

The Buzz on E-Cigarettes

Introduction

WHAT IS AN ELECTRONIC CIGARETTE?

An electronic cigarette, or e-cigarette, is a cylindrical device made of stainless steel or plastic that mimics a cigarette in terms of its appearance and use and sometimes taste, but with a critical distinction—it does not contain tobacco. It is designed to deliver nicotine without subjecting the user to the toxic chemicals in tobacco and tobacco smoke. A typical electronic cigarette consists of three components:¹

- » a cartridge containing nicotine, water, and flavouring in a base of propylene glycol (PG), vegetable glycerine (VG), or polyethylene glycol 400. Both refillable and pre-filled disposable cartridges are available. Note that not all cartridges (nor e-liquid/e-juice solutions) contain nicotine;
- » an atomizer containing a heating element which turns the liquid nicotine into a vapour; and

- » a battery (usually rechargeable) to power the atomizer and the indicator light that glows (usually red) like a lit cigarette when the user inhales on it.

Some versions of the device include only two parts: a battery and a carto-mizer, which combines the cartridge and the atomizer in one unit.

Users, called vapers, draw on the end as they would a cigarette, which heats the liquid nicotine and turns it into an aerosol that is inhaled, leaving a visible mist resembling smoke that is exhaled.

The Chinese company Ruyan claims to have invented the e-cigarette, which was first marketed in China in the mid 2000s. Since then there has been a proliferation of companies manufacturing electronic cigarettes and selling them worldwide through the internet.²

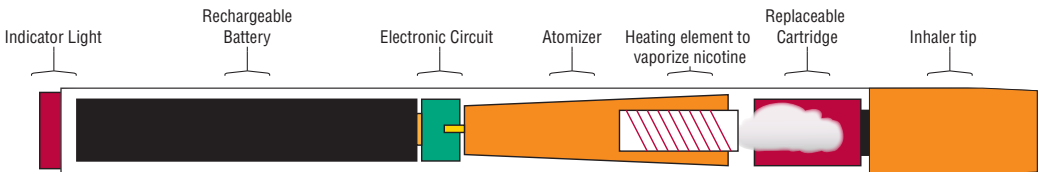


Diagram of an E-Cigarette

What's All the Fuss About?

The e-cigarette controversy comes down to two opposing views. Proponents believe that the e-cigarette represents a clean drug delivery device that can satisfy smokers' addiction to both nicotine and smoking behaviours (the physical sensations of handling the cigarette and inhaling smoke) and thus greatly reduce their risk of disease and death. Proponents also emphasize that even though e-cigarettes may not have undergone rigorous scientific testing, they cannot be as harmful as cigarettes, since with cigarettes, it is the mode of nicotine delivery—the tobacco smoke—that is responsible for most of the disease not the tobacco itself or the nicotine in it.

Those opposed believe that e-cigarettes should be treated like other therapeutic products containing nicotine; that is, their sale should not be permitted until they have undergone clinical trials to prove their safety and their efficacy in helping smokers quit. Opponents fear that the widespread promotion and use of e-cigarettes will result in dual use (of electronic and real cigarettes)—rather than increased quitting—and will undermine efforts to denormalize smoking. Opponents are also concerned that as novelty gadgets with perceived low risk, e-cigarettes may be attractive to youth and may lead to nicotine addiction and subsequent tobacco use.

Health Canada's Position

In March 2009, Health Canada issued an Advisory to Canadians not to use e-cigarettes³ and a Notice to stakeholders indicating that all electronic products intended to administer inhaled doses of nicotine are considered new drugs and as such fall under the *Food and Drugs Act*.⁴ Under the *Act*, before any new drug can be imported, marketed, or sold in Canada, Health Canada must grant market authorization following a review of scientific evidence demonstrating the safety, quality, and efficacy of the product. In addition, the delivery system in an e-cigarette containing nicotine must comply with the *Medical Devices Regulations*. Anyone aware of a violation under the *Act* is asked to submit a complaint to Health Canada.

The Notice applies only to e-cigarettes “intended” to deliver nicotine, which has created a regulatory grey zone that has been widely exploited. E-cigarettes that do not make any health claim and do not contain nicotine may legally be sold in Canada. Thus, many vendors are openly selling the device with nicotine-free cartridges or with cartridges claiming to be nicotine-free and then are selling cartridges and e-liquid containing nicotine under the table or are referring customers elsewhere to obtain nicotine. Some smokers reportedly find it helpful to use these devices without nicotine, but they represent a small proportion of e-cigarette users.

Under the *Food and Drugs Act*, the sale of nicotine is illegal without a prescription (except for specified nicotine replacement therapies), and there are strict conditions on the manufacture, importation, and advertising of prescription drugs, including nicotine. It is clear that the sale of nicotine cartridges and liquid is being carried out in violation of the federal *Act*.

Under the *Medical Devices Regulations*, manufacturers of all classes of medical devices must provide objective evidence that their products meet the safety and efficacy requirements of the law and are effective for the uses for which they are sold and represented. In other words, it is illegal for an e-cigarette manufacturer to make a health claim, including that the product is effective in helping smokers quit, unless it has substantiated this claim with scientific evidence.

Three years after the Notice was issued, no e-cigarette manufacturer has applied for market authorization. Health Canada has received only a few complaints about sales of the product, and anecdotal reports indicate that very few of these complaints have been acted upon. More complaints have come from individuals wanting to import and/or sell electronic tobacco products.⁵

What Other Countries Are Doing

In the US, the Food and Drug Administration (FDA) had sought to regulate e-cigarettes as drugs and devices under the *Food, Drug and Cosmetic Act*, requiring clinical trials for safety and efficacy. However, a legal challenge by several distributors led to an Appeals Court ruling that e-cigarettes are not drugs or devices unless they are marketed for therapeutic purposes. Rather than appeal the decision, the FDA announced that it will regulate products “made or derived from tobacco” including e-cigarettes as “tobacco products” under the *Family Smoking Prevention and Tobacco Control Act*.⁶ Various countries do not permit the sale of electronic tobacco products, including Australia, New Zealand, Singapore, Thailand, and Brazil.⁷ The sale of e-cigarettes is legal in a few countries, including Latvia and the Netherlands.

Promotion & Sales

Many vendors in various provinces across Canada, including convenience stores, gas stations, tobacconists, and mall kiosks, are openly selling e-cigarettes. Other retailers only proffer an e-cigarette when a customer asks for one or indicate that they can obtain one quickly.

In recent years, e-cigarette manufacturers and distributors have increased their promotional efforts. Electronic cigarettes are being promoted to



Ad in shop window, Milton, ON, June 2010



Brantford, ON, October 2011

retailers through retail trade journals, such as *Specialty Retail*,⁸ and to the public through advertisements in the in-flight magazines of various discount airlines.⁹ Marketing efforts, however, focus on less traditional marketing vehicles. In March 2011 several Ontario public health units received a “fax blast” from a company selling e-cigarettes—an easy and inexpensive way to promote the product to many people.

The greatest source of e-cigarette promotion is the internet.¹⁰ Numerous websites, forums, and blogs of advocacy organizations and user groups feature information, product reviews, and testimonials trumpeting the many benefits of electronic cigarettes versus their tobacco counterpart.¹¹ Many e-cigarette companies market their products through YouTube videos, Facebook pages, websites, and paid ads on popular search engine sites.

That e-cigarettes can be smoked in defiance of smoking bans is a common theme in many promotions, as shown in the advertisement at top.

Other promotions focus on the novelty aspects of the product: unique or varied flavourings, many of which have obvious appeal to youth, such as Bubblegum, Snickerdoodle, and Sweet Tarts;¹² adjustable smoke volume (LoongTotem E-cigarette Industrial Co. Ltd); and technology that lets users find and communicate with each other (blu).¹³

Some brands emphasize the value of e-cigarettes as smoking cessation aids, through advertising, the packaging itself, or frequently, through testimonials on their websites from users who claim to have quit smoking by switching to an electronic cigarette. For example, one website claims, “Stay healthy, live longer: Make the switch to e-cigarettes.”¹⁴ Other brands come close to making a health claim without overtly doing so: “V2 Cigs gives you the power to smoke on your terms.... Begin your new life today.”¹⁵ Some companies, however, are careful to include a disclaimer, such as “This product is sold purely for recreational purposes—it is not a smoking cessation product and has not been tested as such.”¹⁶

Numerous e-cigarette distributors are exploiting endorsements of their products—whether paid or spontaneous—by Hollywood celebrities. Photos of celebrities using e-cigarettes, including Katherine Heigl, Lindsay Lohan, Paris Hilton, Leonardo DiCaprio, and Johnny Depp, appear on websites promoting electronic tobacco products.¹⁷ Given the massive and growing public interest in and influence of the celebrity culture, endorsements of e-cigarettes by Hollywood A-list stars can only mean a boon to sales.



Celebrity Lindsay Lohan
<http://www.theedge.co.nz/>

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www.smokingeverywhere.com

Nature of the Problem

TOBACCO CONTROL POLICIES UNDERMINED

There are many reasons why health groups are concerned about the burgeoning use of e-cigarettes. The primary concern is that e-cigarettes will undermine tobacco control policies, in particular workplace and public place smoking bans that protect people from second-hand smoke and promote quitting. In the past year, health units across Ontario have reported a growing number of incidents in which the alleged use of an e-cigarette served to complicate enforcement of the *Smoke-Free Ontario Act*:

- » In several cases, a person charged with smoking where prohibited under the *Smoke-Free Ontario Act* claimed that he was using an e-cigarette. As a result, enforcement

officers now face the additional challenge of trying to obtain the cigarette butt as evidence in case their testimony is not sufficient to convince a Justice of the Peace that an offence took place.

- » Several schools have reported that students are flaunting their use of e-cigarettes on school property. Authorities suspect that in some cases students are re-jigging the devices to ‘smoke’ illegal substances.

In addition to thwarting smoking bans, the use of e-cigarettes in places where smoking is not permitted increases social exposure to smoking and may contribute to the ‘renormalization’ of cigarette use, important factors in youth smoking uptake.¹⁸ Public use of e-cigarettes also provides visual cues to smoke, which undermines quit attempts and promotes relapse.¹⁹ As well, e-cigarettes are often promoted in the same ways that cigarettes were before most tobacco marketing was banned, giving rise to fears that these promotions may serve to make smoking ‘cool’ again. Attractive young women (and sometimes men) exuding sex appeal are often featured in e-cigarette ads.²⁰ And e-cigarette companies have begun sponsoring popular events such as car racing,²¹ long a favourite sponsorship activity of Big Tobacco.

UNPROVEN CESSATION AID

Health groups are likewise concerned that some brands of e-cigarettes are making unsubstantiated health

claims. The “Health E-Cigarette,” for example, claims that “Smoking is harmful for health E-Cigarette is good for health.” A package leaflet states that e-cigarettes reduce smoking frequency, “smoking kill,” and produce no harm from second-hand smoke. Health claims also include promoting the devices as cessation aids, when they have not undergone rigorous testing to establish their effectiveness in helping smokers quit. A small study of two e-cigarette brands with 16 mg and 18 mg nicotine cartridges found very little increase in nicotine levels in the blood of participants and little impact on craving reduction.²² As well, the variability in design among e-cigarette brands and the lack of manufacturing standards mean that nicotine delivery varies significantly both among brands and within a brand.²³ Nicotine delivery has also been found to diminish throughout the life of a cartridge.²⁴ The fact that nicotine dosing is not uniform calls into question the usefulness of the e-cigarette as a nicotine replacement therapy²⁵ and could lead to compensatory smoking, as has been found with some other products intended to reduce harm.²⁶

UNCERTAIN HEALTH & SAFETY RISKS

At present there is insufficient data to evaluate the health risks to users from short- or long-term use of e-cigarettes, leading many researchers to call for further research to be done on an urgent basis.²⁷ E-cigarette manufacturers have failed to provide full disclosure



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Lack of quality controls

Uncertainties over the health risks of e-cigarettes are compounded by the lack of quality controls in manufacturing the product.³⁶ Testing by the FDA on a sample of 18 different cartridges from two major brands found that the information on the labels often did not reflect the actual nicotine in the product. **Almost all products labelled as being nicotine-free were found to contain nicotine.** FDA analysis also found a significant variation in nicotine delivery among products with the same label.³⁷ As well, many brands simply label the product as “no,” “low,” “medium,” and “high”—at best an imprecise indication of the level of nicotine the user will be inhaling. One study found that even where the product was labelled with the number of milligrams of nicotine, “It was not clear if this was mg/cartridge or mg/ml.”³⁸ A related issue is the lack of regulation of the e-liquid. While some is made in laboratories, much of it is produced in basements by people without qualifications and proper equipment.

of the chemical components in their products, and they have not proven that the chemicals are safe for inhalation into the lungs. An analysis of a small sample of e-cigarettes by the FDA found several toxic constituents in half the samples, including detectable levels of nitrosamines which are known to cause cancer in humans.

As well, tobacco-specific impurities which are suspected of being harmful to humans were found in a majority of the samples, and diethylene glycol—a toxic ingredient in antifreeze—was detected in one cartridge.²⁸ The fact that e-cigarettes generally require stronger suction to smoke than cigarettes also raises concerns, as it is not known whether more intense inhalation has any adverse effects on health.²⁹ One study also found that the amount of vapour produced by an e-cigarette decreases during smoking, necessitating increasing puff strength to produce the vapour. And, unlike pharmaceutical nicotine replacement products or cigarettes themselves, e-cigarettes are sold without government-mandated health warning labels and in many cases with no warning of any kind.³⁰

The storage and handling of the nicotine used in e-cigarettes is likewise cause for concern. One distributor in London, Ontario, for example, mixes the e-liquid in his basement and even asks customers to return the vials for refilling or recycling.³¹ Refill bottles of e-liquid can be purchased that contain over 1,000 mg of nicotine, when a lethal dose of nicotine for adults (30-60 mg) and children (10 mg) is a fraction of that.³²

A growing trend is the use of Whole Tobacco Alkaloids (WTA) in e-liquids rather than pharmaceutical grade nicotine alone, which users claim gives a more satisfying experience that more closely approximates smoking ciga-

rettes. In contrast to pharmaceutical-grade nicotine which is manufactured to a very high standard, e-liquid containing WTA is not produced to any known standard. In the absence of a standard or regular laboratory testing, the chemical constituents of WTA, including the presence of carcinogens, and the long-term health consequences of its use remain unknown.³³

Questions have likewise been raised about the health risks to others from the second-hand vapour. Propylene glycol, the primary chemical in most e-cigarette vapour, is also the main constituent of a common type of theatrical fog. The few studies that have been conducted on this fog have observed increased headaches and respiratory symptoms (dry throat, dry cough) and decreased lung function at higher levels of exposure and chronic wheezing and chest tightness with increased cumulative exposure.³⁴

There is one reported case of an e-cigarette exploding in a user's mouth, causing serious harm, including the loss of his teeth and part of his tongue as well as facial burns. A faulty battery is the suspected cause.³⁵

E-Cigarettes as a Harm Reduction Device

LIKELY SUBSTANTIALLY LOWER HEALTH RISKS THAN CIGARETTES

Proponents of e-cigarettes underscore the fact that electronic cigarettes contain no tobacco and involve no combustion and therefore pose substantially less risk to health than traditional cigarettes. Dr. Murray Laugesen, former Chief Medical Officer in the New Zealand Ministry of Health and now a consultant, contends that an e-cigarette is "100 to 1000 times safer than a tobacco cigarette."³⁹ Authors of a study of one brand of e-cigarette state that "to our knowledge, no deaths or hospitalisations from ENDD [electronic nicotine delivery device] use have been reported."⁴⁰

There are very few ingredients in e-cigarettes, namely flavouring, a liquid base that turns into a vapour, and in most cases, nicotine. All three liquids used in e-cigarette cartridges are popular food additives, serving as humectants and preservatives. The most



An e-cigarette is “100 to 1000 times safer than a tobacco cigarette.”

— Dr. Murray Laugesen, consultant

common, propylene glycol, has been used in asthma inhalers and nebulizers since the 1950s, and is often found in atomized medication. Propylene glycol also produces the fog in theatrical stage productions. It is included on the FDA's list of substances that are Generally Recognized as Safe (GRAS).⁴¹ Many e-liquids contain a blend of PG and VG in order to control the viscosity of the liquid, the amount of vapour produced, and its sweetness.⁴² A report by Laugesen on the safety of Ruyan e-cigarettes, which was funded by the manufacturer, concluded that “it is very safe relative to cigarettes, and also safe in absolute terms on all measurements we have applied.”⁴³ It should be noted that in several cases, the conclusion that the e-cigarette vapour contained safe levels of a chemical was based on a single study. Trace levels of tobacco-specific nitrosamines (TSNAs) were found, with the highest levels of TSNAs in the cartridges with

the highest nicotine concentration (16 mg); however, Laugesen contends that the level of 8 nanograms per gram is extremely small and equals the amount in a nicotine patch.

POTENTIALLY EFFECTIVE IN GETTING SMOKERS OFF CIGARETTES

There are thousands of anecdotal reports on the internet that e-cigarettes have helped smokers to stop smoking cigarettes, but no scientifically rigorous evidence. A small, single blind study of one brand involving 40 smokers not intending to quit found that the 16 mg e-cigarette scored highest for enabling participants to refrain from smoking and for serving as a potential aid in quitting. The 16 mg e-cigarette delivered approximately 10% of the nicotine per puff of a regular cigarette, indicating that the e-cigarette works more like a nicotine replacement therapy than a cigarette. The 16 mg e-cigarette and the nicotine inhaler received similar ratings for satisfaction and ease of use. One-third of participants who underwent additional testing showed no increase in blood nicotine when using the e-cigarette.⁴⁴

Recommendations and Conclusions

There is a disturbing lack of research on e-cigarettes on both sides of the debate. The studies conducted to date, both research demonstrating safety and benefits of use and research showing potential risks to health, have all involved very small samples and have not been randomized controlled trials. The problem is exacerbated by the lack of quality controls in the industry.

The WHO Study Group on Tobacco Product Regulation has called for research at both the individual and population levels, including clinical trials, behavioural and psychological studies, and post-marketing studies, and for a prohibition on claims imputing health benefits, reduced harm, or effectiveness as a cessation aid until the claims have been scientifically proven.⁴⁵ The group recommends that electronic smoking products be regulated as nicotine delivery devices (i.e. drugs). While this approach theoretically provides the greatest level of protection to consumers, in reality, e-cigarettes are widely available and largely unregulated. Moreover, the high costs and time required to seek regulatory approval mean that most manufacturers are unlikely to do so.

An alternative, endorsed by the UK Royal College of Physicians and some prominent researchers is the creation of a nicotine regulatory framework that would facilitate the development of alternative nicotine products and control their marketing and sale according to their risk profile.⁴⁶ This regime recognizes that many smokers are either unable or unwilling to quit and that safer nicotine delivery systems are needed to satisfy their cravings without subjecting them to the toxins in tobacco smoke.

A third approach would be to regulate electronic smoking devices as tobacco products, a much less restrictive regime than that for drugs. As tobacco products, e-cigarettes would be covered by smoking bans and thus could neither promote dual use nor thwart the progress in denormalizing tobacco use. They would also be subject to youth access laws and prohibitions on advertising, sponsorship, and retail display, measures that would help reduce the risk of experimentation and subsequent nicotine addiction by youth. In addition, regulations could require that they meet specified manufacturing standards.

Under the current regulatory situation in Canada, the perfect has become the enemy of the good. By regulating e-cigarettes and nicotine cartridges/liquid under the *Food and Drugs Act* but not actively enforcing the provisions, Health Canada is protecting consumers *in theory only* from the potential risks of using e-cigarettes and is allowing promotion and sales to go unchecked. A realistic regulatory regime is needed, with meaningful enforcement. As a minimum, Health Canada should ensure that the product meets consumer safety standards and that the information provided to Canadians is accurate. Health Canada should also ensure that the marketing, sales, and use of e-cigarettes are controlled to protect valuable gains in tobacco control that have reduced tobacco use and related harms.

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