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Electronic cigarettes, smoking and population health

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Tobacco smoking is addictive and causes more death and disability in the UK, and contributes more to social inequality in health, than any other avoidable cause. One in five adults in the UK, or about 10 million people, still smoke, and half of these will die prematurely as a consequence of their smoking. However, experience of this burden of disease is becoming rare among those in higher managerial and professional occupations, of whom only one-in-ten smoke.[1] In contrast, one in three people in routine and manual occupations are smokers,[1] as are more than half of the unemployed, over 40% of people with longstanding mental health problems,[2] and more than 70% of people who are homeless or imprisoned.[2] Consequently, death and disability from smoking is now the domain of the most disadvantaged, dispossessed, marginalised and mentally ill in society. It is Britain's silent, biggest and increasingly unseen killer.

Millions of these deaths can be prevented by motivating smokers to try to quit through population measures such as tobacco price increases, media campaigns and smoke-free policies, and encouraging those who attempt to quit to maximise their chance of success by using medical services offering nicotine or other pharmacotherapy in conjunction with behavioural support.[3,4] However, less than 10% of smokers who try to quit actually use these services, as most try without any help at all; these people are around three times less likely to succeed as a consequence.[5] A complementary approach, promoted by the Royal College of Physicians (RCP) in 2007, is to encourage smokers who are not otherwise ready or able to quit smoking to substitute cigarettes with alternative, but safer, forms of nicotine, available as a simple consumer choice at the point of sale.[6] At the time of the 2007 report the available product options comprised of smokeless tobacco, the least hazardous forms of which are illegal in the UK,[6] and conventional nicotine replacement therapy (NRT) products, which have limited appeal to many smokers.[6] Electronic cigarettes (e-cigarettes), which appeared in the UK at around the time the 2007 report was published, have transformed this market, and are now providing clear proof of the concept that, if offered attractive, socially acceptable and affordable alternatives to tobacco, large numbers of smokers will use them. By the end of May 2014 over 15% of smokers in England had tried electronic cigarettes, and one in ten, or about 1 million people in the UK, were using them daily.[7] There are now more smokers who want to quit using e-cigarettes than conventional NRT, and they tend to use e-cigarettes as a partial, and in some cases then a complete, substitute for tobacco.[7] While it is not clear how high the prevalence of electronic cigarette use will rise, this transformation in the way that nicotine is used in UK society offers vast potential to improve public health. Almost inevitably, that potential health benefit is accompanied by potential threats.

Several other countries have also seen rapid growth of electronic cigarette use, including the USA where the market has recently been estimated to be worth $1.85 billion per year.[8] The first e-cigarettes were produced in China, to largely unknown standards of purity and delivery, and probably delivered nicotine with a pharmacokinetic profile similar to a conventional NRT inhalator.[9] However, their distinguishing characteristic was that their appearance and use resembles that of tobacco smoking, and also that they acquired an image as an unconventional, non-medical and socially acceptable alternative to smoking. Subsequent innovations have generated products that no longer directly resemble a cigarette, and may have improved nicotine purity and delivery, though quality and performance data remain scarce. This lack of information on quality, the lack of controls on marketing and use, their rapid uptake in society and the growing involvement of the transnational tobacco companies in this market have caused considerable concern, particularly in the health professions, about the place of these products in public health. Rather than discuss these and many other concerns in individual detail we have attempted to summarise them, with a response or counter-argument, in Table 1. Collectively, however, they fall into three domains:

- the ethics of sustaining a theoretically avoidable addiction in society
- the regulatory approach (if any) needed to protect against market abuses or avoidable adverse effects
- the engagement of the tobacco industry in a product that could both threaten, or be manipulated to protect, their core business of selling tobacco.

While there are many who are concerned that e-cigarettes provide a means by which existing smokers might continue their nicotine use, and new users may become hooked into a lifetime dependence on nicotine, this argument is countered by

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Table 1. Arguments and counter-arguments on risks of electronic cigarettes.

Risk or concern	Benefit or counter-argument
Smokers who switch to e-cigarettes remain addicted to, and continue to use, nicotine.	Nicotine addiction is, of itself, a relatively minor health risk: nicotine is not a carcinogen, and long-term use has no major adverse effect.[15]
Long-term health effects are currently unknown; in particular, use of inhaled nicotine, propylene glycol or other vapour constituents may cause lung damage or other adverse effects.	Among users who were former smokers, any hazard is negligible in relation to smoking. Risks can be minimised by improved product regulation and post-marketing surveillance.
Dual use – perpetuation of smoking by using e-cigarettes when smoking not allowed or acceptable, rather than quitting smoking completely.	Has not been a problem with conventional NRT; no evidence to date that electronic cigarette availability has reduced quitting.[7] Use of NRT as a means to cut down or for temporary abstinence increases the likelihood of a subsequent quit attempt.[16]
Use of e-cigarettes in places where smoking is currently prohibited will 'renormalise' smoking.	Use in these settings normalises electronic cigarette use, not smoking.
E-cigarettes are similar in appearance to cigarettes and makes smoke-free policies difficult to enforce.	E-cigarettes may look like cigarettes but they are also visually easily distinguishable, and the appearance and smell of tobacco smoke is very different from electronic cigarette vapour. It is therefore easy to distinguish these products and hence to enforce smoke-free policy.
Use of e-cigarettes indoors pollutes the environment and may harm others.	This is a valid concern, but is preventable in most settings by requesting users to respect others' right to a clean atmosphere, or prohibiting electronic cigarette use if necessary (unless there are overriding reasons to allow it).[17] Product licensing may reduce levels of pollutants in vapour.
Promotion to, and use by, young people could result in nicotine addiction among young people.	The government is legislating to prohibit sale to people aged under 18 years. Medicines licensing would require pre-screening of advertising for licensed products to prevent direct targeting of children, while EU regulation will prohibit most advertising of unlicensed products. Nicotine addiction itself is not, however, a serious health hazard unless addiction leads to tobacco smoking (see below). Use by young people as a substitute for smoking would be positive for individual and public health.
May provide a 'gateway' progression to smoking, particularly among young people.	This would cause significant harm to any individual involved, and if common would cause significant public health harm. However, experimenters with e-cigarettes are likely to arise from the population of young people who currently experiment with nicotine from tobacco (over 40% by the age of 25 years in 2012, with 23% being regular smokers).[1] Unless e-cigarettes entice the 59% who do not currently experiment with nicotine to do so, and causes more of them to become smokers than they prevent those who would currently become smokers from doing so, e-cigarettes will reduce rather than increase smoking uptake.
Electronic components may be unsafe.	This can be resolved through improved product standards regulation.
There is potential for overdose of stock solutions, particularly for children.	Avoidable by requiring child-resistant packaging
Companies marketing e-cigarettes have a financial interest in promoting widespread use through low prices, easy availability, advertising and building social acceptance of use.	Low prices, easy availability, advertising and social acceptability generate a population reach far greater than that achieved by medical services and hence reduces smoking prevalence.
Smokers who attempt to quit using e-cigarettes without support from NHS Stop Smoking Services (SSS)[3,4] may be less likely to quit successfully than if they had accessed SSS.	The same concern applies to over-the-counter nicotine replacement therapy (NRT), which is less effective than NRT used with behavioural support. This can be reduced by printing Quitline number on packets, providing information on stopping smoking in pack inserts or other health promotion media, and by encouraging SSS to integrate e-cigarettes to complement or substitute conventional NRT.
Tobacco companies will circumvent the tobacco advertising ban by using e-cigarettes that look like cigarettes in paid-for advertising, product placement and sponsorship to promote smoking.	Advertising that encourages smokers to switch to e-cigarettes is good for health. Advertising that promotes uptake among non-users would be prevented for licensed products by pre-authorisation, while most advertising of unlicensed products will be prohibited under the EU Tobacco Products Directive (2014/40/EU).[18]

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Table 1. ***(Continued)***

Risk or concern	Benefit or counter-argument
> The tobacco industry may use e-cigarettes to circumvent restrictions on involvement in health policy and practice under the terms of the WHO Framework Convention on Tobacco Control.	> This can be prevented under the terms of guidance on implementing Article 5.3 of the Convention.[19]
> There may be a 'design to fail' strategy by tobacco companies seeking to minimise the threat of e-cigarettes to the core business of selling tobacco.	> The electronic cigarette market currently includes many independent businesses with a commercial incentive for their products to succeed.
> There may be distaste and distrust arising from low ethics and integrity of the tobacco industry.	> From past experience this is justified, but if a product is beneficial to health it should be used irrespective of who profits from it.
> E-cigarettes are currently unregulated.	> E-cigarettes are regulated under general product sales laws, which can be adapted to deal with specific problems. Manufacturers can, however, apply for a medicines license from the UK MHRA; unlicensed products will soon be subject to tighter regulation under the new EU Tobacco Products Directive.[18]

EU = European Union; MHRA = Medicines and Healthcare Products Regulatory Agency; NHS = National Health Service; NRT = nicotine replacement therapy; SSS = Stop Smoking Services; WHO = World Health Organisation.

the fact that, at present, this same process occurs with tobacco, and kills. Smokers smoke for nicotine but are killed by smoke,[10] and despite uncertainty over the potential hazard to health from the nicotine vapour produced by e-cigarettes, any such hazard is evidently minimal in relation to that arising from inhaling tobacco smoke. Therefore, ethical considerations of perpetuating nicotine addiction need to be balanced against those of denying addicts access to an effective yet much less hazardous alternative. They also apply, but have neither been expressed nor emerged as a problem with conventional NRT. As for young people becoming addicted to nicotine – in the UK in 2012, over 40% of people aged 25 years or under have been, and nearly one in four are still, regular smokers.[1] Any moral risk of uptake of e-cigarette use needs to be contextualised in relation to the likely alternative, which is that significant numbers of users would otherwise take up smoking. While not without risk, long-term use of nicotine from e-cigarettes is likely to have even less impact on health and life expectancy that that of low-nitrosamine smokeless tobacco.[11] While the ideal outcome for society might be to end all nicotine use, the reality is that for as long as people smoke, it is unethical, illogical, paternalist and damaging to both individual and public health to deny access to reduced-hazard products such as e-cigarettes.

The second area of controversy relates to how e-cigarettes should be regulated to maximise their health potential to individuals and society, while minimising risks. Electronic cigarettes are currently marketed in the UK under general product safety regulations which do not impose specific standards of purity or efficacy, and control advertising through voluntary codes of practice.[12] These codes of practice are now being reviewed,[13] but at the moment deal with breaches reactively, in response to complaints, rather than proactively, through pre-screening. Proponents of this approach maintain that it minimises regulatory barriers and costs to product development and innovation, and that freedom to advertise maximises exposure across the smoking population. Opponents hold that general product regulation does not ensure that products deliver nicotine reliably, or without unnecessary and potentially hazardous components or contaminants, and allows inappropriate marketing, for example to children or to non-smoking adults. To address these concerns the UK Medicines and Healthcare Products Regulatory Agency (MHRA) announced in 2013 that from 2016 e-cigarettes and other nicotine-containing products would be subject to medicines regulation, thus requiring manufacture to medicinal purity and delivery standards, and proactive controls on advertising.[12] However, in February 2014 the European Parliament moved to end marketing under general product safety regulations from 2017, when a new Tobacco Product Directive (TPD) will, among other things:

- prohibit most advertising of unlicensed nicotine devices
- require products to carry health warnings
- meet, as yet undefined, purity and emissions standards
- require data on nicotine uptake
- limit nicotine content
- require suppliers to take full responsibility for quality and safety when used 'under normal or reasonably foreseeable conditions'.[13]

In practice, this means that from 2017 at the latest, suppliers will have a choice between opting for the probably lower manufacturing costs but greater marketing restrictions imposed by the TPD, or accepting the higher manufacturing costs of MHRA standards but be able to advertise, qualify for 5% (instead of 20%) sales tax in the UK, and be prescribed by health professionals. It remains to be seen which proves more popular.

The involvement of the tobacco industry in the e-cigarette market is perhaps the factor that has caused greatest distaste and concern among health professionals. Long recognised as a pariah industry, their involvement in a product that provides a potential route out of smoking challenges much conventional wisdom that the tobacco industry has no part to play in the solution to the problem it has created. Already British American Tobacco, through a subsidiary company, has applied for UK medicines licenses for both an electronic cigarette and a novel cigarette-like nicotine inhaler device,[14] raising the

prospect of competition between pharmaceutical and tobacco companies for a much enlarged medicinal nicotine market. Aside from worries over tobacco industry motives, including use of e-cigarettes to sustain or promote smoking, health professionals are soon likely to have to deal with the prospect of prescribing medicines made by, and hence contributing to the profits of, tobacco companies.

Electronic cigarettes thus pose many challenges to conventional thinking on the use of nicotine in society and the treatment of nicotine addiction. However, the evident popularity of these products, and the improvements that further product innovation may bring, indicate that these and other nicotine-containing devices currently in development have the potential to enhance conventional tobacco control policies and achieve significant further reductions in smoking prevalence, particularly in those sectors of society in which more conventional approaches to tobacco control have been relatively ineffective. The RCP supports improved regulation to ensure quality and safety and to protect against unscrupulous marketing, but recognises the important role that such products can play in assisting smokers to give up smoking completely. ■

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