

Electronic Smoking Products

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ENDS [electronic nicotine delivery systems], therefore, represent an evolving frontier, filled with promise and threat for tobacco control. Whether ENDS fulfill the promise or the threat depends on a complex and dynamic interplay among the industries marketing ENDS (independent makers and tobacco companies), consumers, regulators, policy-makers, practitioners, scientists, and advocates.

World Health Organization¹

Electronic smoking products (ESPs), also called electronic nicotine delivery systems (ENDS)—or more commonly referred to as electronic cigarettes or e-cigarettes—consist of a cartridge that stores a liquid solution, a battery-operated heating element and an atomizer. When heated, the atomizer slowly creates an aerosol (commonly known as vapour) that is inhaled by the user, which has become known colloquially as “vaping.”²

The cartridges of ESPs can be replaced or refilled with liquid, commonly known as e-liquid, or e-juice, which is sold separately. The e-liquids are available in a variety of different flavours and are available with and without nicotine, though the selling of cartridges containing nicotine is illegal in Canada, as is making any health claims about ESPs.³ Although ESPs that do not include nicotine are not required to be regulated under Canada’s Food and Drug Act, no ESPs have been granted market authorization in Canada, regardless of whether or not they contain nicotine.

As of January 2014, there were 466 brands of e-cigarettes on the market and 7764 unique flavours of e-liquids.⁴ Some of the flavours are identified with particular tobacco industry brands while others, such as menthol, are commonly associated with conventional tobacco products.

History

The first electronic cigarette was patented in 1963 based on steam release of nicotine from tobacco; however, it never achieved commercial success.⁵ A Chinese inventor patented an early version of the present-day e-cigarette in 2003.⁶ Since becoming commercially available in China in 2004 and worldwide since 2005, sales have grown dramatically,⁷ with global sales of ESPs reported to be \$3 billion in 2013.⁵

The earliest versions of ESPs were made to look like conventional cigarettes. Both disposable and refillable versions of these devices are currently available.⁵ Subsequent versions of ESPs do not resemble cigarettes with some brands including larger compartments for the e-liquid and higher voltages for the heating elements and separate components can be purchased for users to modify and personalize their ESPs.⁵ Another recently introduced innovation by one of the tobacco companies is a hollow pen-like device that heats tobacco to a maximum of 350 °C, which releases a nicotine vapour rather than smoke.⁸ The company believes that, because the product contains real tobacco, it will be more attractive to cigarette smokers.

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Viewpoints

Opinions regarding the safety of ESPs and their role in tobacco cessation vary widely. The use of ESPs has generated a great deal of controversy, chiefly among three groups:

1. those who oppose any form of tobacco use and see ESPs as a threat to the gains made in tobacco cessation
2. those who advocate for harm reduction and regard ESPs as less harmful than smoking
3. those who see ESPs as a personal choice

One of the major concerns of the first group is that ESPs will contribute to re-normalizing smoking.¹ They are particularly concerned that the high numbers of youth who have tried ESPs may then go on to start smoking.⁹ This is reinforced by the fact that ESP manufacturers have been able to advertise in U.S. media, despite the ban on cigarette advertising that has been in place since 1971.¹⁰ As well, some ESP users have been permitted to vape in places where smoking tobacco is banned.

The second group has taken the position that harm reduction is an important public health strategy for other drugs and should be extended to nicotine. They cite studies that suggest ESPs cause less harm than smoking, both for the users and others around them. In contrast to the position of the first group, they state that most of those using ESPs are already smokers, and the devices do not appear to be acting as a gateway to conventional cigarettes.

The third group is predominantly users, who are portrayed as a new vanguard by ESP marketers. One of the leading e-cigarette manufacturers

targeted this group with a 2012 YouTube ad in which a popular actor said, "We're all adults here; it's time we take our freedom back."¹¹ Some of those who use ESPs are looking to reduce their smoking and improve their health and draw on studies that have shown ESPs reduced the number of cigarettes smoked.⁵

In catering to those concerned about the health effects of smoking, some manufacturers of ESPs suggest using e-cigarettes with low levels of nicotine or gradually tapering down nicotine levels as a method of reducing or quitting smoking. The use of e-cigarettes has also been promoted, and even allowed, as a way around existing smoking prohibitions and regulations, with some promotional materials for ESPs going so far as to have claimed that the World Health Organization (WHO) supports the use of ESPs as cessation aids. However, the WHO states that the e-cigarette is not a proven nicotine replacement therapy and has requested that marketers "immediately remove from their websites and other informational materials any suggestion that WHO considers it to be a safe and effective smoking cessation aid."¹²

Health Risks

Health Canada advises Canadians not to purchase nor use ESPs because these products may pose health risks and have not been fully evaluated for safety, quality and efficacy.³ Alberta Health Services (AHS) endorses this advice, and use of ESPs is not permitted in AHS facilities nor on AHS property.

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The WHO has taken the position that ESPs should be regulated as a tobacco product in order to ensure that vaping does not glamorize smoking again and that the current downward trend in smoking is not reversed.¹ In a letter to the WHO in May 2014, a group of specialists in nicotine science and public health policy argued that using an ESP is safer than smoking and should be regulated as a harm reduction strategy.¹³ Their argument was that there is no tobacco in the e-liquid, and the vapour contains fewer harmful chemicals than tobacco smoke. They note that very little reduction in smoking rates has been achieved in the last few years, and many of those people who currently smoke are unwilling to quit. The specialists argue that encouraging switching to ESPs by those who are unwilling to quit will lower their likelihood of developing the diseases associated with smoking and will significantly reduce health care costs, both for those who smoke and those exposed to second-hand smoke. Another group of specialists wrote to support the WHO's position on ESPs.¹⁴

Although ESPs are generally reported to contain lower levels of toxic and cancer-causing compounds than tobacco smoke, they are not without health risks to both the users and those around them. Ultrafine particles in the vapour—mainly supersaturated propylene glycol (also known as 1,2-propanediol)—can be deposited in the lung. Propylene glycol is already used in asthma inhalers and other inhaled medications as well as artificial mist or fog in theatrical productions or films; it is “generally recognized as safe” by the FDA.¹⁶ However, some studies have found reduced lung function and other respiratory problems in people in the entertainment industry who are chronically exposed to the aerosols.¹⁷ Aerosolized nicotine

seems capable of increasing the release of the inflammatory signaling molecule nitrous oxide upon inhalation.¹⁸ Signs of airway constriction and inflammation are evident after only five minutes of use,¹⁹ confirming the need for further testing of these products.²⁰ In one instance, a woman developed lipid pneumonia after using e-cigarettes. The pneumonia cleared up when she stopped using e-cigarettes.²¹

Metals (e.g., nickel, cadmium and mercury)²² and other toxic compounds (e.g., diethylene glycol, formaldehyde and benzene)²² have also been found in the e-liquids; some of these compounds occur as the result of users modifying their ESPs to operate at higher voltages.²³ It should be noted that the levels are much lower than those in tobacco smoke. Tobacco-specific constituents suspected of being harmful to humans (anabasine, myosmine and β -nicotyrine) were detected in most of the samples tested.²³

Despite the lower levels of these compounds, the health effects of their long-term inhalation by ESP users have not been studied. It is generally accepted that more study of the long-term effects of aerosol inhalation and standardization of the manufacturing processes for both the ESPs and e-liquid are necessary. As well, there is strong support for banning the sale of these products to minors.^{1,13,14}

Nicotine Exposure

The FDA Center for Drug Evaluation Division of Pharmaceutical Analysis conducted tests on ESPs and concluded that quality-control processes for manufacturing e-cigarettes are substandard or non-existent²⁴ and the concentrations of nicotine

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and other chemicals in the cartridges varied. The FDA results showed that e-cigarette cartridges labelled as nicotine-free contained nicotine and that three different electronic cigarette cartridges with the same label produced markedly different amounts of nicotine with each puff. Some studies show that e-cigarettes can deliver substantial and even toxic amounts of nicotine²⁵ and other chemicals. The lethal dose is considered 0.5 to 1 grams of nicotine for adult humans;²⁶ however, adults who attempted suicide by drinking e-liquids containing up to 1.5 grams survived after treatment by activated charcoal ingestion.²⁷

Health Canada's advisory on ESPs states that "nicotine is a highly addictive and toxic substance, and the inhalation of propylene glycol is a known irritant."³ Health Canada further advises that ESPs may pose risks, such as nicotine poisoning and addiction, and recommends that the electronic products and cartridges be kept out of the reach of children to prevent potential choking incidents or nicotine poisoning.³ Deaths of children from both ingestion of e-liquids and choking on e-liquid containers have been reported.^{28,29,30}

There is sufficient evidence to caution children and adolescents, pregnant women, and women of reproductive age about using ESPs. Fetal and adolescent nicotine exposure can have long-term consequences for brain development.³

The limited research that has been conducted on ESPs has been hindered by the lack of regulatory requirements for product design and content, which means test results may not be applicable beyond the individual products tested.¹⁵ Because of the variability among products, the FDA cautions that their analysis should not be used to draw conclusions about what substances are or are not

present in particular e-cigarettes or brands of e-cigarettes.²⁴

Gateway to tobacco?

The United States Food and Drug Administration (FDA) warns that e-cigarettes can increase nicotine addiction among young people and is concerned that the use of e-cigarettes may lead young people to experiment with conventional tobacco products.¹⁵ However, these products have not been adequately tested for consumer use, and the short- and long-term health effects of using these products are unknown.

The unproven claims of safety made by many manufacturers may be a contributing factor to the rise in popularity of these products.

Other risks

In addition to the health hazards of the e-liquids, ESPs have been reported to explode and catch fire, which have caused injuries.³³ This is a particular problem with ESPs that have been modified to operate at higher voltages by users. Also, some people are reported to have used a different charging system than was provided with their ESP.

Cessation

Health Canada, AHS and the FDA also do not support the use of ESPs as tobacco cessation aids. These aids, including over-the-counter nicotine replacement therapy in the form of nicotine patches, gum and lozenges or prescription medications (bupropion and varenicline) that have been clinically tested and approved by

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Health Canada are available to help tobacco users reduce or quit smoking.³⁰ Bupropion is available in Canada as the anti-depressant Wellbutrin® SR and the smoking cessation drug Zyban®.^{31,32} Bupropion helps smokers quit by controlling nicotine withdraw and reducing urges to smoke. Varenicline (Champix®) is a nicotine receptor partial agonist that reduces nicotine withdrawal and cravings and that prevents pleasurable effects of smoking.^{31,32}

Health Canada has also approved nicotine inhalers as smoking cessation aids.³¹ Nicotine inhalers consist of a small, white, plastic tube with a cartridge that contains a standardized amount of nicotine. Nicotine inhalers are designed to be “puffed” and not actually inhaled; the nicotine is absorbed by the cells in the mouth.

Regulations and Legislation

The FDA is in the process of establishing regulations for ESPs. Although some ESPs, including those made by tobacco companies, have health warnings listed on the packages, these warnings have not been created, regulated or standardized by the FDA.³⁴ The American Cancer Society, American Heart Association, American Lung Association, Action on Smoking and Health (U.S.), Campaign for Tobacco-Free Kids, Americans for Nonsmokers' Rights and the Association for the Treatment of Tobacco Use and Dependence support restrictions on e-cigarettes.

Several countries prohibit the sale of e-cigarettes and a growing number of jurisdictions prohibit the indoor use of e-cigarettes and the sale of the products to minors. In October 2014, WHO developed a report that recommends several regulatory restrictions for ESPs including

- limiting promotion and advertising to reduce the uptake and use by non-smokers, pregnant women and youth
- limiting the ability of manufacturers to minimize potential health risks to ESP users and non-users and to prohibit unproven health claims³⁵

More information on restrictions on the use and sale of electronic smoking products in the United States can be found in the Global Advisors Smokefree Policy (GASP) white paper on electronic cigarettes, which is available at http://www.njgasp.org/wp-content/uploads/2014/05/E-Cigs_White_Paper.pdf.

Some companies have promoted these products as safe to use. Others have even described the vapour as only water,³⁶ which is inaccurate. Some of the ESP manufacturers' websites imply that their products have market authorization in Canada. This is only correct in that ESPs that do not include nicotine are not required to be regulated under Canada's Food and Drug Act. However, no ESPs have been granted market authorization in Canada, regardless of whether or not they contain nicotine. Detailed information from Health Canada that clarifies regulations regarding the sale and importation of ESPs is presented at the end of this document. At a minimum, more research is required to inform potential regulatory options. More research is needed on

- the composition of refill liquids and the aerosols that they release
- toxicology, carcinogenicity and effects of long-term use and exposure
- addictive potential, abuse liability, risks of nicotine refill bottles, adverse effects and efficacy for smoking behaviour (cessation and reduction) currently available forms of nicotine replacement therapy (NRT).^{37,38}

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The Therapeutic Products Directorate (TPD) of Health Canada is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. Prior to being given market authorization, a manufacturer must submit substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act and Regulations. This is done by filing a drug submission to the TPD.

Health Canada has issued the following advice concerning the regulation, production, sale and importation of ESPs:³⁹

- A non-refillable, disposable ESP (e.g., e-cigarette) prefilled with nicotine (or any other drug or natural health product [NHP]) is considered to be a drug (or NHP)/medical device combination product and requires a drug identification number (DIN) or natural health product number (NPN). In this case, its drug delivery system is to be reviewed for safety and efficacy, but a medical device license is not required.
- A refillable electronic smoking product with nicotine or intended to be used with nicotine (or any other drug or NHP) is considered to be a drug (or NHP) delivery system; therefore, a Class II medical device, and its nicotine (or drug or NHP) component requires a DIN (or NPN). (Please note that no medical device license is to be issued until the associated drug or NHP component has received a DIN or NPN.)
- An electronic smoking product associated with a health claim, but not associated with nor intended to be used with nicotine (nor any other drug nor NHP) is considered to be a Class I medical device.

- An electronic smoking product not associated with any health claim and not associated with nor intended to be used with nicotine (nor any other drug nor NHP) is not regulated under the Food and Drugs Act.
- No electronic smoking products have been granted market authorization in Canada including those exempt from the Food and Drugs Act.

About AlbertaQuits

Alberta Health Services provides tobacco cessation support through the AlbertaQuits Helpline (1-866-710-7848(QUIT)—a free, confidential counselling telephone service that offers evidence-based information and support to quit smoking. Callers can access help developing an individual quit plan, receive information or be referred to services available in their community.

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