

E-cigarettes: Balancing risks and opportunities



E-cigarettes: Balancing risks and opportunities

1 Background

Significant numbers of smokers are using e-cigarettes (electronic cigarettes),^a with many reporting that they are helpful in quitting or cutting down cigarette use. There are clear potential benefits to their use in reducing the substantial harms associated with smoking, and a growing consensus that they are significantly less harmful than tobacco use.^{1,2} With appropriate regulation, e-cigarettes have the potential to make an important contribution towards the BMA's ambition to achieve a tobacco-free society, leading to substantially reduced mortality from tobacco-related disease.

It is important, however, that in realising these benefits, any potential risks associated with e-cigarette use are minimised. These include preventing uptake and use by children and young people; ensuring their use does not promote smoking; and limiting health risks to users and bystanders. A regulatory framework for e-cigarettes should seek to minimise these risks while maximising their potential to reduce the health burden associated with smoking.

This paper aims to highlight to policymakers our members' concerns, and potential opportunities surrounding the use of e-cigarettes. It sets out what the BMA believes is an appropriate policy response, taking into account the evolving regulatory and policy environment for these devices in the UK.

1.1 E-cigarette use

E-cigarettes first went on sale in the UK in 2007, and their use increased markedly between 2011 and 2013.¹ According to the smoking toolkit study, a monthly household survey, the prevalence of e-cigarette use in the UK has remained broadly stable, at approximately 5% of the adult population since late 2013.³ This is in line with data from the ONS (Office for National Statistics) Opinions and Lifestyle Survey, which shows that 5.6% of respondents were current e-cigarette users in 2016.⁴

The use of e-cigarettes among smokers and recent ex-smokers has continued to rise slowly, and approximately 12% of people in this cohort now report daily e-cigarette use.³ Survey data from the charity ASH (Action on Smoking and Health) indicates that the vast majority of e-cigarette users in the UK are either ex-smokers or current smokers,⁵ and regular use among 'never smokers' remains very low, at less than one per cent.^{3,5} The level of e-cigarette use by children also remains low, and is discussed in more detail in **Section 2.2**.

1.2 E-cigarette regulation in the UK

When e-cigarettes first appeared in the UK there was limited specific regulation of these devices, with products falling under general product safety regulations. The BMA and a range of other organisations – including the Faculty of Public Health and the Association of Directors of Public Health – expressed concern over the variable quality and safety of e-cigarettes and e-liquids, as well as about the marketing and promotion of these devices.^{6,7,8} There are now a range of regulations governing the manufacture, sale and advertising of e-cigarettes and e-liquids, summarised in **Box 1**.

a E-cigarettes, also known as vaporisers or ENDS (electronic nicotine delivery systems), are handheld battery-operated devices which can deliver nicotine containing vapour. These devices have developed significantly over recent years, and come in a variety of forms. They generally consist of a cartridge containing liquid nicotine (or 'e-liquid'), an atomiser (heating device) and a mouthpiece. Solutions of e-liquid typically contain nicotine, propylene glycol and/or glycerol, as well as flavourings.

Box 1: Summary of key legislation/regulation for e-cigarettes

E-cigarettes and the EU (European Union)

The EU TPD (Tobacco Products Directive) came into effect in May 2016, being transposed into UK law via the Tobacco and Related Products Regulations (2016). As well as new regulations on tobacco, it introduced a new framework for e-cigarettes to be regulated as consumer products.

- E-cigarettes and e-liquids are subject to a notification scheme, for which the MHRA (Medicines and Healthcare Products Regulatory Agency) is the competent authority. This is intended to ensure standards including:⁹
 - child resistant and tamper-evident packaging
 - protection against breakage and leakage
 - banning certain ingredients (including colourings, caffeine and taurine)
 - that devices must deliver a consistent dose of nicotine under normal conditions
 - that tank and cartridge sizes must be no more than 2ml in volume and nicotine strengths of 20 mg/ml
 - product information – including health warning that product contains nicotine on front and back of packs.
- E-cigarettes and refill containers cannot be advertised:
 - on TV or on-demand TV and on radio
 - through information society services (this includes for example internet advertising and commercial e-mail)
 - in certain printed publications – newspapers, magazines, periodicals and similar publications.
- Domestic advertising (billboards, buses etc) is permitted.
- Medicinal claims are not permitted.

Domestic legislation

There has been separate legislation – outside of the TPD – introduced across the UK, aimed at regulating the sale of e-cigarettes.

- Amendment to the Children and Families Act (2014). Since October 2015 it has been illegal in England and Wales to sell e-cigarettes or e-liquids to children and young people under the age of 18. It is also illegal to purchase e-cigarettes on behalf of under 18s.
- The Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016. This introduced the following measures:
 - A ban on the sale of e-cigarettes to under 18s
 - inclusion of e-cigarettes on the Scottish Tobacco Retailer Register
 - powers for Scottish Ministers to introduce restrictions on e-cigarette advertising.

In September 2017, the Department of Health (Northern Ireland) launched a public consultation on draft regulations which will make it an offence to sell e-cigarettes to persons under the age of 18.

In March 2016, the Public Health (Wales) Bill, which would have introduced restrictions on the use of e-cigarettes in certain public places, was voted down. Provisions relating to e-cigarettes were dropped from the new Public Health (Wales) Act, which passed the National Assembly for Wales in May 2017. No other parts of the UK have brought forward legislative plans to restrict where e-cigarettes can be used.

In addition to regulation as a consumer product, a framework is also in place to allow these devices to be licensed as medicines through the MHRA (Medicines and Healthcare Products Regulatory Agency), as summarised in **Box 2**.

Box 2: Medical licensing of e-cigarettes

While the TPD introduced regulations for e-cigarettes sold as consumer products, there are separate provisions for e-cigarettes that are licensed as medicines through the MHRA. Any products licensed as medicines would:

- have to meet set standards for medicines
- be permitted to advertise within rules on ‘over the counter’ medicines
- be permitted to make medicinal claims
- not have the limitations on nicotine content set out in the TPD.

Obtaining a medicines license would enable healthcare professionals to recommend devices for use as a smoking cessation aid. It is expected that e-cigarettes that are licensed as medicines would be provided in the same way as NRT (nicotine replacement therapy), and thus be available to purchase from pharmacies or other retail outlets without a prescription. To date only one product has been approved as a medicine in the UK, with an age of sale of 18 compared to 12 for NRT. It has not yet been brought to market.¹⁰

2 Exploring the most appropriate regulatory framework for e-cigarettes

Following the emergence of e-cigarettes in the UK, BMA members highlighted a number of concerns surrounding their increasing use and the potential implications for tobacco control, including the involvement of the tobacco industry (see **Box 3**).⁶ Some of these concerns have lessened and evolved as the regulatory framework for these products has developed, and with the availability of a wider range of evidence and data. For example, though long-term inhalation of nicotine vapour is associated with some level of risk, and there continues to be debate over the precise level of this risk, several reviews have concluded that it is substantially lower than inhaling tobacco smoke.^{1,2} While NICE guidance states that smokers should always be advised that stopping smoking in one step is the best approach, it also recommends advising those who do not want, are not ready or are unable to stop smoking in one step, to consider a harm-reduction approach.¹¹ It is the tar and other toxins in tobacco smoke, rather than nicotine, that are responsible for most of the harm associated with smoking.^{1,2,11}

Box 3: E-cigarettes and the tobacco industry

Concerns have been expressed about the involvement of multinational tobacco companies in the e-cigarette market, and the potential for this to ‘renormalise’ the tobacco industry. There are particular concerns about companies positioning e-cigarettes alongside or complementing traditional cigarettes, rather than as replacements for them, and that e-cigarette marketing from tobacco companies may be intended to promote dual use rather than to support switching to less harmful products.² These concerns have been exacerbated by the recent launch, by the multinational tobacco manufacturer Philip Morris International, of a \$1 billion fund to create a “smoke-free world”. While there is no regulatory measure that can eliminate any risks of tobacco industry involvement, the measures discussed in this briefing (eg around marketing) aim to ensure their influence is restricted. These measures should be kept under review, and if necessary reinforced. It will remain vitally important to protect health policy from tobacco industry interference, and protect tobacco control from commercial interference, in line with article 5.3 of the WHO Framework Convention on Tobacco Control.¹²

Given the lower levels of harm associated with e-cigarette use, a regulatory approach should support smokers in quitting tobacco, while minimising the potential risks presented by their use. Regulation of e-cigarettes should therefore focus on three broad objectives:

- reducing tobacco-related harm;
- ensuring children and young people do not use e-cigarettes; and
- protecting bystanders.

The appropriate regulatory framework for supporting each of these objectives is discussed in more detail in the following sections.

2.1 Reducing tobacco-related harm

Key messages for policymakers:

Safety

- There is growing consensus that using an e-cigarette is significantly less harmful than smoking tobacco.
- The short-term health risks associated with e-cigarette use appear minimal, but it remains important to monitor any potential long-term health impact on users.
- While the flavourings used in e-cigarettes do not appear to have an acute impact on the health of users, it is important that any long-term assessment of e-cigarette safety includes a focus on flavouring components.

Effectiveness for smoking cessation

- E-cigarettes are the most popular device used in attempts to stop smoking.
- There is a lack of high-quality research into their effectiveness as a cessation aid, though most reported studies demonstrate a positive relationship between e-cigarette use and smoking cessation.
- As with licensed stop-smoking medication, combining e-cigarettes with cessation services that provide behavioural support is likely to be more effective than unsupported use.

Regulation

- Consumer regulations for e-cigarettes introduced as part of the TPD should be kept under review, with a view to ensuring the long-term safety of these devices and assessing the impact of these regulations on attempts to quit smoking. It is a requirement of the directive that the impact of the regulations be reviewed and reported on by 20 May 2021.

Any health gains associated with e-cigarette use arise through their potential to reduce the substantial harms associated with cigarette smoking. The extent to which they are able to reduce harm is dependent upon a range of factors, including the long-term health impact of using e-cigarettes and their effectiveness for smoking cessation. Regulation of these products should seek to ensure they are a safe and effective route out of smoking.

2.1.1 Long-term health impact of e-cigarette use

Research on the long-term impact of inhaling nicotine vapour is limited by the relatively short period of time that these products have been available. The absolute risks of e-cigarette use are therefore unknown, but nevertheless should be put in the context of the substantial harm associated with smoking. There is growing consensus that use of e-cigarettes is significantly less harmful than smoking: Unlike cigarette smoking, e-cigarette use does not involve combustion, and while some of the toxicants present in tobacco smoke have been detected in e-cigarette aerosol, they are present at levels which are much lower.¹³ A 2017 cross-sectional study indicated that former smokers who had switched to using

e-cigarettes had significantly lower levels of certain tobacco-specific toxicants in saliva and urine samples, relative to individuals smoking tobacco cigarettes.¹⁴ This was only seen in individuals that were exclusively using e-cigarettes, and not in e-cigarette users who continued to smoke tobacco. The clearest benefit to health from switching to e-cigarettes is therefore likely to be achieved among smokers who are able to entirely stop smoking conventional cigarettes.

In a 2016 consensus statement coordinated by PHE (Public Health England) a range of health organisations together stated that “*the evidence suggests that the health risks posed by e-cigarettes are relatively small by comparison*” [to smoking].¹⁵ Similarly, a 2017 consensus statement from NHS Health Scotland – endorsed by a range of health organisations – stated that e-cigarettes are “*definitely less harmful than smoking tobacco*”.¹⁶ Although there is consensus that e-cigarettes are less harmful than smoking, and that any risks associated with their use are likely to be significantly lower than tobacco, quantifying the precise level of this risk is complex. The most widely cited estimate of relative risk is from PHE’s 2015 e-cigarette evidence review – which concluded that it would be reasonable to estimate that e-cigarette use is likely to be around 95% safer than smoking.¹ This figure was endorsed by the RCP (Royal College of Physicians) in their 2016 report *Nicotine without smoke: Tobacco harm reduction*, which concluded that “*...the hazard to health arising from long-term vapour inhalation is unlikely to exceed 5% of the harm from smoking tobacco smoke*.”² It should be noted that the evidence base underpinning this figure has been questioned,^{17,18} but also that the authors of PHE’s evidence review have set out their rationale behind the estimate in response.^{19,20}

Smoking is the cause of a wide range of diseases, including lung cancer, cardiovascular disease and COPD (chronic obstructive pulmonary disease). It is likely that the reduction in risk from switching to e-cigarettes will be different for different diseases. Some concerns have, for example, been expressed about the potential impact of nicotine containing e-cigarettes on cardiovascular health,²¹ though observational data indicates that the use of NRT is not associated with any increase in the risk of myocardial infarction, stroke, or death.²² It is important that future research includes a focus on understanding the specific impact of e-cigarette use on the range of diseases associated with tobacco use.

Box 4: E-cigarette flavourings

Specific concerns have been expressed about the safety of particular components used as e-cigarette flavourings.²³ Many flavourings used in e-liquids are ‘food safe’, being considered safe when ingested orally, but their safety after heating and inhalation is not established.²⁴ It has been suggested that the concentrations of some flavouring compounds in e-liquids are sufficiently high for inhalation exposure by vaping to be of concern to health,²⁴ although – as highlighted by the RCP – no studies have yet demonstrated any clear hazard of e-cigarette vapour.² While this is not evidence of an absence of harm, given the large numbers of people using flavoured e-liquids without reporting problems, it is unlikely they are having a significant acute impact on the health of users. Research assessing the long-term health impact of e-cigarette use should, however, include a focus on assessing the potential health impact of the range of flavourings used in e-liquids.

2.1.2 Effectiveness of e-cigarettes for smoking cessation

Significant numbers of smokers are now using e-cigarettes in attempts to stop smoking. The most recent data from the smoking toolkit study indicates that 34% of people trying to stop smoking use an e-cigarette,³ and e-cigarettes are the most popular device used in attempts to quit smoking.³ In comparison, approximately 15% of smokers trying to quit reported using over the counter NRT in 2016. Evidence is continuing to emerge about the effectiveness of e-cigarettes for smoking cessation.

A 2016 systematic review concluded that while most studies demonstrate a positive relationship between the use of e-cigarettes and smoking cessation, the overall evidence remains inconclusive due to the low quality of the research published.²⁵ The review called for more research into the long-term cessation effects of e-cigarettes. Similarly, PHE's 2015 evidence review noted the lack of high quality research, but concluded on the data available that e-cigarettes can help people to quit smoking and reduce their cigarette consumption, suggesting that they potentially offer a "*wide reach, low-cost intervention to reduce smoking*".¹

Given the lack of randomised control trials,^b most evidence of their effectiveness for cessation is derived from population level studies. A large 2014 cross-sectional^c study of English smokers indicated that among those who have attempted to quit smoking without professional support, those who use e-cigarettes are more likely to report continued abstinence than those who used an over the counter NRT product or no aid to cessation.²⁶ Subsequent to PHE's evidence review, a 2016 analysis of smoking trends in the UK indicated that, on a population level, increased prevalence of e-cigarette use was positively associated with the success rate of quit attempts.²⁷ Similarly, analysis from the US has suggested that an increase in e-cigarette use was associated with increased smoking cessation rates.²⁸ Other population level studies have, however, concluded that e-cigarette use is not associated with quitting,²⁹ and one systematic review of various observational^d and clinical studies has suggested that e-cigarette use is associated with reduced likelihood of quitting smoking.³⁰ This review was limited by the difficulty in comparing the results of such a wide range of different studies, including some observational studies that only followed dual users of e-cigarettes and tobacco, and may therefore have excluded those who have successfully quit tobacco use using e-cigarettes.³¹ Overall – while there is a lack of high-quality research into their effectiveness as a cessation aid – most reported studies demonstrate a positive relationship between e-cigarette use and smoking cessation.

A 2014 population study assessing the effectiveness of a range of smoking cessation interventions indicated that those combining behavioural support and licensed medicine when attempting to quit have almost three times the odds of success than those who use neither.³² Evidence appears to favour a combination of behavioural support and prescription medication as providing the highest chance of successfully quitting tobacco use.³² Given the greater popularity of e-cigarettes as a quitting aid, it is important to ensure that those choosing to use an e-cigarette receive sufficient support in their quit attempts. It has been suggested that combining e-cigarettes with smoking cessation services may be effective for smoking cessation. Though high-quality data to support this is currently lacking, relatively high quit rates have been reported for e-cigarette users using these services.³³ Having smoking cessation services that work with e-cigarette users towards stopping smoking, through the provision of behavioural support, would ensure that smokers are able to combine the most popular approach to quitting, with the most effective.^{1,34}

b A study in which people are randomly assigned to two (or more) groups to test a specific intervention. One group (the experimental group) has the intervention being tested, the other (the comparison or control group) has an alternative intervention, a placebo or no intervention at all.

c Cross-sectional studies examine data collected from a population at a specific point in time.

d Observational studies in which individuals are observed or certain outcomes measured without intervention.

Box 5: What impact are e-cigarettes having on smoking prevalence?

Smoking prevalence has declined throughout the UK in recent years, currently 15.8% of adults smoke, compared to 20.2% in 2011.⁴ There have also been significant declines in youth smoking rates, with recent data indicating that only 7% of 15 year olds in England smoke regularly (at least once a week), compared to 8% in 2014, and 20% in 2006.³⁵ The decline in smoking prevalence has coincided with the increasing popularity of e-cigarettes and there are now 2.9 million users of e-cigarettes in the UK.⁴ While those quitting using an e-cigarette will have contributed to the decline in smoking prevalence, it is not possible to be certain of the magnitude of this contribution, and there are a number of other factors that will have also played a role. The significant decline in smoking rates amongst children, for example, has occurred despite regular use of e-cigarettes amongst children being very low. Beyond increased e-cigarette use, there have also been a range of tobacco control measures introduced over recent years that will have contributed to reductions in smoking prevalence, such as increases in taxation, and a generation of children have now grown up in smoke-free public places. The decline in smoking prevalence amongst children and young people also mirrors wider societal trends towards decreased alcohol and drug use in this age group.

2.1.3 E-cigarette product regulation that supports harm-reduction

The way in which e-cigarettes are regulated will influence their potential to reduce tobacco-related harm. All e-cigarettes presently available in the UK are regulated as consumer products, and there are now over 2.9m people using these devices. The wide availability of e-cigarettes as an alternative to tobacco is likely, overall, to be playing a positive role in supporting tobacco-harm reduction, and consumer regulations will ensure a minimum standard of product quality. Nevertheless, consumer regulated products are subject to lower safety standards than medicinal products. Furthermore, while the current consumer market overall is helping some people quit tobacco use, the extent to which individual products can be assured for efficacy in supporting smoking cessation is unclear.

The TPD introduced a range of regulations (see **Box 1** in **Section 1.2**) intended to ensure the safety of e-cigarettes and address concerns about poor product quality. Regulations included limits on tank and cartridge sizes and on nicotine strengths. Some concerns have been expressed that these regulations make e-cigarettes less appealing as a substitute for smoking, though data from ASH –from before the implementation of TPD regulations – suggested that only 6% of people using e-cigarettes were using e-liquid with a nicotine strength higher than that permitted by the TPD.⁵ Continued evaluation of these regulations is necessary to monitor product safety in the long term, and the impact they are having on supporting quit attempts. The UK's decision to exit the EU may provide more flexibility for the UK to respond to emerging evidence with regards to evaluating the legislative provisions introduced within the TPD, and ensuring they remain appropriate for achieving their objectives.

In light of the popularity of e-cigarettes regulated as consumer products as an alternative to smoking, it is unclear what role medical licensing has in the regulatory framework for these devices. Prior to the introduction of regulations contained within the TPD, the BMA supported calls for e-cigarettes to be regulated as medicines, on the grounds that this would help ensure their efficacy, quality and safety, and bring them in to line with other NRT products.⁶ However, no medically-licensed products have been brought to the market yet. It has been suggested that this is most likely because of the prohibitive costs associated with the application process and manufacturing.² There are also particular concerns that licensing and presentation as medicines may reduce the appeal of e-cigarettes to smokers.² In contrast, having some medically-licensed products available may provide an important option for some smokers, and would give health professionals confidence in the safety and efficacy of individual devices.

Given the current absence of medically-licensed products, and that nearly three million adults in the UK are using consumer-regulated e-cigarettes,⁵ doctors and other health professionals should be provided with training and information so they are able to provide general advice on the safety and efficacy of products available on general sale. This should highlight that, while there is currently a lack of long-term evidence on their benefits and harms, many smokers have found them beneficial, and that there is a growing consensus that they are significantly safer than smoking tobacco. Such advice may be of particular benefit for patients who have not succeeded with, or do not want to try, other smoking cessation methods. This is an approach supported by the RCGP (Royal College of General Practitioners), who have suggested that clinicians recommend and support the use of e-cigarettes where patients have not succeeded with other options.³⁶

2.2 Ensuring children and young people do not use e-cigarettes

Key messages for policymakers:

- Though awareness of and experimentation with e-cigarettes is increasing in the UK, few children are becoming regular users of e-cigarettes. Nearly all of those that are currently or have previously smoked.
- Current data on e-cigarette use and smoking does not support concerns that e-cigarettes will promote tobacco use among children and young people. Youth cigarette smoking has declined over the period of time that e-cigarettes have become increasingly available.
- There are now substantial restrictions on the sale, advertising and promotion of e-cigarettes. These should be kept under review to ensure they continue to provide appropriate protection for children and young people.

With the initial emergence and proliferation of e-cigarettes, concerns were expressed – including by the BMA – that they may act as an ‘entry portal’ for non-smoking children into nicotine use and addiction, and therefore act as a gateway to tobacco smoking. The WHO (World Health Organization) have also highlighted concern that the use of e-cigarettes among children and young people may promote tobacco use.³⁷ To date, however, evidence indicates that this is not occurring to any significant extent in the UK.

Among children, awareness of and experimentation with e-cigarettes is increasing,³⁸ with data from the 2016 Smokefree Youth Survey (of 11-18 year olds) indicating that 12% of respondents had tried e-cigarettes at least once, compared to less than 5% in 2013.³⁸ The 2016 survey of smoking, drinking and drug use in England indicated that 25% of 11-15 year olds had tried an e-cigarette in 2016, compared to 22% in 2014.³⁵ Though e-cigarette awareness and experimentation may be increasing, this is not leading to their regular use by non-smoking children. This remains rare: In the 2016 Smokefree Youth Survey only 2% of children said they used e-cigarettes more than once a month, and regular e-cigarette use was almost entirely confined to those children that currently or have previously smoked.³⁸ In the most recent Smoking, Drinking and Drug Use survey for England 2% of 11-15 year olds reported regular e-cigarette use.³⁵ A recent analysis of five separate surveys conducted between 2015-2017 indicated that across the UK there were consistently low levels of regular e-cigarette use among 11-16 year olds.³⁹ There is some data indicating that e-cigarette use among non-smoking adolescents is increasing in certain countries though, particularly the USA.⁴⁰ It will therefore be important to continue to monitor the situation in the UK.

It should be noted that some studies have suggested that there is an association between e-cigarette use and increased likelihood of smoking. For example, a recent study – which surveyed teenagers in the UK over a 12-month period – indicated that individuals that use e-cigarettes are more likely to also start smoking cigarettes.⁴¹ There is also some data from the USA indicating that e-cigarette use among teenagers and young people is associated

with an increased likelihood of smoking.^{42,43,44} It is not possible to conclude from these studies that e-cigarette use is causing smoking.⁴⁵ Importantly, rates of youth smoking in the UK have declined over the same period of time in which e-cigarettes have become increasingly available.⁴⁶ Overall levels of cigarette smoking among teenagers in the USA have also declined over recent years, during the same time period that e-cigarette use has increased.⁴⁷

Aspects of the regulatory approach to e-cigarettes intended to prevent uptake by children and young people include restrictions on their sale to under 18s, and on advertising and promotion. The latter prohibits the advertising or promotion of e-cigarettes:

- on TV or on-demand TV
- on radio
- online and through commercial e-mail
- in certain printed publications – newspapers, magazines, periodicals and similar publications.⁴⁸

Given that regular use of e-cigarettes amongst children and young people in the UK remains low, it is reasonable to conclude that these regulatory measures have been effective in addressing concerns around their use in this population.

Although it does not currently appear to be leading to regular use, awareness of and experimentation with e-cigarettes amongst children and young people appears to be increasing. While there are significant restrictions on advertising, it remains permitted in certain places including in cinemas and via outdoor posters, posters on the sides of buses (not travelling outside of the UK) and through leaflets and direct hard copy mail. It will be important to keep this under review to ensure the regulations continue to provide sufficient protection for children and young people, and that any remaining advertising opportunities are not used in a way that is likely to promote tobacco use among this age group. The BMA, for example, has not supported recent proposals to lift restrictions on e-cigarette advertisements making health claims,⁴⁹ because of concerns that this would allow commercial advertising without nuance, potentially promoting e-cigarettes beyond their use as a substitute for tobacco.

2.3 Protecting bystanders

Key messages for policymakers:

- Although research in this area remains limited, there is a lack of evidence that exposure to the constituents of e-cigarette vapour poses specific health risks to bystanders.
- Current data on smoking and e-cigarette use does not support concerns that e-cigarettes are re-normalising cigarette smoking or undermining compliance with smoke-free legislation.

In response to the rapid emergence of e-cigarettes, coupled with the lack of knowledge about the risk of inhaling vapour, the BMA initially supported a precautionary approach of restricting their use in all enclosed public places and workplaces. This was established principally on the basis of concerns over the need to protect bystanders.

Similar concerns have been expressed by the WHO, which has warned that exposure to e-cigarette vapour has the potential to lead to adverse health effects. They have suggested that second hand aerosol represents “...a new air contamination source for particulate matter...”,³⁷ and highlighted the potential impact of this on those with underlying respiratory conditions such as asthma.³⁷ Others have also highlighted that bystanders may be exposed to potentially harmful constituents of e-cigarette vapour, including flavourants, glycerine, propylene glycol and carbonyls (formaldehyde and acetaldehyde).^{50,51} Although research in this area remains limited, these concerns have not been supported by the evidence that has since emerged, which indicates that the level of exposure to the constituents of e-cigarette vapour for bystanders is extremely low, and does not pose specific health risks.^{1,52}

A further reason the BMA initially supported restrictions in all enclosed public places relates to concerns around the potential for the widespread use of e-cigarettes to re-normalise smoking and undermine smoke-free legislation. However, data showing that the prevalence of adult and youth smoking in the UK is declining (see **Section 2.1.2**), along with very high compliance levels with smoke-free restrictions, suggests that these concerns have not materialised.

Current evidence indicates that exposure to e-cigarette vapour does not pose specific health risks – unlike exposure to second hand smoke – and that their widespread use in public places has not had unintended consequences on re-normalising smoking or on compliance with smoke-free laws. It would therefore be reasonable to support a softer regulatory approach than exists for smoking in public. While such an approach would not restrict e-cigarette use in public places outright, it would also recognise that there are a wide range of public places (for example on public transport or in schools and nurseries) in which it would be entirely legitimate for their use to be restricted. This should be achieved through a pragmatic approach, focused on organisations developing policies for partial or comprehensive restrictions based on key factors - in practice this is already happening across the UK.⁵² It is important that this approach is monitored and evaluated in light of emerging evidence, to ensure it does not have unintended consequences and continues to support compliance with smoke-free law and policies.

3 Next steps

The BMA's ambition is to achieve a tobacco-free society, where there is significantly reduced mortality from tobacco-related diseases.⁵³ Given that e-cigarettes are now the most popular device used in attempts to quit smoking, and that many people have used them to successfully quit tobacco use, they have significant potential to support this ambition, and help reduce tobacco-related harm. The RCP have, for example, called for the use of e-cigarettes, NRT and other non-tobacco nicotine products to be promoted *"...as widely as possible, as a substitute for smoking..."*.² The RCGP have suggested that while more research is needed into the safety and efficacy of e-cigarettes, the benefits *"...in assisting cessation should not be deferred while waiting for the publication of this research."*³⁶

An important aspect of any regulatory system for e-cigarettes is to ensure that adult smokers have access to nicotine products that are less harmful than tobacco. This needs to be balanced against concerns that the use of these products might promote smoking or have harmful effects on users and bystanders. A future regulatory approach to e-cigarettes which maximises their potential for harm-reduction while minimising any risk should broadly focus on:

- 1. Ensuring products are safe and effective:** The impact of new regulations on the manufacturing, sale and advertising of e-cigarettes should be kept under review, to ensure they enable the development of devices that provide a safe and effective route out of smoking, while ensuring they do not act as a route into nicotine use and dependence. While current evidence suggests that e-cigarettes do not appear to pose specific health risks to bystanders, it is important that this continues to be evaluated over the longer-term, especially as these products rapidly evolve and evidence in this area continues to emerge.
- 2. Protecting children and young people:** The current regulatory framework appears sufficient for addressing concerns about the use of e-cigarettes by children and young people, for whom regular use remains low and is largely confined to those that have already smoked. However, given the increasing awareness and experimentation in this age group it is important that the appropriateness of these measures is subject to continued evaluation.

3.1 Research to inform future regulatory and policy approaches

It is important that regulation of e-cigarettes is underpinned by a robust evidence base. Key areas in which continued research is required to inform the future regulation of these devices include:

- **Analysis of the impact of e-cigarette use on smoking behaviours** – including their long-term effectiveness as a cessation aid and the extent to which they are acting as a route out of, or in to, smoking.
- **Assessment of the health impact of e-cigarette use** – in-particular the long-term impact on users, including the impact of different patterns of use, as well as the risks of specific flavouring components. Research into the health impact of e-cigarette use should include an exploration of the impact of switching to e-cigarette use on the range of diseases associated with long-term tobacco use, including lung cancer, cardiovascular disease and chronic lung disease.

References

- 1 McNeill A, Brose LS, Calder R et al (2015) *E-cigarettes: an evidence update*. London: Public Health England
- 2 Royal College of Physicians (2016) *Nicotine without smoke: Tobacco harm reduction*. London: Royal College of Physicians
- 3 www.smokinginengland.info/latest-statistics/
- 4 Office for National Statistics (2017) *Adult smoking habits in the UK: 2016*.
- 5 Action on Smoking and Health (2017) *Fact Sheet on the use of electronic cigarettes among adults in Great Britain*. London: Action on Smoking and Health
- 6 British Medical Association (2014) *BMA calls for strong regulation of e-cigarettes*. London: British Medical Association
- 7 Faculty of Public Health (2014) *UK Faculty of Public Health policy statement on electronic cigarettes*. London: Faculty of Public Health.
- 8 The Association of Directors of Public Health (2015) *Position statement: Nicotine vapourisers and associated products*. London: The Association of Directors of Public Health
- 9 www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-product
- 10 Medicines and Healthcare Products Regulatory Agency. Summary of public assessment report (e-Voke electronic inhaler). Available at: www.mhra.gov.uk/home/groups/par/documents/websitesresources/con616843.pdf
- 11 National Institute for Health and Care Excellence (2013) *Smoking: Harm reduction*.
- 12 World Health Organization (2008): *Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control*.
- 13 Hajek P, Etter J-F, Benowitz N et al (2014) Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction* **109** (11) 1801–1810
- 14 Shahab L, Goniewicz MJ, Blount BC et al (2017) Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study. *Annals of Internal Medicine* **166**(6):390-400
- 15 Public Health England (2016) *E-cigarettes: Developing a public health consensus*. London: Public Health England
- 16 NHS Health Scotland (2017) *Consensus statement on e-cigarettes*. Edinburgh: NHS Health Scotland
- 17 Editorial (2015) E-cigarettes: Public Health England's evidence-based confusion. *The Lancet* **386** No.9996: 829
- 18 McKee M, Capewell S (2015) Evidence about electronic cigarettes: A foundation built on rock or sand? *BMJ* **351**: h4863
- 19 Public Health England (2015) *Underpinning evidence for the estimate that e-cigarette use is around 95% safer than smoking: Authors' note*. London: Public Health England
- 20 McNeill A (2015) Evidence about e-cigarettes: They are much safer than cigarettes and do not lure children to smoking (BMJ 'Rapid Response'). *BMJ* **351**: h4863
- 21 Moheimani RS, Bhetraratana M, Yin F et al (2017) Increased cardiac sympathetic activity and oxidative stress in habitual electronic cigarette users: Implications for cardiovascular risk. *JAMA Cardiology* **2**(3):278-284
- 22 Hubbard R, Lewis S, Smith C et al (2005) Use of nicotine replacement therapy and the risk of acute myocardial infarction, stroke, and death. *Tobacco Control* **14**:416-421
- 23 Allen JG, Flanigan SS, LeBlanc M et al (2016) Flavoring Chemicals in E-Cigarettes: Diacetyl, 2,3-Pentanedione, and Acetoin in a Sample of 51 Products, Including Fruit-, Candy-, and Cocktail-Flavored E-Cigarettes. *Environmental Health Perspectives* **124** (6)
- 24 Tierney PA, Karpinski CD, Brown JE (2016) Flavour chemicals in electronic cigarette fluids. *Tobacco Control* **25** e10-e15.
- 25 Malas M, van der Tempel J, Schwartz R et al (2016) Electronic Cigarettes for Smoking Cessation: A Systematic Review. *Nicotine and Tobacco Research* **18**(10):1926-1936
- 26 Brown J, Bead E, Kotz D et al (2014) Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. *Addiction* **109**(9): 1531–1540.
- 27 Bear E, West R, Michie S et al (2016) Association between electronic cigarette use and changes in quit attempts, success of quit attempts, use of smoking cessation pharmacotherapy, and use of stop smoking services in England: time series analysis of population trends. *BMJ* **354**: i4645

- 28 Zhu S-H, Zuang Y-L, Wong S et al (2017) E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. *BMJ* **358**:j3262
- 29 Grana RA, Popoza L & Ling PM (2014) A Longitudinal Analysis of Electronic Cigarette Use and Smoking Cessation. *JAMA Internal Medicine*. **174**(5):812-813
- 30 Kalkhoran S, Glantz SA (2016) E-cigarettes and smoking cessation in real-world and clinical settings: a systematic review and meta-analysis. *The Lancet Respiratory Medicine*. 2016;4(2): 116–28. Available from doi: 10.1016/S2213-2600(15)00521-4
- 31 Hajek P, McRobbie H & Bullen C (2016) E-cigarettes and smoking cessation (correspondence). *The Lancet Respiratory Medicine* (published online 25.4.16) **4**(6) e23
- 32 Kotz D, Brown J & West R (2013) 'Real-world' effectiveness of smoking cessation treatments: A population study. *Addiction* **109**(3) 491-499
- 33 Hiscock R, Bauld, L, Arnott D et al (2015). Views from the Coalface: What Do English Stop Smoking Service Personnel Think about E-Cigarettes? *International Journal of Environmental Research and Public Health* **12**(12), 16157-16167.
- 34 McEwan A & McRobbie H (2016) *Electronic cigarettes: A briefing for stop smoking services*. London: National Centre for Smoking Cessation and Training.
- 35 NHS Digital (2017) *Smoking, Drinking and Drug Use Among Young People in England 2016*. Available at: digital.nhs.uk/catalogue/PUB30132
- 36 Royal College of General Practitioners (2017) *RCGP Position Statement on the use of non-combustible inhaled tobacco products (E-Cigarettes)*. London: Royal College of General Practitioners
- 37 WHO Framework Convention on Tobacco Control (2016) Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS): Report for FCTC/COP/7/11. Available at: www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf
- 38 Action on Smoking and Health (2016) *Use of electronic cigarettes among children in Great Britain*. London: Action on Smoking and Health
- 39 Bauld L, MacKintosh AM, Eastwood B et al (2017) Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015–2017. *International Journal of Environmental Research and Public Health* **14** 973.
- 40 Editorial (2014) High International Electronic Cigarette Use Among Never Smoker Adolescents. *Journal of Adolescent Health* **55**: 595-597
- 41 Conner M, Grogan S, Simms-Ellis R et al (2017) Do electronic cigarettes increase cigarette smoking in UK adolescents? Evidence from a 12-month prospective study. *Tobacco Control* (published online 17.08.17)
- 42 Barrington-Trimis JL, Urman R, Berhane K et al (2016) E-cigarettes and future cigarette use. *Pediatrics* (published online 13.06.17)
- 43 Primack BA, Soneji S, Stoolmiller M et al (2016) Progression to Traditional Cigarette Smoking After Electronic Cigarette Use Among US Adolescents and Young Adults. *JAMA Pediatrics* **169**(11):1018-1023.
- 44 Miech R, Patrick ME, O'Malley PM et al (2017) E-cigarette use as a predictor of cigarette smoking: results from a 1-year follow-up of a national sample of 12th grade students. *Tobacco Control*
- 45 Etter J-F (2017) Gateway effects and electronic cigarettes. *Addiction* (published online 07.08.17)
- 46 Action on Smoking and Health (2016) *Electronic cigarettes*. London: Action on Smoking and Health.
- 47 National Institute on Drug Abuse (2016) *Monitoring the future survey: Trends in prevalence of various drugs*. Available at: <https://www.drugabuse.gov/trends-statistics/monitoring-future/monitoring-future-study-trends-in-prevalence-various-drugs>
- 48 House of Commons Library (12.06.17) *Advertising of e-cigarette products*
- 49 Committee on Advertising Practice (2017) *Consultation - E-cigarettes: Health claims and public health advertisements*. London: Committee on Advertising Practice
- 50 Hajek P, Etter JF, Benowitz N et al (2014) Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction* **109**(11): 1801-1810
- 51 Goniewicz MJ, Knysak J, Garon M (2014) Levels of selected carcinogens and toxicants in vapor from electronic cigarettes. *Tobacco Control* **23**(2): 133–139.

- 52 Public Health England (2016) *Use of e-cigarettes in public places and workplaces – Advice to inform evidence-based policy making*. London: Public Health England
- 53 British Medical Association (2015) *Promoting a tobacco-free society*. London: British Medical Association.

British Medical Association

BMA House, Tavistock Square, London WC1H 9JP
bma.org.uk

© British Medical Association, 2017
BMA 20170941