



Key points:

- evidence on the safety of e-cigarettes is limited. Whilst unlikely that long-term use of e-cigarettes is as harmful as smoking, documented inconsistencies in product contents and labelling are of concern
- evidence on the efficacy of e-cigarettes as cessation/nicotine maintenance devices is also limited, but anecdotal report and initial published data shows some promise
- the UK Department of Health has recommended a review of current regulations
- the World Health Organisation concluded, in a March 2010 report¹, that 'the safety and extent of nicotine uptake from ENDS (electronic nicotine delivery systems) products have not been established'; 'scientific evidences sufficient to establish their actual nicotine dosing capabilities, their efficacy as smoking cessation aids and safety of use is not yet available'; and 'there is concern that nicotine delivery to the lung might result in stronger toxicological, physiological and addictive effects, and this concern must be addressed in scientific studies.'

What is an e-cigarette?

The electronic cigarette or e-cigarette is a battery operated, nicotine vapour inhaler device. Although the e-cigarette is designed to resemble a traditional cigarette it does not contain tobacco. A typical electronic cigarette contains a nicotine cartridge, a vaporiser, with electronic circuitry and sensors and a battery.

Depending on the brand a cartridge may contain between 0-16mg of nicotine². The cartridge may contain additional chemicals, including propylene glycol, water and various flavourings³. On inhalation the cartridge is heated and a fine mist containing approximately 20 ingredients is produced⁴. This mist is absorbed into the lungs⁵, although some odourless vapour is released into the air as the smoker exhales⁶.

There is anecdotal evidence from communities of e-cigarette users⁷ that some individuals find the e-cigarette to be a satisfactory alternative to continued smoking. This is highly plausible as such devices mimic the behavioural aspects of smoking (e.g. holding a device in the hand, having control over dosage, inhalation of vapour into the respiratory system) as well as delivering the pharmacological effects of nicotine. A recent publication⁸ of the results of an internet survey of e-cigarette users echoes this observation, with respondents reporting that the positive outcomes from e-cigarette use included their usefulness to quit smoking, though this was from a small, self-

selecting population. It is possible that there are unsatisfied users of e-cigarettes whose anecdotes have not been publicised as widely however. As a relatively new product on the market (and one that is under constant product development and evolution), to date there is only limited published scientific evidence on both the safety of such devices and their efficacy as a cessation aid, and the little that exists may not be generalisable to all products currently on the market (particularly recent generations of e-cigarettes).

Development of the e-cigarette

The electronic cigarette was developed in China in 2004 by Beijing SBT Ruyan Technologies and Development⁹. Although around four manufacturers now exist in China, Ruyan is the main manufacturer¹⁰ and reported more than 1 billion yuan in domestic sales in 2006¹¹. At present electronic cigarettes are sold in over 25 countries around the world¹².

In the UK the product began to gain popularity in 2007 and 2008¹³, following the introduction of smoke-free legislation. One company has estimated current sales of '10,000 electronic cigarette kits per month and around 250,000 nicotine cartridges'¹⁴.

Scientific evidence on the e-cigarette

There is a lack of published scientific evidence on e-cigarettes:

- there is no evidence regarding the health effects of long term use¹⁵ though it is almost certainly many times less hazardous than continued smoking
- the World Health Organisation (WHO) has stated that the electronic cigarette is not a proven nicotine replacement therapy; WHO has 'no scientific evidence to confirm the product's safety and efficacy' and has called for marketers to conduct clinical studies and toxicity analyses¹⁶
- a Ruyan commissioned safety report concluded that their e-cigarette is safe, relative to cigarettes, and contained only trace levels of tobacco smoke toxicants¹⁷
- however, tests of two brands by the Food and Drug Administration (FDA) in the United States revealed trace levels of several toxic chemicals and inconsistent quality control processes¹⁸
- tests carried out by manufacturer NJOY in response to the FDA study found no evidence of carcinogenic tobacco-specific N-nitrosamines in the aerosol from NJOY electronic cigarettes¹⁹
- Greek research institute Demokritos found no evidence of polycyclic aromatic hydrocarbons in its toxicological analyses on electronic cigarettes²⁰
- one independent clinical trial by the National Cancer Institute (NCI) and the National Institute on Drug Abuse (NIDA) evaluating the acute effects of electronic cigarettes has been completed (November 2009)²¹
- e-cigarettes suppressed cravings less effectively than cigarettes and failed to increase nicotine levels significantly in tests carried out as part of this trial²²

- however, a further trial²³ found that a Ruyan brand e-cigarette containing nicotine alleviated the desire to smoke as well as a conventional Nicorette nicotine inhalator, performed significantly better than a placebo e-cigarette, and was rated more pleasant to use than the inhalator
- higher vacuums may be required to smoke e-cigarettes²⁴ and as aerosol density tends to drop after the first ten puffs, still stronger suction is required thereafter. Although it is too early to know exactly what effect stronger inhaling and diminishing amounts of aerosol will have on human health, these factors may lead to compensatory smoking, as has been seen previously with 'light' tobacco cigarettes
- a clinical trial²⁵ found that 'in spite of delivering no measurable nicotine, both electronic cigarettes tested in this study reduced ratings of "craving a cigarette" and "urge to smoke" and increased subjective ratings of product acceptability (e.g. "satisfying," "taste good," "pleasant"). These results are consistent with anecdotal reports from long-term electronic cigarette users and support the notion that electronic cigarettes may provide an alternative, perhaps a substitute, to cigarette smoking in some cases.'

Regulatory issues

Electronic cigarettes have been problematic to regulate; they do not comfortably fit into current legislation for several reasons:

- e-cigarettes are not tobacco products and therefore are not regulated by Tobacco Product Regulations
- although they both contain nicotine the electronic cigarette is not automatically subject to the same regulations as nicotine replacement therapies.

Several nations have opted to ban the sale and importation of electronic cigarettes outright; these include Thailand²⁶. Others nations have opted to classify electronic cigarettes as medicinal products and regulate accordingly; these include Denmark²⁷. The European Commission has reviewed electronic cigarettes and EC legislation and suggested that whether electronic cigarettes are a medical device depends on the 'claimed intended use and whether this intended use has a medical purpose or not'²⁸. National authorities should decide the status of each product on a case-by-case basis²⁹.

UK regulations

The tobacco control strategy introduced in February 2010 by the previous Westminster Government suggests that all products which contain nicotine should be regulated under medicines safety legislation³⁰. The Medicines and Healthcare products Regulatory Agency (MHRA) had a consultation on the issue of nicotine-containing product regulation which closed in May 2010³¹. Responses were invited on proposals to regulate all nicotine-containing products as medicines by function, rather than by claim, therefore e-cigarettes

and other nicotine-containing products would be regulated in the same way as existing pharmaceutical nicotine products. The conclusions and results of the consultation have yet to be announced.

Within the UK the electronic cigarette is currently regulated under two different schemes:

- medicines and medical devices are regulated by the MHRA; electronic cigarettes which market themselves as smoking cessation devices (explicitly or implicitly) must be approved by the MHRA³².
- no marketing authorisation has been granted to an e-cigarette to date³³
- products which market themselves as alternatives to cigarettes are not currently subject to regulation by the MHRA; these devices may instead be regulated by trading standards bodies
- the safety of e-cigarettes marketed as tobacco alternatives is currently controlled by general product safety legislation and the Chemicals (Hazard Information & Packaging for Supply) Regulations 2002 (CHIP). These require electronic cigarettes to be supplied with child-resistant packaging and toxic warning labels³⁴
- LACORS (the Local Authorities Coordinators of Regulatory Services) has carried out testing on several brands of electronic cigarette. All have failed to comply with the requirements of the Chemicals (Hazard Information & Packaging for Supply) Regulations 2002 (CHIP)³⁵
- tests carried out by Highland Council Trading Standards Officers in 2008 led to the withdrawal from sale of an electronic cigarette brand in Inverness³⁶.

The Department of Health is working with LACORS and local authorities to ensure compliance with current regulations. It is hoped that bringing all electronic cigarettes into regulation under the MHRA will ensure products are of the requisite quality, efficacy and safety to eliminate or reduce the harm from smoking³⁷.

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