

Electronic cigarettes in physician practice

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Ethical considerations

- Medical practitioners have a duty of care to provide the best possible management at each patient encounter. Withholding a legitimate treatment option that could prevent a life-threatening illness is a breach of that obligation.
- A policy that specifically allows the widespread sale and use of nicotine in its most lethal delivery system yet denies access to a far safer alternative is hard to justify on ethical grounds.
- Government interventions to restrict the rights and behaviour of individuals are not justified in the absence of evidence of material harm to others.

Introduction

Electronic cigarettes (e-cigarettes) were invented by a Chinese pharmacist in 2003 as an aid to quitting smoking. Their use has grown exponentially and they are now the most popular quitting aid in many countries. Currently, 1.2% of Australians aged 14 years and older use e-cigarettes (vape). Younger people try them mainly out of curiosity, whereas most adults use them as a less harmful alternative to smoked tobacco or as a short-term cessation aid.¹

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Abstract

There is growing evidence for the effectiveness of e-cigarettes as a quitting aid and, although not completely harmless, the scientific consensus is that they are substantially less harmful than smoking tobacco. More research is needed, but there is now sufficient empirical evidence and real-world experience over more than a decade to consider their use as a legitimate tobacco harm reduction tool for smokers who are unable or unwilling to quit with conventional strategies. Smokers should be advised that the highest success rates occur with daily use with nicotine e-liquid and newer e-cigarette models. After quitting smoking, it is preferable to aim ultimately to cease vaping if possible, but long-term use of e-cigarettes is safer than relapsing to smoking.

Conflicting views about e-cigarettes have arisen as research has lagged behind their rapid growth. According to the UK Royal College of Physicians, 'it is important to promote the use of e-cigarettes, NRT [nicotine replacement therapy] and other non-tobacco nicotine products as widely as possible as a substitute for smoking' although 'they are not currently made to medicines standards and are probably more hazardous than NRT'.² However, Australia's National Health and Medical Research Council has taken a precautionary approach, stating that 'further research is needed to enable the long-term safety, quality and efficacy to be assessed'.³

Nevertheless, smokers and ex-smokers are using these devices and physicians need to be informed to answer questions about them or advise on their use. This article provides an update on the latest evidence on e-cigarettes. It examines the indications for their use, their effectiveness for tobacco harm reduction, safety, legal issues and controversies. Finally, practical advice for their use by patients is presented.

Tobacco harm reduction

The main indication for e-cigarettes is tobacco harm reduction.² The reality is that many smokers are unable or unwilling to quit with approved therapies in spite of repeated attempts to do so. Switching to vaping can satisfy the smoker's need for nicotine and provides 'a smoking experience' without the vast majority of constituents in tobacco smoke which cause most of the harm to health.⁴

Nicotine has only relatively minor adverse health effects and harm from long-term exposure to nicotine is likely to be minimal.² Nicotine acutely increases heart rate and blood pressure and may cause arrhythmogenesis and increased insulin resistance. Nicotine can impair foetal brain and lung development. There is some evidence in animal studies that nicotine can alter brain development in adolescents.

Harm reduction principles have been applied with success to other risky behaviours, such as long-term methadone for heroin users and clean needles and syringes to reduce the risk of HIV/AIDS in drug users. E-cigarettes now offer, for the first time, an affordable, well-tolerated reduced-harm product for smokers.

What are e-cigarettes?

E-cigarettes are battery-powered devices that heat a liquid solution (e-liquid) into an aerosol for inhalation, simulating the act of smoking. E-cigarettes are consumer products designed to replace another much more harmful consumer product, combustible tobacco. They are not marketed as pharmaceutical products or medical devices.

E-cigarettes consist of a battery, a vaporiser (heating element) and a reservoir for e-liquid. E-liquid consists of nicotine in varying concentrations (typically 0–3.6%) and flavourings dissolved in propylene glycol and vegetable glycerine. When the user breathes in or presses a button, the vaporiser is activated creating a fine mist for inhalation. Some of the aerosol is exhaled as a visible mist.

Early devices looked like cigarettes and are often referred to as ‘cigalikes’. Second- and third-generation models are larger, have more powerful, rechargeable batteries and refillable ‘tanks’ or replaceable cartridges of e-liquid. These models are more complicated to use but generally deliver more nicotine and are more satisfying (Fig. 1).

Vaping is considerably less expensive than smoking. This is an important consideration as smoking is increasingly concentrated in lower socioeconomic groups and causes considerable financial stress.⁵

Are they effective for smoking cessation?

There is a growing evidence for the effectiveness of e-cigarettes as a quitting aid from changes in population




Electronic cigarettes		
First generation (cigalikes)	Second generation	Third generation
Resemble cigarettes	Larger refillable tank	Larger refillable tanks
Low nicotine delivery	Higher capacity battery	Replaceable components
	Deliver higher nicotine doses	Higher capacity battery
		Adjustable power output
		Deliver higher nicotine doses
		

Figure 1 Electronic cigarettes.

smoking, observational studies, randomised trials and widely reported user experience.

The uptake of e-cigarettes has coincided with significant reductions in population smoking rates in many countries and it is likely that e-cigarettes are contributing to this.⁶ Millions of smokers report having quit using e-cigarettes.^{7,8}

Longitudinal studies using national survey data suggest that e-cigarettes are increasing quit rates. In the United States, Zhu *et al.* found that smokers who used e-cigarettes were more likely to have successfully quit smoking for at least 3 months compared with non-users.⁶ In England, Beard *et al.* reported that the increase in use of e-cigarettes was also associated with higher success rates of quit attempts.⁹

The few randomised controlled trials tested early e-cigarette models which had poor nicotine delivery, but found similar efficacy to nicotine replacement therapy.^{10,11} Later-generation models deliver nicotine more efficiently and are likely to have higher quit rates.¹²

Not all studies have shown a benefit. Some observational studies or meta-analyses of both observational and randomised studies have found no net quitting benefit. However, these studies suffered from limitations, such as selection bias, imprecise measures of frequency and duration of use, failing to indicate whether users were trying to quit and unmeasured confounders.¹¹

While anecdotal reports are not strong scientific evidence, the large number of individuals who have used e-cigarettes to quit smoking forms part of the evidence base.

Safety

Although further research is needed, there is very little evidence so far of serious harm from 10 years of real-world use and from studies up to 2 years.¹⁰ The most common adverse effects are irritation of the mouth and throat and dry cough, which tend to be mild and self-limiting.¹⁰

The scientific consensus is that e-cigarettes are substantially less harmful than smoking. Like all new drugs or treatments, the long-term effects of vaping are not yet known.² However, the Royal College of Physicians' report concluded that the risk from long-term vaping is unlikely to exceed 5% of the harm from smoking tobacco.² As regular e-cigarette use is almost exclusively confined to smokers and ex-smokers, any risk should be compared to the considerable risks of continuing to smoke.^{8,13}

Almost all the harm from smoking is from the tar, carbon monoxide and other toxic chemicals caused by burning tobacco. As there is no tobacco or combustion in e-cigarettes, no smoke or products of combustion are

produced. Some potentially harmful constituents are present in e-cigarette vapour, but at much lower levels than in cigarette smoke and in most cases below the levels known to cause harm.¹⁴

Furthermore, there is a dramatic reduction in carcinogens and other toxicants measured in the blood and saliva of users compared to tobacco smokers.¹⁵

A recent study estimated the cancer risk from vaping as less than 1% that of smoking, based on levels of known cancer-causing agents reported in studies of e-cigarette vapour.¹⁶

Indeed, many studies have found significant health improvement when smokers switch to vaping, including improved asthma, chronic obstructive pulmonary disease, blood pressure, cardiovascular health, lung function and reduced pneumonia risk.^{17–19}

Modelling studies show a net positive public health effect based on current estimates of the risks and benefits of vaping. A study by Levy *et al.* estimated that up to 6.6 million premature smoking-related deaths could be prevented in the United States if most smokers switched to e-cigarettes over the next 10 years. Using pessimistic assumptions, an estimated 1.6 million deaths could be averted.²⁰

Potential health concerns of vaping include exposure to second-hand vapour, nicotine dependence and burns from malfunctioning batteries. The evidence is clear that the levels of toxicants in vapour are unlikely to pose any significant health concerns for bystanders in most situations.² Dependence on e-cigarettes is less than for combustible cigarettes.² Cases of e-cigarette batteries exploding or catching fire have been reported but are rare.

Diacetyl, a flavouring chemical in some e-liquids, has been linked to bronchiolitis obliterans, a serious, rare lung disease ('popcorn lung'). However, levels of diacetyl are much lower in vapour than in tobacco smoke and there are no reported cases of the condition caused by smoking or vaping.²¹ High levels of formaldehyde were found in early laboratory tests, but subsequent studies have found very low levels when tested under realistic use conditions.²² Fine particulate matter is present in e-cigarette aerosol; however, its composition is very different to smoke particles and its toxicity is likely to be much less.²

Electronic cigarettes are not currently regulated in Australia, raising uncertainties about safety, quality and labelling accuracy.

Controversies

A prominent issue raised is that vaping may entice young people who would never have smoked to take up smoking, the so-called 'gateway' effect. However, while young people may experiment with e-cigarettes, regular

use is almost exclusively confined to those who already smoke.²³ Young people who try vaping are also more likely to try smoking, but there is little evidence of cause and effect. Furthermore, the great majority of young people who vape do not use nicotine e-liquid.²⁴

Another concern is that vaping may undermine decades of tobacco control efforts to denormalise smoking by making smoking behaviour appear socially acceptable again. However, population studies show that the opposite effect appears to be occurring – uptake by never-smoking adults is rare and there is no evidence of long-term former smokers relapsing to smoking.¹³

A third concern is dual use (using an e-cigarette while still smoking). This could be important as any amount of smoking tobacco is harmful. However, evidence is emerging that dual use is frequently part of a transition phase to quitting for many smokers and dual users are more likely to quit than exclusive smokers.⁶ Furthermore, dual users smoke less intensely and most studies have demonstrated reduced biomarkers compared to smoking alone.²⁵

Use in physician practice

Smoking remains the leading cause of preventable illness and death in Australia.²⁶ Physicians are confronted daily

Table 1 Practical advice for patients on e-cigarette use²⁷

- First-line smoking cessation treatment is professional counselling combined with approved pharmacotherapies (nicotine replacement therapy, varenicline, bupropion).
- Smokers who are unable to quit with approved therapies may benefit from switching to an e-cigarette.
- E-cigarettes deliver nicotine to reduce the urge to smoke and replicate the habits and rituals of smoking.
- Explain that e-cigarettes are not risk-free but evidence suggests they are a much less harmful than smoking and are less addictive. The most common side effects are irritation of the mouth and throat and dry cough. Try different e-cigarettes, flavours and nicotine strengths to find the combination that works best.
- Specialist vape shops can provide advice on devices that are suitable for smokers who are new to vaping.
- More advanced models are generally more effective.
- Daily use is more effective for quitting than intermittent use.
- Persevere for several weeks as satisfaction and nicotine delivery improve with practice.
- The addition of behavioural counselling and other stop-smoking medication, such as varenicline or the nicotine patch, may improve quit rates.
- Stop smoking completely as soon as possible and cease vaping within 3–6 months if possible. However, long-term use of e-cigarettes is safer than relapsing to smoking.
- Long-term dual use should be discouraged.
- Keep nicotine e-liquid in childproof containers and keep out of the reach of children.

Table 2 Legal status in Australia

- It is legal to possess e-cigarettes without nicotine.
- No e-cigarettes have been approved by the TGA as therapeutic products.
- Nicotine for non-therapeutic use is classified as a Schedule 7 dangerous poison and it is an offence to use or possess nicotine without an authority.[†]
- Nicotine e-liquid for inhalation for therapeutic use is classified as a Schedule 4 prescription medicine.[†]
- Laws on use in smoke-free areas, marketing and display and sales to minors vary between jurisdictions.

There are two legal pathways for using nicotine e-liquid to quit smoking, both requiring a prescription from a medical practitioner

- Patients can import 3 months' supply of nicotine at a time from overseas for a therapeutic purpose, such as quitting smoking.[‡]
- Some Australian compounding pharmacies prepare nicotine-based, e-liquid solutions.[§]

[†]Poisons Standard July 2016. [‡]TGA Personal Importation Scheme, www.tga.gov.au/personal-importation-scheme [§]Therapeutic Goods Regulation 1990.

with people suffering from smoking-related diseases. Many patients will have tried to quit with approved therapies yet have failed repeatedly. Physicians have an ethical obligation to explore all strategies to improve health and switching to an e-cigarette is now a legitimate, evidence-based option for reducing harm.

Suggested guidelines for counselling patients on e-cigarettes are listed in Table 1.²⁷

Patients should also be advised about the legal pathways for using e-cigarettes (Table 2).

Conclusion

Electronic cigarettes are a valid alternative for smokers who have been unable to quit using the available first-line therapies. Evidence for effectiveness is growing and the scientific consensus is that they are substantially less harmful than smoking. Although more research is needed, there is now sufficient empirical evidence and real-world experience to consider their use as a legitimate tobacco harm reduction tool.

Practice points

- E-cigarettes are battery-powered devices that heat a liquid solution into an aerosol for inhalation and simulate the act of smoking.
- E-cigarettes are used almost exclusively by smokers to quit smoking or reduce the harm from tobacco.
- There is growing evidence for the effectiveness of e-cigarettes as a quitting aid from population studies, longitudinal studies and randomised controlled trials.

- The scientific consensus is that e-cigarettes are substantially less harmful than smoking.
- Almost all the harm from smoking is from the tar, carbon monoxide and other toxic chemicals caused by burning tobacco.
- These harmful and potentially harmful chemicals are mostly absent from, or present in substantially lower amounts in, e-cigarette vapour.
- While young people may experiment with e-cigarettes, regular sustained use by never-smokers is very rare and there is very little evidence in support of their role as a gateway product to smoking.

- E-cigarettes have a role in physician practice for smokers who are unable or unwilling to quit smoking with approved therapies.
- There is now sufficient empirical evidence and real-world experience to support their use as a legitimate tobacco harm reduction tool.

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