BMA calls for stronger regulation of e-cigarettes

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A briefing from the Board of Science and the Occupational Medicine Committee

Summary

- There is emerging evidence that e-cigarettes are being used by some smokers to help cut down or quit; yet, they are subject to limited regulation, are not licensed as a medicine in the UK, and there is no peer-reviewed evidence that they are safe or effective for this purpose.
- While e-cigarettes have the potential to reduce tobacco-related harm (by helping smokers to cut down and quit), a strong regulatory framework is required for the sale and use of e-cigarettes to:
  - ensure they are safe, quality assured and effective at helping smokers to cut down or quit
  - restrict their marketing, sale and promotion so that it is only targeted at smokers as a way of cutting down and quitting, and does not appeal to non-smokers, in particular children and young people
  - prohibit their use in workplaces and public places to limit secondhand exposure to the vapour exhaled by the user, and to ensure their use does not undermine smoking prevention and cessation by reinforcing the normalcy of cigarette use.
- Health professionals should encourage their patients to use a regulated and licensed nicotine replacement therapy to help quit smoking. Where a patient is unable or unwilling to use or continue to use an approved and tested nicotine replacement therapy, health professionals may advise patients that while e-cigarettes are unregulated and their safety cannot be assured, they are likely to be a lower risk option than continuing to smoke.

Background

Electronic cigarettes (e-cigarettes), or electronic nicotine delivery systems (ENDS), have become increasingly popular since the mid-2000s with their own advocacy groups, marketing and increasing online interest.[1,2,3] The legal status of e-cigarettes varies around the world. In some countries (eg Denmark, Canada, Israel, Singapore, Australia and Uruguay) the sale, import, or marketing of e-cigarettes is either banned, regulated in various ways, or the subject of health advisories by government health organisations.[4,5] In others (eg New Zealand), e-cigarettes are regulated as medicines and can only be purchased in pharmacies.[4] The UK has few restrictions on the sale and use of e-cigarettes.

What is an e-cigarette?

E-cigarettes are battery-powered products designed to replicate smoking behaviour without the use of tobacco – some look like conventional cigarettes, while others appear more like an electronic device (see **Figure 1**).[6,7] They consist of a cartridge containing liquid nicotine, an atomiser (heating element), a rechargeable battery, and electronics.[7] They turn nicotine, flavour and other chemicals into a vapour that

is inhaled by the user.[4,6,7] The exhaled vapour can be seen, and some products have a light emitting diode (LED) at the tip that lights up when the user inhales.[8]

Figure 1

Who uses e-cigarettes?

While e-cigarettes have become increasingly popular since the mid-2000s, there are limited data on usage levels in the UK. Emerging evidence suggests that they are mainly used in attempts to quit smoking.[8,9,10,11] A 2012 Action on Smoking and Health (ASH) online survey of 10,000 adults (aged 18+) in England found that:

- one fifth of smokers had tried e-cigarettes, but only a third of those who had tried them were still using them
- one out of five users of e-cigarettes have quit smoking altogether
- four out of five e-cigarette users continue smoking, and use e-cigarettes primarily as a substitute where smoking is not allowed, and to help them quit and to cut down
- less than 1 per cent of never smokers had tried them.[9]

According to the findings of the Smoking Study Toolkit, in 2012, e-cigarettes were the most popular single type of nicotine product, with seven per cent of cigarette smokers in England also using e-cigarettes (as of October 2012).[10,11] The study has also found that:

- e-cigarette use has substituted for use of licensed nicotine products rather than growing the market

- compared to users of licensed nicotine product users, e-cigarette users are slightly less motivated to stop smoking and less likely to have tried to stop; more likely to be male, older and to be 'white collar'; and less cigarette dependent.[10,11]

E-cigarettes and harm reduction

A 2011 review of the evidence regarding the safety of e-cigarettes concluded that they are a safer alternative to tobacco cigarettes.[12] Their use has therefore been suggested as a way of reducing the harm[a] associated with smoking tobacco.[12.13] Despite this, there has been little research into the efficacy of e-cigarettes as aids to stop smoking or cutting down,[4,13] and they are subject to limited regulation in the UK (see **Box 1**).

Box 1 – e-cigarette regulation in the UK

In the UK, e-cigarettes are subject to regulation under the General Product Safety Regulations 2005, the Chemicals (Hazard Information & Packaging for Supply) Regulations 2009, and by trading standards.[4,14] There are no regulations on the sale of e-cigarettes as age restricted products, including their sale to children.[14] The UK Medicines and Healthcare products Regulatory Agency (MHRA) – which is tasked with ensuring that medicines and medical devices work and are safe – is currently considering how e-cigarettes and other nicotine containing products should be regulated. The MHRA have stated that a final decision will be made in Spring 2013, and in the interim, have committed to work with the e-cigarette industry to develop a self-regulatory code.[15]

Safety and efficacy

A 2008 review by the World Health Organization (WHO) does not exclude the possibility that the e-cigarette could be useful as a smoking cessation aid, but concluded that no rigorous, peer-reviewed studies have been conducted showing that the e-cigarette is a safe and effective nicotine replacement therapy.[16] There is evidence that e-cigarette products are highly variable in the efficacy of their vaporisation of nicotine,[b,17] and that the labelling of nicotine levels may be inconsistent and misleading.[18] An analysis of the total level of nicotine generated by e-cigarettes which vaporise nicotine effectively found that the amount inhaled from 15 puffs was lower compared with smoking a conventional cigarette.[b] In 2009, the United States Food and Drug Administration (FDA) released results of an analysis of some e-cigarette products.[18] The analysis found that the e-cigarette cartridges contained carcinogens and toxic chemicals. Analysis of two leading brands revealed:

- diethylene glycol (a toxic chemical) in one cartridge at approximately 1 per cent

[a] The National Institute for Health and Clinical Excellence (NICE) is currently developing guidance on 'Tobacco: harm reduction approaches for smoking'. The BMA supports the development of a tobacco-free harm reduction approach as a part of a structured programme leading to permanent smoking cessation, focusing on the use of licensed and regulated pure nicotine products.

[b] This study analysed sixteen e-cigarette brands (based on their popularity in the Polish, UK and US markets) – the total level of nicotine in vapor generated by 20 series of 15 puffs varied from 0.5 to 15.4 mg. Most of the analysed e-cigarettes effectively delivered nicotine during the first 150-180 puffs. On an average, 50- 60 per cent of nicotine from a cartridge was vaporised.

- tobacco-specific nitrosamines (which are human carcinogens) in half of the samples
- tobacco-specific impurities suspected of being harmful to humans (anabasine, myosmine, and ß-nicotyrine) in a majority of the samples.[18]

The tests also suggested that quality control was inconsistent or non-existent:

- cartridges with the same label emitted a markedly different amount of nicotine with each puff
- one high-nicotine cartridge delivered twice the amount of nicotine compared to a nicotine inhalation product approved by the FDA.[18]

The Trading Standards Institute and others have stated that safety concerns have come to light around some brands of e-cigarettes, including electrical safety, the need for proper labelling, and the provision of child resistant packaging.[14,19]

Promotion and sales

With the exception of statements about the product needing to be substantiated, the promotion of e-cigarettes – which includes point-of-sale displays, and advertising via television, radio, in print media and online – is not specifically controlled.[14] Their promotion ranges from being advertised as 'cigarette substitutes' and 'a healthier alternative to smoking traditional tobacco products', to evocative advertising with phrases such as 'an exceptional alternative smoking experience', 'vape with style', and 'add flavour to your lifestyle'. The advertising also frequently makes positive associations with recreational activities and can incorporate celebrity endorsements. It is worth noting that the provisions of the 2002 Tobacco Advertising and Promotion Act (TAPA) prohibit any brandsharing or connections with tobacco products.

E-cigarettes are sold online and can be bought from a variety of high street outlets, ranging from pubs, chemists and newsagents to specialist shops. The cost of using e-cigarettes is comparatively lower than using tobacco cigarettes – while the initial cost of the e-cigarette starter kits can be four or five times higher than a pack of 20 tobacco cigarettes, the ongoing costs (of cartridge refills and other components) is lower than that of purchasing tobacco cigarettes. This lower cost is commonly highlighted as a benefit to using e-cigarettes compared to smoking.

Strengthening the regulatory framework

It is clear that the existing regulatory framework is inadequate in ensuring that e-cigarettes are safe and effective as a nicotine replacement therapy. This may in turn undermine cessation attempts. To be used as part of a harm reduction approach, there is a need to strengthen the regulation of e-cigarettes to ensure they are safe, quality assured and effective at helping smokers to cut down or quit. This includes the requirement for clear unambiguous labelling and packaging that details the contents of the cartridges and the conditions for its safe use. There is also a need to restrict the marketing, sale and promotion of e-cigarettes so that it is only targeted at smokers as a way of cutting down and quitting, and does not appeal to non-smokers, in particular children and young people. Until this regulatory framework is in

place, e-cigarettes should not be considered as a smoking cessation aid or a lower risk option than continuing to smoke.

E-cigarettes in workplaces and enclosed public places

Restrictions on where e-cigarettes can be used are limited and variable in the UK – ranging from being prohibited in some restaurants and workplaces, to restrictions in controlled environments.

Stronger controls are needed on where e-cigarettes can be used in order to:

- protect others from being exposed to e-cigarette vapours. While the concentrations of the constituents of these vapours (propylene glycol, glycerine, flavouring substances, and nicotine) are lower than with smoked cigarettes, 'passive vaping' has been found to occur with the use of e-cigarettes.[20,21,22]
- ensure their use does not undermine existing restrictions on smokefree public places and workplaces, by leading people to believe it is acceptable to smoke. Of particular concern to BMA members is their use by patients, visitors and staff in hospitals and other healthcare settings. Exposure to nicotine from e-cigarettes (either directly through their use by an individual or indirectly from the vapours they produce) may adversely impact on patients, such as those with heart or circulatory conditions, and their use may also become a source of conflict between staff and patients. Similar concerns exist in other settings, such as the use of e-cigarettes on airplanes.
- ensure their use does not undermine the success of conventional tobacco control measures by reinforcing the normalcy of smoking behaviour in a way that other nicotine containing products do not.[23] This specifically relates to the way these devices commonly resemble tobacco cigarettes, in terms of appearance, nomenclature and the way they are used, as well as features such as flavouring and styling that are potentially highly attractive to children, and may include cigarette brand reinforcement.

In light of these concerns, the BMA believes the existing smokefree legislation in place in the UK should be extended to include vapour from e-cigarettes. As an interim measure, we also encourage employers to implement organisation-wide policies prohibiting the use of e-cigarettes in their workplaces.

Advice for health professionals

In light of the lack of scientific evidence about the efficacy and safety of e-cigarettes, coupled with the absence of a robust regulatory framework in the UK, health professionals should encourage their patients to use a regulated and licensed nicotine replacement therapy to help quit smoking. Where a patient is unable or unwilling to use or continue to use an approved and tested nicotine replacement therapy, health professionals may advise patients that while e-cigarettes are unregulated and their safety cannot be assured, they are likely to be a lower risk option than continuing to smoke.

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