalter, R. (2017). Tobacco use in Canada: Patterns and trends (2017 ed.). Retrieved from https://uwaterloo.ca/ tobacco-use-canada/tobacco-use-canada-patterns-and-trends.
- tobacco-use-canada/tobacco-use-canada-patterns-and-trends.

 Standing Committee on Health (2015). Vaping: Towards a regulatory framework for e-cigarettes. Report of the Standing Committee on Health. Retrieved from http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=7862816.