

Electronic cigarettes

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Summary

- Nicotine containing products (NCPs) such as e-cigarettes are evolving and there is increasing evidence to suggest that some if not all products provide effective nicotine delivery.
- There is little real-world evidence of harm from e-cigarettes to date, especially in comparison to smoking.
- E-cigarettes are used by both smokers and ex-smokers, but there is little evidence of use by those who have never smoked or by children.
- ASH supports regulation to ensure the safety and reliability of e-cigarettes but, in the absence of harm to bystanders, does not consider it appropriate to include e-cigarettes under smokefree regulations.
- ASH supports regulation to ensure that e-cigarettes are safe, and effective.

ASH welcomes the guidance by the National Institute for Health and Clinical Excellence (NICE) on harm reduction, which supports the use of licensed nicotine products as an aid to cutting down or quitting smoking and as a substitute for smoking.

Electronic cigarettes currently are regulated as general consumer products. Once the EU Tobacco Products Directive (TPD) comes into effect in Member States in mid-2016, electronic cigarettes containing up to 20 mg/ml of nicotine will come under the TPD. Above that level, or if manufacturers and importers decide to opt in they will come under medicines regulation.¹

Nicotine Substitution

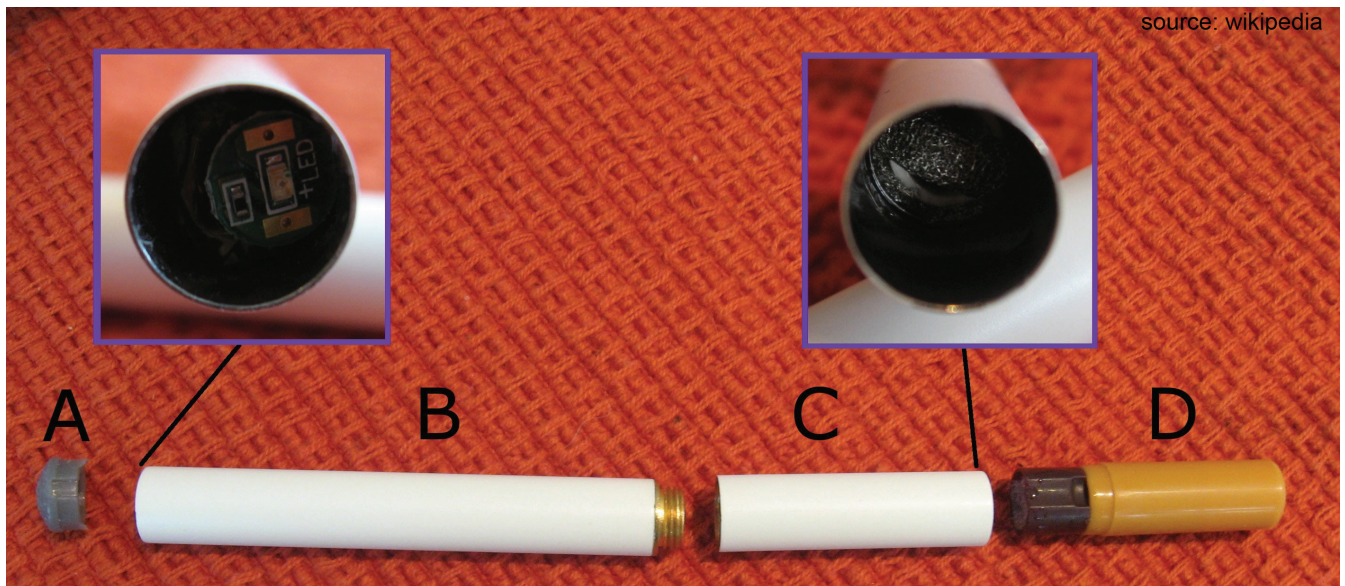
Smoking is the largest, preventable cause of premature mortality in the UK. The goal of public health is to diminish the harm caused by tobacco products. While the ideal remains that people should stop using tobacco completely and permanently, consensus currently supports a properly regulated harm reduction approach^{2,3,4} – a framework by which the harmful effects of smoking are reduced without requiring the elimination of a behaviour that is not necessarily condoned. Such strategies have proved successful in the past, for example within the contexts of needle exchange programmes for illicit drug use and the promotion of safer sex to prevent HIV infection.^{5,6}

In 1976 Professor Michael Russell wrote: “People smoke for nicotine but they die from the tar.”⁷ Indeed, the harm from smoking is caused primarily through the toxins produced by the burning of tobacco. By contrast, non-burnt pure nicotine products, although addictive, are considerably less harmful. Electronic cigarettes consequently represent a safer alternative to cigarettes for smokers who are unable or unwilling to stop using nicotine.

The National Institute for Health and Care Excellence (NICE) has developed guidance on a harm reduction approach to smoking.⁸ NICE’s recommendations aim to inform on how best to reduce illness and deaths attributable to smoking through a harm reduction approach. As part of this guidance, NICE supports the use of licensed nicotine containing products (NCPs) to help smokers cut down, for temporary abstinence and as a substitute for smoking, possibly indefinitely.

What are electronic cigarettes?

Electronic cigarettes, also known as electronic nicotine delivery systems (ENDS),⁹ are often designed to look and feel like cigarettes. They have been marketed as cheaper and healthier alternatives to cigarettes and for use in places where smoking is not permitted since they do not produce smoke.



A. LED light cover | B. battery (also houses circuitry) | C. atomizer (heating element) | D. cartridge (mouthpiece)

A typical e-cigarette consists of three main components: a battery, an atomiser and a cartridge containing nicotine. Most replaceable cartridges contain nicotine suspended in propylene glycol or glycerine and water. The level of nicotine in the cartridges may vary and some also contain flavourings.¹⁰ Some electronic cigarettes also have an indicator light at the end that glows when the user draws on the device to resemble a lit cigarette. When a user sucks on the device, a sensor detects air flow and heats the liquid in the cartridge so that it evaporates. The vapour delivers the nicotine to the user. There is no side-stream smoke but some nicotine vapour is released into the air as the smoker exhales.

Are electronic cigarettes safe to use?

A draft review by the WHO's Tobacco Regulatory Group in 2009 notes that the extent of nicotine uptake and the safety of electronic cigarettes have yet to be fully established.⁹ Certainly, in the absence of thorough clinical evaluation and long term population level surveillance absolute safety of such products cannot be guaranteed. By comparison, the harm from tobacco smoking – the leading cause of preventable death in the UK – is well established.

Most of the safety concerns regarding electronic cigarettes relate to the absence of appropriate product regulation and inconsistencies in quality control. The current lack of any authoritative oversight (although the MHRA is in the process of developing guidelines, see section on regulation) means that there is significant variability in device effectiveness, nicotine delivery and cartridge nicotine content both between and sometimes within product brands.¹⁰

Furthermore, a recent study by the US Food and Drug Administration (FDA) has raised some safety concerns over the presence of toxins, released in low concentrations, from the vaporisation process of certain cartridges.¹¹ However, one study showed that after switching from tobacco to electronic cigarettes nicotine exposure was unchanged while exposure to selected toxicants was substantially reduced.¹²

There is little evidence of harmful effects from repeated exposure to propylene glycol, the chemical in which nicotine is suspended.^{13,14} One study concludes that electronic cigarettes have a low toxicity profile, are well tolerated, and are associated with only mild adverse effects.¹⁵

Is there a risk to non-users from e-cigarette vapour?

Although electronic cigarettes do not produce smoke, users exhale a smoke-like vapour which consists largely of water. Any health risks of secondhand exposure to propylene glycol vapour are likely to be limited to irritation of the throat. One study exposed animals to propylene glycol for 12 to 18 months at doses 50 to 700 times the level the animal could absorb through inhalation. Compared to animals living in normal room atmosphere, no localised or generalised irritation was found and kidney, liver, spleen and bone marrow were all found to be normal.¹²

The fact that electronic cigarettes look similar to conventional cigarettes has been said to risk confusion as to their use in public places, such as on public transport.^{16,17} However, given that the most distinctive feature of cigarette smoking is the smell of the smoke, which travels rapidly, and that this is absent from electronic cigarette use, it is not clear how any such confusion would be sustained.

Furthermore, the absence of risk from “secondhand” inhalation of vapour from electronic cigarettes has been described as an “often unconsidered advantage” of electronic cigarettes.¹⁸ As an alternative to smoking, electronic cigarettes are preferable in situations where secondhand smoke poses serious health risks to others, such as in vehicles or in the home.

Are electronic cigarettes effective?

The degree of effectiveness depends on what effect is being measured. Public health professionals may be most concerned about their effectiveness in smoking cessation. There are four benefits most widely perceived by smokers: these are the degree to which they satisfy the desire to smoke (60% of smokers), help to cut down cigarettes (55%), help quit entirely (51%) and eradicate the smell of stale smoke (51%).^{19,20} Effectiveness also varies between products and between users according to their experience in use.²¹

Currently in the UK, any nicotine-containing product which claims or implies that it can treat nicotine addiction is considered to be a medicinal product and is therefore subject to regulation by the MHRA. Consequently, e-cigarette manufacturers have avoided making such explicit claims. Furthermore, the WHO has stated that “the electronic cigarette is not a proven nicotine replacement therapy”.²²

Nevertheless, survey data suggests that about 4 in 10¹⁹ users do use them in an attempt to quit smoking and internet searches for the devices now exceed those for any other smoking cessation or nicotine replacement product.²³ There is some evidence to suggest that e-cigarette use leads to abstinence among some smokers who had not intended to quit.²⁴

Empirical data on the effectiveness of e-cigarettes as a stop-smoking aid is limited and the risks and benefits are still being studied. Some reports from the published literature suggest that electronic cigarettes are inefficient nicotine delivery devices and result in only modest and unreliable increases in plasma nicotine levels.²⁵

Such findings appear to apply particularly to new users whereas studies using participants experienced in electronic cigarette use have been found to derive more reliable nicotine

intake levels.¹⁴ Whether experienced users are able to use these devices in a way in which their nicotine intake is maximised, or the variability is down to such users preferring certain devices which might significantly differ from those used by inexperienced users, is yet to be determined.^{25,26}

Nevertheless, growing evidence suggests that electronic cigarettes are becoming more reliable in their nicotine delivery and that they have a beneficial impact in reducing subjective cravings and, in turn, number of cigarettes smoked.¹⁵ Moreover, some studies have demonstrated an ability for certain brands of electronic cigarettes to reduce subjective nicotine cravings despite delivering low plasma nicotine levels.²⁸

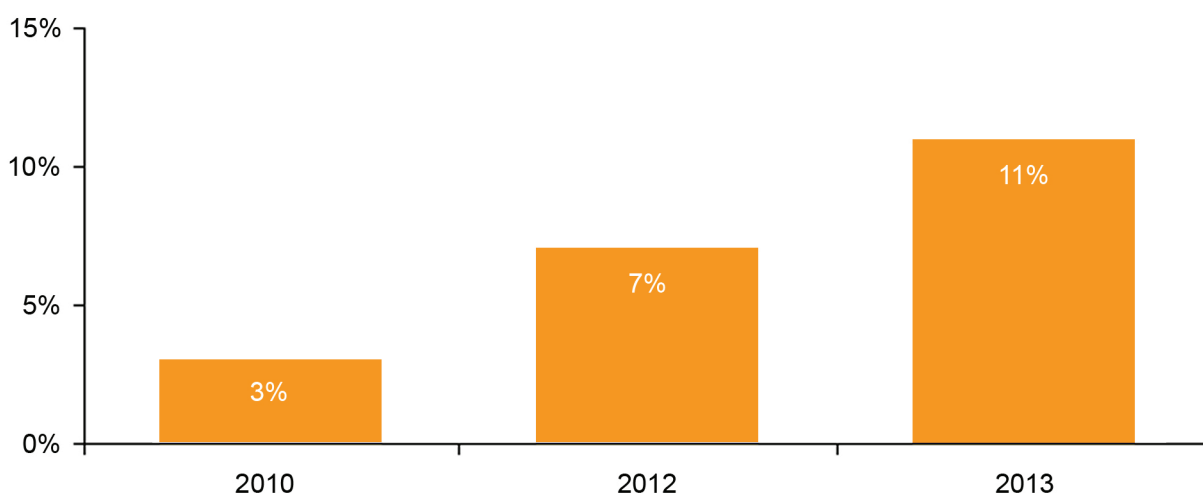
Another feature of electronic cigarettes that apparently lends to their effectiveness is an ability to satisfy the “hand to mouth” behavioural component that is not sufficiently addressed in most nicotine replacement therapies. This has been demonstrated by users exhibiting reduced cravings, withdrawal symptoms and number of cigarettes smoked per day even when given a placebo electronic cigarette.¹⁵

The potential value, and perceived effectiveness, of electronic cigarettes in aiding smoking cessation has been assessed in user surveys. Caution must be exercised with this data as the sample was recruited from e-cigarette users’ websites. However, one such survey conducted internationally reported that 72% of users believed that electronic cigarettes were beneficial in reducing cravings and withdrawal symptoms while 92% declared that the devices had reduced the number of conventional cigarettes they smoked. Indeed, in the same survey, 96% of former smokers claimed that electronic cigarettes had helped them quit, and 79% reported a fear that if they stopped using them they would start smoking again.¹⁰

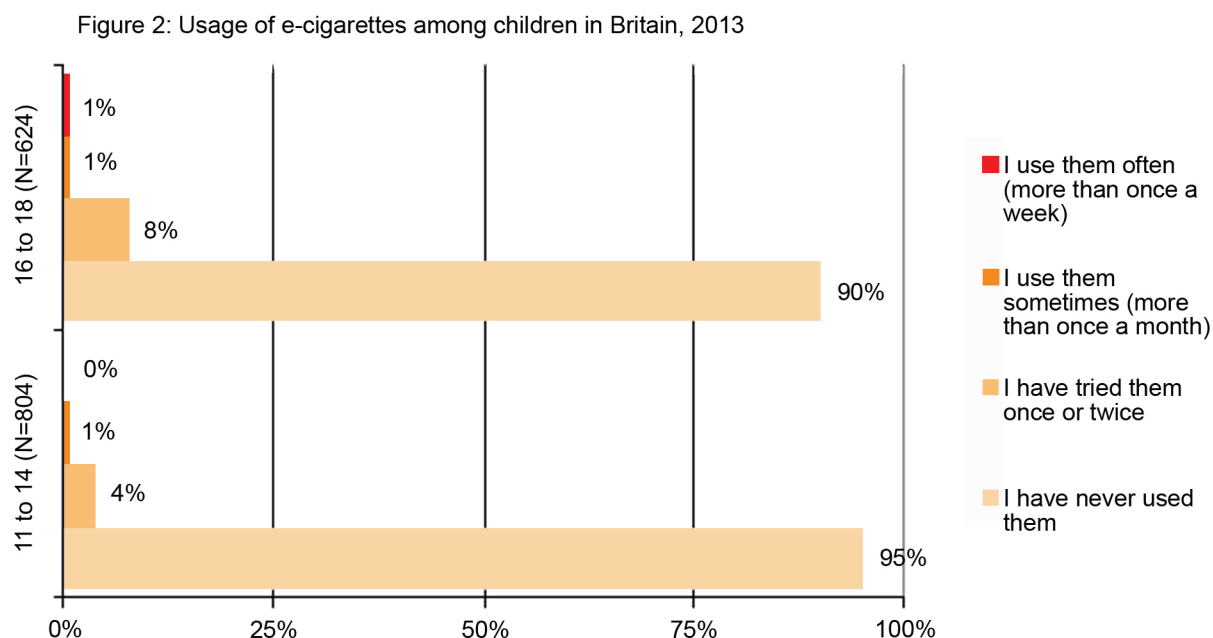
Who uses electronic cigarettes in the UK?

Public awareness of electronic cigarettes has grown substantially in recent years with online media playing an integral role in the growing popularity of the product. Between the years 2009 and 2011 searches via the search engine Google using the terms ‘electronic cigarette’ increased by fifty fold,²⁹ a fact the industry has attempted to capitalise on by funding various online adverts, web-pages and social networking site groups.³⁰ In addition to the influence of online media, there is also evidence to suggest that tighter tobacco control measures are also positively driving e-cigarette behaviour.³¹

Figure 1: Usage of e-cigarettes amongst adult smokers in Britain



According to a survey commissioned by ASH, 3% of smokers reported using e-cigarettes in 2010, a figure that increased to 7% in 2012 and 11% in 2013 (see figure 1). Similarly, the number of people reporting having tried electronic cigarettes has increased significantly, more than doubling from 9% in 2010 to 22% in 2012 and 35% in 2013. Among children, current electronic cigarette use is confined to those who have already tried smoking.^{32,33} (see figure 2)



ASH estimates that there are 1.3 million current users of electronic cigarettes in the UK. This number is almost entirely made of current and ex-smokers; with perhaps as many as 400,000 people having replaced smoking with electronic cigarette use. There is little evidence to suggest that anything more than a negligible number of non-smokers regularly use the product.^{31,34}

For further information see ASH Factsheet: [Use of electronic cigarettes in Great Britain among adults and young people](#) (pdf)

Regulation

In February 2014 the EU Tobacco Products Directive was passed by the European Parliament. Electronic cigarettes containing up to 20 mg/ml come under the TPD. Above that level, or where medicinal claims are made they come under medicines regulation.¹

Once the TPD comes into force, which is expected to be in May 2014, Member States will have two years to transpose the new rules into national law. Until then electronic cigarettes not licenced as medicines will continue to be subject to general consumer protection law and it is the responsibility of trading standards officers to rule on their safety.

Core requirements set out in the TPD are as follows:

- A limit on nicotine strength of 20mg/ml (vaper websites say this is the strength usually found suitable by average smokers³⁶)
- A size limit for e-liquids of 10 ml for dedicated refill containers and 2 ml for e-cigarette cartridges and tanks.

- Safety mechanisms (such as childproof fastening and opening) for e-liquid containers, cartridges and tanks.
- Warnings on the two largest surfaces of the packs and any outside packaging covering 30% of the external area. These must state either 'This product contains nicotine which is a highly addictive substance' or the above plus 'It is not recommended for use by non-smokers'.
- Consumer information must also include instructions on use, information on addictiveness and toxicity, a list of all ingredients and information on nicotine content along with a prohibition on promotional materials on packs.
- Manufacturers and importers bear full responsibility for the quality and safety of their product and must notify detailed information about their products to competent authorities in each Member State.
- Prohibition on cross-border advertising promotion and sponsorship in line with that for tobacco products
- Member States will be able to introduce extra safeguards for example on age-limits and flavourings in electronic cigarettes.

The MHRA has said that it “continues to encourage companies to voluntarily submit medicines licence applications for electronic cigarettes and other NCPs as medicines”.³⁷ ASH supports this recommendation. In the UK medicines regulation has some advantages for electronic cigarette manufacturers and importers over regulation under the TPD. For example as licensed nicotine products:

- Only 5% VAT is levied compared to 20% for consumer products.
- Products could be made available on prescription.
- Advertising, promotion and sponsorship is allowed.
- Limits of 20 mg/ml on strength, 10 ml on size of refill containers and 2 ml on cartridges or tanks would not be mandatory.
- Products would be widely available.

Following a referral from the Department of Health, NICE published guidance on tobacco harm reduction on 5th June 2013.⁸ This guidance recommended the use of licensed NCPs, which are nicotine replacement therapy products licensed by the MHRA (and do not at the current time include electronic cigarettes) for harm reduction purposes. Such purposes include using licensed NCPs as a substitute for tobacco, possibly indefinitely, to cut down prior to quitting, to smoke less, or to temporarily abstain from smoking.

Currently, electronic cigarettes are not regulated under smokefree law in the UK. In general, users are free to use them in most public places such as bars, restaurants and on public transport, although the managers of some premises have prohibited their use.

An oft quoted advantage of smokefree legislation is that it de-normalises smoking, effectively distancing the behaviour from what is an accepted social norm. The ban on smoking in public places has reinforced in many people's minds that such behaviour has gone from a normal, widely accepted activity to one that is abnormal and unacceptable. There are concerns that e-cigarettes will undermine this process, threatening the now established practice of smokefree public places, such as at work or on public transport. However to date there is little evidence to suggest this is the case.

Conclusion

ASH recognises that whilst efforts to help people stop smoking should remain a priority, many people either do not wish to stop smoking or find it very hard to do so. For this group, nicotine substitution products which have been properly regulated to ensure product safety, quality and efficacy should be made available as an alternative to tobacco. Most of the diseases associated with smoking are caused by inhaling smoke which contains thousands of toxic chemicals. By contrast, nicotine is relatively safe.

Electronic cigarettes, which deliver nicotine without the harmful toxins found in tobacco smoke, are likely to be a safer alternative to smoking. In addition, electronic cigarettes reduce secondhand smoke exposure in places where smoking is allowed since they do not produce smoke. Nonetheless, nicotine is an addictive substance, electronic cigarettes currently available are of highly variable safety and efficacy, and smokers are uncertain about the effectiveness of the product.

In the UK smokefree legislation exists to protect the public from the demonstrable harms of secondhand smoke. ASH does not consider it appropriate for electronic cigarettes to be subject to this legislation.

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Adults:	Children:
March 2010: 2,297 adult smokers	March 2013: 2,178 children aged 11-18
March 2012: 12,436 adults	
February 2013: 12,170 adults	

Surveys were conducted online and results weighted to reflect the British population, as appropriate.
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