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ELECTRONIC NICOTINE DELIVERY DEVICES

CDP – Tobacco Program November 2014



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INTRODUCTION

Electronic Nicotine Delivery Devices (ENDS), of which electronic cigarettes are the most common type, are battery operated products that deliver an aerosol (commonly called vapour) by heating a solution that users inhale. For the purposes of this report we will refer to these products as electronic or e-cigarettes. The solution typically consists of a mixture of propylene glycol or glycerol (glycerin), flavoring and may or may not contain nicotine. (6,10,15) "Electronic cigarettes are a relatively new product first patented in China in the early 2000s". (6) Electronic cigarettes are often shaped to look like their conventional tobacco counterparts, however, they can also take the form of everyday items such as pens, USB storage devices, and larger cylindrical or rectangular devices. (10,15) Electronic cigarettes containing nicotine are a noncombustible product designed to deliver nicotine to the user without the toxic chemicals in tobacco and tobacco smoke. Electronic cigarettes, with or without nicotine, are readily available in Canada online as well as in various retail outlets. "The use of electronic cigarettes is booming. It is estimated that in 2014 there were 466 brands and that in 2013 in the US \$3 billion was spent on electronic cigarettes products globally and sales are forecasted to increase by a factor of 17 by 2030. Recently, all of the major transnational tobacco companies have entered the electronic cigarette market."(15)

Electronic cigarettes with nicotine cannot be legally manufactured, imported, sold, or marketed in Canada. Canada's Food and Drug Act requires that products containing nicotine must be approved by Health Canada and at the present time no product has received approval. Electronic cigarettes that make a health claim cannot be legally sold in Canada however electronic cigarettes without nicotine and that do not make a health claim can be legally imported, marketed, and sold. ^(5, 8,10) Despite their illegality, electronic cigarettes with nicotine are readily available for purchase in Canada online and at retail, with little federal enforcement of the current regulations.

No formal safety requirements exist regarding product development, ingredient disclosure, nicotine levels, product safety, or packaging.^(7,8) Electronic cigarettes are also not subject to the packaging, labeling, advertising, promotion, and sponsorship restrictions that apply to conventional tobacco cigarettes and other tobacco products. Electronic cigarettes are increasingly being marketed to youth and young adults through product flavouring, celebrity endorsements, event sponsorship, and free product offers. ⁽¹²⁾ As a result of not being a "lit tobacco product", electronic cigarettes are not subject to the restrictions of the 2006 Smoke-Free Ontario Act (SFOA) which prohibits smoking in public places, workplaces, on school and child-care properties, and near entrances to health care facilities, and prohibits sales to minors. They are also not subject to restrictions of our various municipalities' by-laws that restrict smoking near building entrances, in or near municipal properties and/or parks and playing fields.

WHO IS USING ELECTRONIC CIGARETTES?

A 2014 study by Czoli, Hammond, and White of Canadian youth and young adults age 16-30 years, found that close to half of respondents (43.4%) had seen e-cigarettes advertised or for sale. A total of 16.1% reported trying an e-cigarette (5.2% nonsmokers, 18.9% former smokers, and 34.5% current smokers) and 5.7% reported use in the past 30 days (0.8% non-smokers, 1.4% former smokers, and 15.0% current smokers). Compared to non-smokers, former smokers and current smokers were more likely to have tried e-cigarettes (OR=4.25 and OR=9.84, respectively) and current smokers were more likely to have tried e-cigarettes than former smokers (OR=2.32). Current smokers were also more likely to be current users of e-cigarettes than both former smokers (OR=15.15) and non-smokers (OR=4.43). Smokers were interested in trying e-cigarettes to help them quit smoking (80.4%), as a long-term replacement for cigarettes (77.8%), or to use in places where they cannot smoke (80.9%). These findings are consistent with existing research. In contrast, reporting trying electronic cigarettes was not higher among males in this sample, as has been reported in other studies. Awareness of e-cigarettes among surveyed youth and young adults is quite high. (3)

For the first time in 2013, the Ontario Student Drug Use and Health Survey asked secondary students in grades 9-12 whether they have ever tried an e-cigarette. Among students in grades 9-12, 14.6% reported using an e-cigarette in their lifetime. This represents about 99,800 students in Ontario. Specifically, 4.1% used an e-cigarette with nicotine, and 10.5% used an e-cigarette without nicotine. Males (18.6%) were significantly more likely than females (10.3%) to report ever using an e-cigarette. (1)

ISSUES RELATED TO ELECTRONIC CIGARETTES

Electronic cigarettes are the subject of much public health debate and "represent an evolving frontier, filled with promise and threat to tobacco control. Whether electronic cigarettes fulfill the promise or the threat will depend on a complex and dynamic interplay among industries marketing electronic cigarettes (independent makers and tobacco companies), consumers, policy-makers, practitioners, scientists, and advocates."⁽¹⁵⁾ Issues related to electronic cigarettes fall into three main categories:

- 1. Health risks to users and non-users;
- 2. Efficacy in helping smokers to quit smoking and ultimately nicotine dependence; and
- 3. Interface with existing tobacco-control efforts.

Health Risks

Electronic cigarettes are almost certainly less harmful than tobacco cigarettes, but they are not without risk. Most electronic products have not been independently tested and there is wide variation in the nature of the toxicity of contents and emission. ^(6, 10, 15) "This is dependent on the

capacity of the individual product to deliver nicotine, battery voltage, unit circuitry, user puffing behaviour and nicotine solution concentration, all of which increase the variability of potential harms to the user." (15) Nicotine is the addictive component in tobacco and while not a carcinogen itself, "recent studies have indicated it may function as a "tumour promoter" and may contribute to cardiovascular disease. Nicotine exposure can have adverse effects during pregnancy and has the potential for long-term consequences for brain development from childhood and adolescent exposure." (15)

E-cigarettes do not burn or smolder the way conventional cigarettes do, and so they do not emit side-stream smoke; however bystanders are exposed to aerosol exhaled by the user. ⁽⁶⁾

"The particle size distribution and number of particles delivered to users of e-cigarettes are similar to those of conventional cigarettes, with most particles in the ultrafine range (modes, ≈100–200 nm). Particle delivery appears to depend on the nicotine level in the e-cigarette fluid but not the presence of flavours. Smokers exhale some of these particles, which expose bystanders to "passive vaping." Like tobacco cigarettes, e-cigarette particles are small enough to reach deep into the lungs and cross into the systemic circulation. At a minimum, this shows that e-cigarette aerosol is not merely "water vapour" as is often claimed in the marketing for these products. Tests show much lower levels of most toxicants, but not particles, than conventional cigarettes. The thresholds for human toxicity of potential toxicants in e-cigarette vapour are not known and the possibility of health risks to primary users and those exposed passively to their emissions must be considered." ⁽⁶⁾

Although data is limited, it is clear that e-cigarette emissions are not merely "harmless water vapour", as is frequently claimed and can be a source of indoor air pollution. Smoke-free policies protect non-smokers from exposure to toxins and encourage smoking cessation. One hundred per cent smoke-free policies have larger effects on consumption and smoking prevalence than weaker policies. Introducing e-cigarettes into clean air environments may result in population harm if use of the product reinforces the act of smoking as socially acceptable or if use undermines the benefits of smoke-free policies. (6, 8)

Of further concern is the harmful and potential lethality of nicotine in a highly concentrated and liquid form. The Centers for Disease Control and Prevention have reported a dramatic increase in calls to Poison Control Centers across the US regarding electronic cigarette liquid. Calls have increased from one call per month in September 2010 to 215 calls per month in February 2014. Most cases of poisoning were caused by ingestion or inhalation of the nicotine containing liquids and vapours, and through skin or eye exposure. More than half of these calls (51%) involved children under five years old. (2)

Electronic Cigarettes and Tobacco Cessation

Some early research studies have demonstrated some potential cessation benefits of electronic cigarettes with nicotine; however, overall the evidence for the effectiveness of electronic

cigarettes as a method for quitting tobacco smoking is limited and inconclusive. (6, 8,15) The evidence at this time, although limited, indicates use of electronic cigarettes may lead to a reduction in cigarette use rather than complete quitting, and demonstrates high levels of dual use of electronic cigarettes with conventional cigarettes. While some may support the concept of harm reduction through reduced cigarette use being a valid goal, the 2014 report of the US Surgeon General concluded that "reducing the number of cigarettes smoked per day is much less effective than quitting entirely for avoiding the risks of premature death from all smoking-related causes of death. Use of electronic cigarettes to cut down on the number of cigarettes smoked per day is likely to have a much smaller beneficial effect on overall survival compared with quitting smoking completely". (6,14)

Impact on Tobacco Control Efforts

Electronic cigarettes may "present a range of potential benefits to smokers but there is much concern and debate in the tobacco control community as to whether electronic cigarettes will prove to have a positive or negative impact on population health and in particular tobacco control." The main areas of concern include the possibility that children (non-smokers) will initiate nicotine use with electronic cigarettes and once addicted to nicotine, will switch to cigarette smoking and the possibility that everything that makes electronic cigarettes attractive to smokers may enhance the attractiveness of smoking itself and perpetuate the smoking epidemic. Additionally as mentioned in the section above, some experts have suggested that the dual use of conventional cigarettes with electronic cigarettes may actually delay or deter smoking cessation, rather than support it. (6)

Other Issues Include:

Blurring of the Core Message of Tobacco Control

The core message of tobacco control has been that tobacco use should not be started and if started should be stopped. The promotion of electronic cigarettes and harm reduction efforts creates conflicts with use of messages such as: a) Try to quit smoking and if everything else fails use an electronic cigarette; b) You do not need to quit nicotine, just smoking; c) You do not need to quit smoking, use electronic cigarettes when you cannot smoke. (4, 15)

The Role of the Tobacco Industry

"The electronic cigarette market was initially dominated by independent companies, but in recent years has seen all of the main transnational tobacco companies enter the electronic cigarette market. Given the history of the corporations that dominate the industry, this is of grave concern to tobacco control advocates. If prior interest of the tobacco industry in products promoted as harm reduction products (i.e. smokeless tobacco, snuff, etc.) serves as a precedent, their interest lies in maintaining the status quo in favour of cigarettes for as long as possible, while simultaneously providing a longer-term source of profit should the cigarette model prove unsustainable." (15) Some experts also fear involvement in electronic cigarettes and

a focus on harm reduction may provide opportunities for the tobacco industry to engage in health policy and use their involvement as a strategy to create a semblance of corporate social responsibility. (4, 15)

Challenge to Smoke-free Policies and Smoking Denormalization

In addition to protecting non-smokers from secondhand smoke, smoke-free policies also provide incentives to quit smoking and act to denormalize smoking, given that adolescents are particularly susceptible to visual cues and social norms. (15) "The use of electronic cigarettes in places where smoking is not allowed, can interfere with smoke-free policies as it increases exposure to exhaled aerosol toxicants in otherwise "clean" environments, reduces quitting incentives, may conflict with the smoking denormalization effects, and given the resemblance to conventional tobacco products, will make enforcing smoke-free policies more difficult." (15)

Marketing and Sales

Electronic cigarettes are being marketed to consumers through many channels including television, sports and cultural sponsorship, celebrity endorsement, social networking, online advertising, point-of-sale displays, pricing strategies, and product innovation. All of these are strategies that clearly emulate the very successful tobacco advertising of the past that tobacco control advocates worked so hard to undo. (12,15) "The marketing message to tobacco control stakeholders is one of alignment of the industry and public health interests which could lead to proposals of partnership between government and industry, as industry claims a meaningful seat at the table in the so-called harm reduction debate." (4,15)

While the controversy and debate over the risks versus benefits of electronic cigarettes continues, there is clear alignment on the following:

• The need for regulation of electronic cigarettes to establish a scientific basis on which to examine the effects of electronic cigarette use, ensuring adequate research is conducted, providing the public with current reliable information as to the potential risks and benefits of electronic cigarettes, and that the health of the public is protected. (15)

Regulatory recommendations consistently include prohibition of use and/or sale of electronic cigarettes anywhere conventional tobacco products are banned; banning the sale of electronic cigarettes to minors; product regulation for safety, efficacy, and quality control; restrictions on unsubstantiated health claims; prohibition on lifestyle advertising, promotion and sponsorship; and transparency from electronic cigarette companies advocating for and against legislation and regulation, both directly and through third parties. No matter what role the tobacco industry plays in the future of electronic cigarettes, this industry, its allies, and front-groups can never be considered to be a legitimate public health partner or stakeholder while it continues to profit from tobacco and its products. (6,8,10,15)

CURRENT STATE OF ELECTRONIC CIGARETTE REGULATION IN ONTARIO, CANADA, AND BEYOND

The following section is a summary of action to date to advance tobacco control and regulate electronic cigarette use in Canada and the United States.

Innisfil, Ontario

• In January 2014, added electronic cigarette use to their smoke-free outdoor sports and recreational spaces by-law no. 111-13.

Toronto, Ontario

 On August 25, the City of Toronto voted 36-2 in favour of banning e-cigarettes from all City of Toronto workplaces.

Peel Region, Ontario

• Peel Region's Smoking in the Workplace policy prohibits electronic cigarette use at Region of Peel workplaces by employees, contractors, and visitors.

Town of Hantsport, Nova Scotia

 Hantsport's <u>by-law no. 62</u>, Protection from Second-Hand Smoke, prohibits smoking in a variety of outdoor public places, and has a broad definition of smoking that includes electronic cigarettes.

Red Deer, Alberta

- BY-LAW NO. 3345/2005 received legal opinion that supports that "vaping" an e-cigarette falls under their by-law definition of smoking so the same regulations against regular cigarettes apply to e-cigarettes.
- "Smoke" or "Smoking" means to inhale, exhale, burn, or have control over a lighted cigarette, cigar, pipe, hookah pipe, or other lighted smoking implement designed to burn or heat tobacco or any other weed or substance for the purpose of inhaling or tasting of its smoke or emissions.

U.S. State and Local Laws Regulating Use of Electronic Cigarettes (as of July 3, 2014)

- http://www.no-smoke.org/pdf/ecigslaws.pdf
- This list includes U.S. states and municipalities with laws currently in effect that regulate where use of electronic cigarettes (e-cigarettes) is prohibited. The rationale used in the U.S. regarding use of e-cigarettes in workplaces and public places is that it is a significant public health concern, not only because of their unregulated constituents and the potential health impact of the vapor on users and bystanders, but also because e-cigarette use causes public confusion as to where smoking is allowed, resulting in compliance problems with smoke free laws.

PUBLIC HEALTH ACTIONS IN ONTARIO

On August 1, 2014, Toronto Public Health (TPH) released a staff report and position statement that reviewed available evidence on e-cigarette use, safety, health effects, and potential as a cessation aid; as well as actions in other jurisdictions and regulatory gaps at the federal, provincial, and municipal levels. Based on this review, a number of concerns have been identified about e-cigarette safety, impact on youth smoking initiation, and potential to normalize smoking behaviour and undermine existing tobacco control legislation. A number of Canadian and international jurisdictions have proposed or taken action to address these concerns. As a result, TPH has developed a position statement on e-cigarettes and health outlining current concerns and summarizing appropriate regulatory and policy approaches to address them. (13)

This report recommends that the Minister of Health and Long-Term Care amend the Smoke-Free Ontario Act (SFOA) to include e-cigarettes, such that the Act would prohibit e-cigarette use wherever cigarette use is currently prohibited in Ontario; and prohibit the sale of e-cigarettes to minors (under 19 years of age). If provincial action is not taken by February 2015, the Medical Officer of Health will consult with the City Solicitor, other City Divisions and relevant stakeholders and report to the Board of Health on municipal measures to prohibit e-cigarette use where smoking is prohibited under the SFOA or City by-laws. This report also recommends SFOA amendments to address youth friendly e-cigarette flavours and amendments to federal legislation to ensure labelling and manufacturing consistency of e-cigarettes. In the interim, the Medical Officer of Health will work with the City Manager to explore development of an internal policy prohibiting e-cigarette use at City workplaces. Of note, in August 2014 Toronto City Council adopted the following: 1) City Council prohibit use from City of Toronto workplaces and recommend the same to the City's agencies and corporations; 2) City Council requested the General Manager of Solid Waste Management explore the environmentally sound disposal of e-cigarettes and batteries. (13)

Hamilton Public Health Services was directed in May of 2014 by the City of Hamilton Board of Health to work with the City of Hamilton City Solicitor for the purpose of identifying what municipal authority exists in the area. Legal Services' initial verbal opinion is that the "general authority" as set forth within the Municipal Act would allow local governments to regulate these products in specific ways. There is also precedence in this area regarding other types of activities and regulation. The Chair of the City of Hamilton Board has sent letters to the Ministers of Health and Long-Term Care as well as Municipal Affairs and Housing requesting a meeting/consultation between Ministry staff and Hamilton Public Health Services and Legal Services staff. The goal is to gauge the provincial government's agreement and support for the City of Hamilton introducing certain municipal regulation concerning these products. (K. McDonald, personal communication, July 16, 2014)

Middlesex-London Health Unit (MLHU) created a position statement in September 2013 that looks at e-cigarettes through both the protection lens as well as a cessation lens. The position

statement commits to a regular review of the evidence and they will be doing another review this fall. MLHU has helped workplaces adopt policies that have included e-cigarettes in their 'smoking bans'. ⁽⁹⁾

ADDITIONAL POLICY INFORMATION

In February 2014, the European Parliament voted for tighter restrictions on the e-cigarettes containing nicotine. These include banning advertising for e-cigarettes, warnings about the addictiveness of nicotine and nicotine-containing products, and establishing standards for the amount of nicotine in e-liquids.

Nova Scotia has proposed to revise its' Smoke Free Places Act and to restrict the use of ecigarettes in public places, in line with regulations in place around public tobacco smoking.

Information regarding e-cigarette regulation was presented at the sixth session of the Conference of the Parties to the WHO Framework Convention for Tobacco Control (FCTC) which was held in Moscow, Russia, October 13-18, 2014. The regulatory options posed for consideration by parties are consistent with the recommendations previously described in this backgrounder (see 'Impact on Tobacco Control Efforts' section and recommendations from the Toronto Public Health e-cigarette report, above).

SMDHU LEGAL OPINION

In October 2014, SMDHU sought a legal opinion regarding the authority for municipalities to pass by-laws related to the use of e-cigarettes indoors or outdoors. The following is the opinion provided by HGR Graham Partners LLP:

• The Municipal Act provides municipalities with the authority to enact by-laws to specifically prohibit and regulate the smoking of tobacco in public places. Without revisions by the provincial legislature, these sections of the Municipal Act cannot be interpreted to provide municipalities with the authority to prohibit or regulate the use of electronic cigarettes that don't use tobacco. Instead, municipalities will have to rely on their broad areas of authority, specifically the authority to pass a by-law for the health, safety, and wellbeing or to prohibit or regulate public nuisances.

RECOMMENDATIONS FROM THE CDP-TOBACCO PROGRAM

Based on the information and evidence presented in this report, it is recommended that the Board of Health of the Simcoe Muskoka District Health Unit support the following position regarding the regulation of the use of electronic cigarettes:

 Electronic cigarettes should be prohibited anywhere smoking is currently prohibited, whether provincially or municipally mandated, including public places and workplaces.

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