

The Voice of Public Health

# A PUBLIC HEALTH APPROACH TO NICOTINE-CONTAINING VAPING DEVICES

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# THE VOICE OF PUBLIC HEALTH

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# **Nicotine-containing vaping devices**

Vaping devices (vapour devices or e-cigarettes) are devices that heat a liquid consisting of a carrying solution and a combination of flavourings and/or nicotine. The resultant vapour is inhaled. There are two categories of vaping devices: those that contain nicotine and those that do not. In Canada, about 9% of Canadians 15 years of age and older, and 20% of youth in the age groups 15-19 and 20-24 respectively, have tried vaping devices.<sup>1</sup> Of those who tried vaping devices, 55% reported that the last device they used did not contain nicotine, 26% reported using a nicotine-containing device and 19% were unsure.

Vaping devices first entered the North American marketplace in 2007,<sup>2</sup> and in 2009 Health Canada issued an advisory against the nicotine-containing product, as insufficient evidence was available to support the safety of the devices.3 The Canadian Public Health Association (CPHA) supported this prohibition. There has been limited enforcement of the advisory, and nicotine-containing products remain available through, for example, e-commerce and storefronts that sell the product illegally. The sale of non-nicotine-containing products was not affected by the advisory. In 2016, the federal government introduced Bill S-5, An Act to Amend the Tobacco Act and the Non-Smokers Health Act and to make consequential amendments to other acts. Its purpose is to require plain packaging of tobacco products, and to provide the legislative framework necessary to permit the sale of nicotine-containing vaping devices in Canada.

CPHA maintained a watching brief on vaping devices from 2013 until Autumn 2016, at which time the Association recognized that the maturation of the industry and the availability of health and safety information concerning the nicotine-containing products, coupled with the introduction of Bill S-5, merited a statement from a public health perspective. A working group was established to review the available evidence and provide recommendations concerning the sale of nicotine-containing vaping devices in Canada.

## RECOMMENDATIONS

CPHA calls on the federal government to:

- Approve and implement the provisions of Bill S-5\* and develop regulations to permit the sale of nicotine-containing vaping devices in Canada, should health and safety provisions be met, including:
  - Establish a legal age for the purchase of nicotinecontaining vaping devices in line with that for tobacco products;
  - Apply restrictions, based on toxicity, on the flavours and carrying fluid used in vaping devices;
  - Limit the use of flavours that could be appealing to children and youth;
  - Develop and implement regulations and guidelines that address safety concerns associated with the manufacture of these products; and

<sup>\*</sup> Currently at "Committee Reporting the Bill with Amendments" stage, March 20, 2018

- Subject the products to the provisions of the *Food* and Drugs Act, should the manufacturer wish to make claims regarding their use as smoking cessation devices.
- Support research concerning vaping devices, including:
  - Investigate their effect on health, especially in relation to particulate emissions and carcinogens, notably 1,3-butadiene;
  - Conduct comparative research on the toxicity of nicotine-containing vaping devices compared to that of tobacco products;
  - Investigate the use of nicotine-containing vaping devices as smoking cessation devices; and
  - Examine the societal influences that lead youth and adolescents to start using nicotine-containing products, and develop programs to address these issues.
- Limit the sale and advertising of nicotinecontaining vaping devices by:
  - Prohibiting their use, including in-store testing, in all enclosed public spaces, workplaces and other specified outdoor areas;
  - Prohibiting the sale of vaping devices in all places where the sale of tobacco products is also prohibited; and
  - Establishing regulations for the display and promotion of vaping devices at places where they are sold.

CPHA calls on provincial/territorial governments to:

• Establish a pricing structure that acts as a deterrent to the purchase of the nicotine-containing products, similar to that used for tobacco products.

CPHA calls on all governments to:

- Support health promotion activities, including:
  - Increase public education and information around smoking cessation in general, and the use of vaping devices in particular, and fund access to

evidence-based smoking cessation products and services; and

 Restrict advertising related to these nicotinecontaining products, similar to the restrictions on the advertising of tobacco products.

## CONTEXT

Vaping devices first entered the Asian marketplace in 2004 and their use spread rapidly. In 2011, the market was estimated at \$2 billion (USD)<sup>4</sup> and was anticipated to reach \$10 billion (USD) by 2017 in the United States alone.<sup>5</sup> Most traditional tobacco companies have investments in the vaping device industry.

Complicating this rapid growth was a general lack of evidence concerning the health effects and safety of both the nicotine- and non-nicotine-containing products. There were also unsubstantiated claims that the nicotine-containing product could be used as a smoking cessation device, or would prove 'safer' than tobacco products, as the user was not being subjected to the complex array of potential carcinogens resulting from tobacco use.

A body of scientific evidence concerning health and safety considerations of nicotine-containing vaping devices has developed since their introduction, and has been subject to two systematic literature reviews in Canada.<sup>6,7</sup> Representatives from both groups (conducting the systematic reviews) were included on the CPHA working group. The working group completed a comparative assessment of the two reviews and supplemented the work with additional scientific evidence up to January 2017. The results are presented as Appendix A. Both reviews highlighted the need for additional information, and noted that:

 There was limited information concerning the use of vaping devices as cessation devices;

- There is conflicting information concerning the likelihood, especially among youth, of vaping devices acting as a gateway to tobacco use;
- The effect of second-hand vapour on non-users (second-hand vaping) requires investigation; and
- The long-term health effects of inhaling the vapour requires further research.

It should be noted that research on vaping devices is ongoing and the evidence continues to evolve. The recommendations included in this position statement reflect our current understanding.

Internationally, several countries have moved to regulate nicotine-containing vaping devices. For example:

- The United States has developed regulations that include provisions with regard to ingredients, warning labels, and age restrictions on sales;<sup>8</sup>
- The United Kingdom provides regulations under general product safety laws, and provides the option for applying for a "medicines license" for a vaping device as a smoking cessation aid;<sup>o</sup> and
- The 2016 European Union Tobacco Products Directive requires member states to prohibit advertising, add warning labels and meet purity standards.<sup>10</sup>

In Canada, several provinces have placed restrictions on vaping device use, while municipalities, local school boards and boards of health have enacted their own by-laws and regulations to address this issue. Similarly, the House of Commons Standing Committee on Health, Environment, and Social Affairs (HESA) has reviewed their sale in Canada and provided recommendations for their regulation.<sup>11</sup> On November 11, 2016, federal legislation with the purpose of providing for plain packaging of tobacco products, and a legislative framework to permit the regulation of nicotine-containing vaping devices was introduced. During August 2017, proposals for the regulation of vaping products were released for consultation by the Government of Canada.<sup>12</sup>

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### APPENDIX A

# Comparative assessment of two systematic literature reviews concerning vaping devices

#### Purpose

The rapid rise in popularity of vapour devices has opened debate on their possible harms as well as benefits. Some proponents claim that they can be used as smoking cessation aids, while others claim that the devices can lead to the normalization of smoking and act as a gateway to smoking cigarettes, particularly among youth and adolescents. Vapour devices rose in popularity at a rate that outpaced the research; as such, there were gaps in the knowledge regarding potential harms and benefits, as well as a lack of standardization in their production and that of liquids available for use. These gaps in knowledge have led to confusion among the public about the safety of vaping and the potential dangers of second-hand vapour, as well as uncertainty among legislators regarding how vaping devices should be regulated.

#### **Current Status**

Two knowledge synthesis projects were conducted in order to consolidate the research on vaping devices and identify gaps. The Clearing the Air Project (University of Victoria) and the Ontario Tobacco Research Unit (OTRU) conducted systematic reviews; the research conducted by the OTRU also included surveys, interviews and analysis of existing population data.<sup>1,2</sup> Both documents cover similar topics, including:

• Cessation aid

- Second-hand vapour
- Transition to tobacco

• Patterns of use

• Health effects

Both projects conclude that further research is needed in the areas of long-term health effects and use as a cessation aid, and that regulation should limit uptake by youth while acknowledging the potential use of vaping devices in harm reduction and cessation programs. These results are presented in Table 1 and are discussed below. The Clearing the Air study included evidence published up to April 2016 and the OTRU study included evidence published up to August 2015.

Main Issues	Clearing the Air Findings	OTRU Findings	Differences
Cessation	No consistent evidence that using a vaping device influences a dual user regarding cigarette use.	Insufficient high-quality studies to know for certain the effectiveness of vaping devices as a cessation aid.	None.
Transition to tobacco	Vapour device use does not lead to tobacco use among youth.	There is insufficient evidence to suggest that use of vaping devices is a catalyst for smoking.	The studies disagree on whether there is sufficient evidence to make a statement on whether vaping devices lead to tobacco use.
Health effects	Vaping produces lower levels of carcino- gens; however, no independent research has focused on emissions of 1,3-buta- diene. The type of device and how it is used results in differences in emissions.	Nicotine, PM <sub>25</sub> and toxicant yield suggest there are potential health effects. For current smokers, switching to vaping devices will decrease the risk of tobacco-related disease, but long-term health effects are unknown.	Clearing the Air study includes information on physiological differences between smokers and vapers. OTRU study includes data on perceived health risk.
Second-hand vapour	Vapour-produced absorption of nicotine in bystanders; conflicting findings on emissions of particulate matter, polycy- clic aromatic hydrocarbons, and metals.	Nicotine, PM <sub>2.5</sub> and other compounds are released into the environment; long-term health effects of passive exposure are unclear.	Clearing the Air study includes information on physiological re- sponses to second-hand e-cigarette vapour and particulate matter.
Patterns of use	Few youth have established a regular pattern of consumption that could serve as the behavioural basis for regular tobacco use.	There is an increased acceptability and use of vaping devices among youth and adults.	OTRU study contains greater detail on device use, nicotine use, and co-use.

Table 1. Main issues, findings and differences of the Clearing the Air and OTRU e-cigarette studies

#### Issues

Both groups identified use of vaping devices as a cessation aid, the transition from vaping devices to tobacco among youth and adolescents, and health effects, including those related to carcinogens, as the main issues requiring further study.<sup>1,2</sup>

#### Cessation Aid

Conflicting evidence exists on the effectiveness of vaping devices as a cessation aid for tobacco, and firm conclusions are difficult to draw due to the lack of randomized controlled trial (RCT) studies comparing vaping devices with other cessation methods. However, both the Clearing the Air and the OTRU studies concluded that there was sufficient evidence in favour of vaping devices as a cessation aid to justify further research, and that "claims of a negative impact were unjustified."<sup>1</sup> The OTRU study suggested that vaping devices may be more effective as a cessation aid when they contain nicotine and are used as part of nicotine replacement therapy (NRT).<sup>2</sup>

#### Transition to Tobacco

The Clearing the Air research concluded that there was no support for the belief that using vaping devices would lead youth and adolescents to begin smoking tobacco,<sup>1</sup> while the OTRU study indicates that there is insufficient evidence to determine whether vaping devices can be considered a gateway to tobacco.<sup>2</sup> In the majority of cases, it is smoking tobacco that leads to e-cigarette use. A critique of studies that claim a relationship between vaping devices and tobacco uptake by youth is that they use "ever-use" or "past-30-day-use" as a measure for e-cigarette use, and that this should not be considered a measure of "regular" or "current" use.<sup>1</sup> A measure of "past-30-day-users" will overestimate the number of "regular" or "current" users, as it will include those who may have tried once or twice but did not continue. Research examining the link between e-cigarette use and smoking tobacco cigarettes should consider "regular" users of vaping devices.

#### Health Effects and Carcinogens

Research shows that the aerosol and vapour produced by vaping devices contains significantly fewer toxicants and carcinogens at much lower concentrations than those found in traditional cigarette smoke.<sup>1,2</sup> While the vapour also remains in the air for much less time than cigarette smoke does, providing less time for passive exposure, this tends to be overlooked in studies of second-hand vapour.1 These reduced carcinogen levels have prompted the investigation of vaping devices as a harm reduction tool. Due to the relative novelty of vaping devices, however, there are currently no data on their longterm health effects, either in relation to direct use or as a result of second-hand vaping. There have also been no studies on 1,3-butadiene (BDE) emissions, which is the largest source of cancer risk from tobacco cigarettes. Further research into both the long-term effects of vaping and the differences between devices and liquids is required. Although further research is required into the differences between devices, there is sufficient evidence that the aerosol from vaping devices contains enough toxins for the OTRU study to recommend that non-smokers should not vape.<sup>2</sup>

#### **Research Update**

A literature scan was performed to determine whether there was any new information regarding the issues identified in the Clearing the Air and OTRU studies. The results are outlined below.

#### Cessation Aid

Since the completion of the Clearing the Air report, there continue to be conflicting studies published on vaping devices as smoking cessation aids. Studies published later than April 2016 have demonstrated a negative association between vaping devices and cessation;<sup>3</sup> other studies report no association.<sup>4</sup> This is in contrast to studies that demonstrated that among dual users, vaping devices maintain smoking reduction, lessen withdrawal<sup>5</sup> and are associated with a higher rate of quitting over the long term.<sup>6</sup>

A systematic review that analyzed RCTs and cohort studies determined that, while there is a reduction of tobacco cigarette use among regular e-cigarette users, there was not sufficient evidence for conclusive results about the effectiveness of vaping devices.7 Most individuals who begin using vaping devices do so in an attempt to quit smoking,1,2 which makes it unclear whether vaping devices would be any more effective than other NRT methods. While the evidence supports the effectiveness of vaping devices as a cessation aid, success has been demonstrated only among those who want to quit. The studies on the effectiveness of vaping devices as a cessation aid tend to compare cessation rates of those who use vaping devices to rates of those who do not; therefore there continues to be a need for research comparing the effectiveness of vaping devices to other established NRT methods.

#### Transition to Tobacco

While Clearing the Air and the OTRU came to different conclusions on the evidence that vaping devices act as a gateway to tobacco, methodological flaws and biases resulted in low confidence in the results.2 A recent study found that adolescents and young adults who used vaping devices were more likely to reveal an intention to smoke.8 However, "past-30-day-use" or "intention to smoke" may not be appropriate predictors of future smoking behaviour, as those who use vaping devices may display sensation- or risk-seeking behaviour, and the intention to smoke may not be related to the use of vaping devices. One study found that of those who were "never-smokers", only 1.2% to 2.3% report having ever tried an e-cigarette.9 Other studies published since the Clearing the Air study have also noted associations between the use of vaping devices and smoking in adolescents.10,11 Whether use of vaping devices is the cause of a transition to tobacco cigarettes is still unclear. Future research should focus on regular and current users of vaping devices who are also "never smokers", as that would be more likely to be indicative of a behavioural basis for tobacco use.1

#### Health Effects

There continues to be uncertainty around the extent of the health effects of vaping devices. Much of this uncertainty is due to the wide range of available devices and liquids. While decreased levels of volatile organic compounds and carbon monoxide have been observed in individuals who switched from tobacco to a vaping device,12 the level of toxicants released can depend on the device used, the type of liquid used, and how the device is used.1 The lack of standardization makes it difficult to assess the potential health risks. For example, recent studies have shown that among 27 different vaping products, nicotine levels were found to vary from a yield of less than one to more than three combustible cigarettes,13 making it difficult to generalize findings. Furthermore, under certain conditions, the addition of sweeteners to e-liquids has been found to result in furfural (a toxic furan) levels comparable to those found in traditional tobacco cigarettes.14 Besides the variation caused by the type of device or the liquid used, further variation in the toxicants released can be caused by altering the voltage, and the age of the device can be a factor.<sup>15</sup> The vast number of devices and liquids available, and lack of standardization in manufacturing, render it difficult to definitively assess the potential health risks, making the long-term health effects of vaping devices another area requiring further study.

#### Harm Reduction

Both the Clearing the Air and the OTRU studies briefly mention the potential of vaping devices as a harm reduction tool, but neither included the topic in the research questions covered. While the potential exists for vaping devices to be used in tobacco harm reduction, as they contain significantly fewer toxicants, questions remain about the ethics of their use. The ethical considerations have been reviewed and are related to the issues outlined above, including product safety, efficacy for smoking cessation, use among non-smokers, and use among youth.<sup>16</sup> One concern is that uptake by non-smokers could lead to increased net public health harm due to nicotine addiction. This concern is countered by limiting the sale of nicotine-containing liquids (which are prohibited in Canada) to those individuals using vaping devices as part of physician-prescribed NRT. Further research into the issues outlined in the Clearing the Air and OTRU studies will shed light on the potential use of vaping devices in harm reduction strategies.

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