



# Electronic Cigarettes



Electronic cigarettes produce a vapour typically containing nicotine, which users inhale. There is debate about their potential role in tobacco smoking reduction and cessation. This POSTnote summarises the evidence on the safety and quality of electronic cigarettes, explores some of the social issues raised and reviews current UK and EU regulation.

## Nicotine containing products

There are over 100,000 smoking-related deaths per year in the UK (see Box 1 for recent trends). The value of the health gains associated with a single successful quit attempt is £74,000.<sup>1</sup> One public health strategy to reduce or stop smoking is to encourage the use of medically-licensed nicotine-containing products (NCPs), such as patches and gum.<sup>2</sup> Nicotine is the addictive substance in tobacco but in its pure form is much less harmful than tobacco. The chance of quitting smoking is tripled with NCP use plus behavioural support, though new evidence suggests that using NCPs without support may not help smoking cessation.<sup>3</sup> As a new product containing nicotine, e-cigarettes have the potential to be used as a smoking cessation tool.

## Electronic cigarettes

E-cigarettes produce a vapour containing nicotine which users inhale. They have three components:

- a battery-powered heating element
- a cartridge (disposable, replaceable or refillable) containing a solution with or without nicotine (nicotine content typically up to 36mg/ml). The solution also contains propylene glycol or glycerine and water, additives and flavourings
- an atomiser that when heated, vapourises the cartridge contents.

## Overview

- Electronic cigarettes produce a vapour typically containing nicotine that users inhale.
- An estimated 1.3m people in the UK use e-cigarettes.
- These products have the potential to reduce smoking-related disease and death, but concerns remain about their safety and quality, their marketing, the involvement of tobacco industry, impact on smoke-free legislation, and whether the products will re-normalise tobacco smoking.
- Regulatory options include a complete ban of e-cigarettes, regulating them as a tobacco or consumer product or medical regulation.
- The EU has produced draft legislation to regulate them as consumer products with certain restrictions.

## Box 1. UK Smoking Statistics and Public Health

The number of smokers has declined in recent decades. Currently:

- About 10m adults smoke tobacco; two-thirds started before age 18.
- 22% of men and 19% of women smoke. In 1970, 55% of male adults over 16 years old smoked.
- 9% of individuals from 'higher professional households' smoke tobacco, compared to 31% from 'routine occupation households'
- 25% of 11-15 year olds smoke, compared to 53% in 1982.
- 200,000 children start smoking every year. By age 15, 11% of children in England smoke at least one cigarette per week.
- Tobacco smoking accounts for over four-fifths of lung cancer deaths, over one-quarter of cancer deaths, and about one-seventh of cardiovascular disease deaths. Action on Smoking and Health (ASH) estimates that smoking costs the NHS £2.7-5.2bn a year.

Measures to reduce smoking include public education about the health risks, increasing taxation, and banning advertising and smoking in public places. The Treasury earned £12.1bn from tobacco duties in the 2011-2012 financial year (including VAT). Taxation accounts for 77% of the cost of a packet of cigarettes.

Flavourings such as tobacco, fruit, menthol, chocolate and coffee are seen as potentially appealing to users. Innovation is fast, with hundreds of manufacturers and considerable product diversity. E-cigarettes differ widely but this POSTnote considers three characteristics of e-cigarettes: effectiveness at nicotine delivery, resemblance to tobacco cigarettes and the potential to customise (Box 2).

**Box 2. Types of Electronic Cigarette**

- **Cig-a-Likes** (first generation products) resemble tobacco cigarettes. They generally deliver low concentrations of nicotine to the user (though nicotine delivery efficiency is improving). They can be disposable. Availability is widespread. Retailers display the products either on tobacco counters or with pharmacy products.
- **Bespoke products** (second or third generation products) do not look like tobacco cigarettes. Some can be personalised by mixing components, allowing user control of battery size, nicotine concentration and flavour. They are a niche market often used by experienced vapers, purchased online or in specialised shops.

**Current usage**

Usage of e-cigarettes ('vaping') is widespread in the UK:<sup>4</sup>

- an estimated 1.3m people use e-cigarettes
- 35% of tobacco smokers have tried an e-cigarette and 11% currently use them
- use is confined almost entirely to current or ex-smokers
- among children, e-cigarette use appears confined to older children and those who have already used tobacco
- 30-38% of those who try e-cigarettes use them again, but only 14% become daily users.

Awareness of e-cigarettes is highest among younger white smokers with higher incomes and there is no gender difference. Less data are available on how e-cigarettes are used (quitting or partial substitution) and duration of use.

**E-cigarette market**

Predictions for the growth of the e-cigarette market vary. Some estimate that e-cigarettes could overtake tobacco sales in a decade, while others consider that regulation, consistency of product and user experience will all limit their use. The tobacco industry has joined the market recently, with some larger companies acquiring e-cigarette companies. Some stakeholders are concerned about tobacco industry involvement in the e-cigarette market, because the tobacco industry has no public health incentive. Others have suggested that this could lead to the tobacco industry moving from tobacco to e-cigarettes.

**Impact on consumers****Benefits to consumers**

In surveys, users report the following perceived benefits:

- less coughing and breathing difficulties compared with smoking tobacco
- providing a sensory experience similar to smoking
- control of nicotine intake
- an aid for smoking reduction and cessation.

Such surveys can include bias since participants are often self-selected.

Other benefits include cost (they are cheaper than tobacco products) and rapid delivery of nicotine to the user (users report a stronger 'nicotine hit' compared with other NCPs). Preliminary evidence also suggests that addictiveness to e-cigarettes is perceived by users as less than that for smoking tobacco. However, consumers have reported mouth and throat irritation caused by propylene glycol.

**Quality and safety**

There is debate on the approach to take to the health risks of e-cigarettes. Some argue for a strict precautionary approach. Others claim that safety concerns should be considered relative to significant health risks from tobacco.

*Technical safety*

Early studies have reported flaws in e-cigarette labelling and design, such as leaking nicotine solution and a lack of information and warnings on liquid content. They have also raised concerns over the poor shelf life of some cartridges. Recent studies suggest improved manufacturing standards (especially by larger companies), but there is a huge diversity of products on the market and so far no evidence to suggest that quality is consistently high across all products.

*Long-term health effects*

Limited data from animal studies suggest that significant adverse effects from nicotine or propylene glycol inhalation are unlikely in humans, but it is too early to be sure. The consensus is that any long-term effects are likely to be much safer than tobacco smoking, which causes cancer and other diseases.

*Cartridge and nicotine content*

Product analysis shows that nicotine content varies across and, in some cases, within brands. Nicotine levels in liquids often do not correspond to those in the vapour and brands differ in efficiency and consistency of nicotine vapourisation. Recent studies suggest improvements in the accuracy of nicotine content labelling.

Reports on cartridge content suggest they may contain low levels of heavy metals, nicotine-related impurities, and some potentially cancer causing substances such as nitrosamines. Levels are significantly (9-450 times) lower than those of tobacco products and are thought to be unlikely to pose a health risk. However, variation between some products makes it hard to generalise. Vapour composition (which differs from the liquid in the cartridge and is much more important in terms of toxicity studies) is less well researched since it is more difficult to study. The health implications of inhaling some of the flavourings and other impurities are uncertain.

**Delivery of nicotine to the user**

The way in which individuals use e-cigarettes (the duration and strength of suction) varies, directly affecting nicotine delivery and consumption. Moreover, some e-cigarettes are less efficient in delivering nicotine to the user. Overall, e-cigarettes typically deliver lower levels of nicotine than tobacco cigarettes.

**Effectiveness as a smoking cessation tool**

The number of people using e-cigarettes in their last quit attempt surpassed those using over-the-counter NCPs, at just over 30%. Evidence for the effectiveness of e-cigarettes as a quit aid is limited. It has been assessed in clinical trials and user surveys (see Box 3).

**Box 3. The Value of E-Cigarettes as a Smoking Cessation Aid**

Examining the role of e-cigarettes in smoking cessation is an active area of research. However, at the time of writing, data are limited.

**Clinical/public health studies**

The two small randomised controlled trials conducted so far suggest that e-cigarettes might be comparable to nicotine patches as a smoking cessation tool:

- participants were not using tobacco after six months when they used e-cigarettes containing 16mg nicotine (7.3%), a nicotine patch (5.8%), and an e-cigarette containing no nicotine (4.1%)
- participants were not using tobacco after a year having used e-cigarettes with 7.2mg (13%), 4.8mg (9%), and 0mg nicotine (4%).

Some public health experts think that these results underestimate e-cigarettes' potential as a quit aid since the products used were old models inefficient at delivering nicotine. Larger trials using modern e-cigarettes would provide more statistical reliability. Other less robust trials also suggest e-cigarettes are an effective cessation aid, even for dual users (who use tobacco and e-cigarettes) and tobacco users otherwise not intending to quit.

**User surveys**

Surveys that rely on self-reporting tend to over-estimate quit rates. Even so, they suggest a role for e-cigarettes in reducing cravings, and for tobacco smoking reduction and cessation:

- One survey reported 92% of smokers saying that e-cigarettes helped them to reduce their smoking.
- Another survey showed 74% of smokers reported not smoking for at least a few weeks since starting e-cigarettes. 14% said e-cigarettes dramatically reduced their cigarette consumption.

**Wider social impacts**

Public health professionals, medical associations and charities seek to de-normalise smoking. Some are concerned that e-cigarettes may reverse this trend and act as a 'gateway' to smoking by attracting non-smokers (especially children) to tobacco. Others are concerned that smokers who might otherwise have quit will instead either become permanent vapers addicted to the nicotine in e-cigarettes, or use them as well as tobacco. Suggested factors that could encourage this include:

- the sale, advertising, marketing and promotion of e-cigarettes, especially to young audiences, including the glamorisation of e-cigarettes by celebrity endorsements
- flavoured e-cigarettes that may appeal to children, for example, bubble gum, fruit and chocolate flavours
- vaping in public places.

Industry stakeholders, some scientists involved in e-cigarette research and some public health experts suggest that there is little evidence of re-normalisation or a gateway effect. For instance:

- there is no evidence of regular use of e-cigarettes in children who have never smoked before
- e-cigarette use by adolescents and young adults is increasing but levels are still low and mostly restricted to current smokers
- evidence suggests that e-cigarettes do not stop people trying to quit nicotine or tobacco<sup>5</sup>
- there has been a small but significant increase in tobacco quit rates in England.

Moreover, some stakeholders speculate that e-cigarettes could replace smoking. Some also argue that even if people do get addicted to the nicotine in e-cigarettes this nicotine

addiction is a moral problem rather than a public health problem. This is because nicotine poses a much lower health risk to the user than tobacco. They suggest that from a public health perspective it would be preferable for children who would otherwise experiment with and become addicted to tobacco to use e-cigarettes instead. They note that the bespoke e-cigarettes do not resemble tobacco cigarettes, and thus further de-normalise tobacco smoking.

**Regulation and regulatory issues**

Possible regulatory responses to e-cigarettes are banning them, or regulating them as consumer products, as tobacco products, as medicines, or a combination of these.

**National regulation**

E-cigarettes are regulated in the UK under various EU Directives and national Acts relating to general product safety. They do not incur tobacco-specific taxes. The Trading Standards Institute has produced guidance to highlight the key relevant legislative Directives. The industry is self-regulated by the Electronic Cigarette Industry Trade Association (ECITA). Members are audited to monitor compliance with legislation. Remedial action is taken for non-compliance.

The Department of Health (DH) has stated that UK regulation of e-cigarettes will now be developed in line with European requirements (see below). DH intends to ban sales to under 18s shortly. E-cigarettes will be considered consumer products unless companies choose to license them with the Medicines and Healthcare Products Regulatory Agency (MHRA) as medicinal products. This would enable them to make specific health claims, such as smoking reduction and cessation claims (as with other NCPs). Currently, two companies have products going through this regulatory process. MHRA regulation is supported by stakeholders such as Action on Smoking and Health (ASH), the British Medical Association (BMA), the Royal College of Physicians, GlaxoSmithKline, Johnson and Johnson, and some public health experts. Arguments include that regulation would:

- allow health professionals to recommend e-cigarettes in line with NICE guidance for licensed NCPs
- allow health professionals to prescribe e-cigarettes (free prescriptions are of benefit to poorer smokers)
- help promote access to other smoking cessation tools, such as NHS support, which have been shown to be beneficial for patients trying to quit
- ensure minimum standards of safety, quality and performance and allow reporting of adverse events
- provide a regulatory 'level playing field' for all NCPs.

Other public health experts argue that e-cigarettes should not be regulated as medicines, but rather, should be on a level playing field with tobacco. They state that medical licensing would inhibit product development, increase costs and help to maintain the market monopoly of tobacco products, which would be damaging for public health. Another argument is that e-cigarettes are recreational consumer products and not medicines.

## European regulation

The European Commission is updating the Tobacco Products Directive and draft legislation on e-cigarettes was agreed in December 2013. Following formal acceptance by member states and consideration by the European Parliament it is likely to become law in Spring 2014. Member states will have two years to transpose it into national law. The draft Directive (Box 4) states that e-cigarettes should be regulated as consumer products. Member states reserve the right to regulate them as medicines. Manufacturers wishing to make health claims will have to submit their products for licensing procedures that apply to medicines and medical devices. The permissibility of flavours, age restrictions and smoke-free legislation will be regulated domestically.

Leading researchers have written to the EU Health Commissioner challenging how the scientific evidence has been used to inform the draft Directive.

## International regulation

International regulation of e-cigarettes varies. Brazil, Egypt, Australia, New Zealand, Canada, and Singapore have all banned or regulated the sale, import, or marketing of e-cigarettes. The US Food and Drug Administration (FDA) and some European regulators (Germany, Hungary, Estonia, and the Netherlands) have failed in attempts to regulate e-cigarettes as medicines/medical devices for legal reasons. The FDA has subsequently taken steps to regulate e-cigarettes as a tobacco product.

## Regulatory issues

### *Using e-cigarettes in enclosed public places*

E-cigarettes are not covered by UK smoke-free law but several councils, schools and businesses (pubs, restaurants and train companies) have banned them. Reasons cited include intrusiveness and difficulties with enforcement (a blanket ban is easier to enforce than permitting e-cigarettes only). Stakeholders support bans on several public health grounds:

- **Safety:** The BMA and WHO<sup>6</sup> argue that although there is no evidence of immediate health risks, the long term impacts of secondary vaping are uncertain. However, other experts are concerned that discouraging vaping in the home may result in smokers using tobacco instead, possibly around children.
- **Delaying tobacco smoking cessation:** Vaping enables tobacco smokers to 'smoke' in smoke-free environments. Some organisations are concerned that this will delay or prevent cessation in smokers who might otherwise quit. However, there is no evidence for this at the current time.
- **Normalisation:** The BMA, Public Health Wales and WHO argue that vaping in public places threatens the established practice of smoke-free public places, re-normalising smoking. In response, industry and others such as ASH argue that vaping in public places will positively discriminate between e-cigarettes and tobacco products and encourage recognition of the benefit in transfer from one to another.

ASH and other experts are also concerned that if vapers are

## Box 4. Draft regulations proposed by Tobacco Products Directive

Draft guidance for e-cigarettes not regulated as a medicine requires:

- notification when an e-cigarette is intended to be placed on the market
- mandatory safety and quality standards for nicotine content, ingredients and devices as well as refill mechanisms
- importers and manufacturers to bear full responsibility for quality
- the maximum concentration of nicotine in liquids to be 20mg/ml
- products to deliver nicotine consistently
- obligatory consumer information leaflets
- restrictions on radio, online, print and television advertising
- adverse effects of e-cigarettes to be monitored. Immediate action is permitted at a domestic level if there is evidence of harm.

outside with smokers, this would increase the likelihood of vapers returning to tobacco products.

### *E-cigarette marketing*

The Advertising Standards Authority (ASA) does not permit broadcast advertising of products resembling cigarettes. In non-broadcast media, images of products are currently permitted and commonplace. Many companies promote products by using images of young, attractive men and women, celebrity endorsements, through social networking sites, sports sponsorship and by offering loyalty cards and discounts.<sup>7</sup> The ASA banned a television advert because of its potential appeal to children and is investigating others. Adverts cannot make smoking cessation claims unless the product is licensed by the MHRA for that purpose, but often highlight other benefits as:

- a healthier and cheaper alternative to tobacco products
- useful to get around smoke-free legislation
- unlike other NCPs, they can replicate the act of smoking.

There is some evidence that smokers are receptive to e-cigarette advertising and report an intention to try the product after viewing an advert.<sup>8</sup> The ASA will consult on specific rules for e-cigarettes for implementation later in 2014. The consultation will examine the protection of children, the indirect promotion of tobacco products and the acceptability of health claims. Most stakeholders support limitations on advertising and some have called for restrictions in terms of age and target audiences. In fact, some public health experts speculate that any advertising undermines previous efforts to ban smoking adverts.<sup>9</sup> Others are concerned that overly strict advertising controls will have negative public health implications.

### Endnotes

- 1 Impact assessment – unlicensed nicotine containing products, MHRA
- 2 Tobacco: harm reduction approaches to smoking, NICE, June 2013
- 3 Kotz et al. Real-world effectiveness of smoking cessation treatments: a population study. *Addiction* 2013 Dec 20. doi: 10.1111/add.12429.
- 4 ASH briefing on electronic cigarettes, January 2014
- 5 Etter & Bullen. A longitudinal study of electronic cigarette users. *Addictive Behaviours* Vol 39 Issue 2 491-494, 2014
- 6 Background Paper on E-cigarettes, Center for Tobacco Control Research and Education University of California, San Francisco. WHO Collaborating Center on Tobacco Control, 2013
- 7 The Marketing of Electronic Cigarettes in the UK. Commissioned by Cancer Research UK, De Andrade et al, 2013
- 8 Kim et al Adult smokers' receptivity to a television advert for electronic nicotine delivery systems (2013), Tobacco Control, Online first
- 9 Tobacco Harm Reduction and Nicotine Containing Products, Research Policy and Policy Directions, Cancer Research UK, May 2013.