

2016

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Recommended Citation

Clancy, L. & Babineau, K. (2016). E-cigarettes: Effective Cessation Tools or Public Health Threat? *QJM: An International Journal of Medicine*, vol. 109, no. 2. doi:10.1093/qjmed/hcv223

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COMMENTARY

E-cigarettes: effective cessation tools or public health threat?

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In a short time, electronic cigarettes have become a multi-billion dollar industry. Since their introduction to the market, prevalence of ever-use among smokers in the USA appears to have increased from ~2% in 2010 to >30% in 2012, and the rate of increase appears to be similar in the United Kingdom, Ireland and other Western countries according to a special Eurobarometer survey in 2014.¹ The e-cigarette market is estimated to be worth over \$3 billion. However, there is no consensus on the role of e-cigarettes and their contribution to the provision of smoking cessation (SC) services, nor to global tobacco control.

At the Conference of the Parties to the WHO Framework Convention on Tobacco Control in September 2014, the secretariat presented a report outlining the current facts concerning e-cigarettes, put forth an opinion on these devices, and offered considerations on options for regulation.² This was on the tail of two contrasting letters to Margaret Chan, Director General of the WHO, submitted by scientists from many disciplines including tobacco control, public health, epidemiology, pharmacology and the clinical sciences (Letters to Dr Chan; June 2014). One letter stated that e-cigarettes offer huge prospective gains by reducing the prevalence of cigarette smoking and subsequently, the harm done by smoking. Those in favour of this position therefore requested support for the introduction and widespread availability of e-cigarettes. The other letter cautioned restraint, citing the possible damage that e-cigarettes could have on tobacco control.

For those favouring the widespread proliferation of e-cigarettes, the main considerations appear to be the efficacy and safety of e-cigarettes with regards to SC and potential for harm reduction. For those cautioning restraint the main consideration seems to be the possible effects these products may have on broad tobacco control measures such as smoking

prevalence among children and young people, the possibility of relapse among ex-smokers, the impact on smokefree laws, the effects on advertising and sponsorship and the feared influence of the tobacco industry. Although both groups are, of course, concerned about all these issues, the discourse suggests that priorities may be somewhat different for different scientists.

So what does the evidence say? On the whole, it remains inconclusive.

With regard to the potential efficacy of e-cigarettes as a smoking cessation tool, two randomized controlled trial (RCT) studies suggest that e-cigarettes may be helpful. One study found that e-cigarettes containing nicotine are as effective as nicotine patches for smoking cessation when used as directed.³ In this study [$n=657$], one group of participants received vouchers for nicotine patches by post and were encouraged to use them, while the other groups were given e-cigarettes—one with and one without nicotine. In another RCT [$n=300$], smokers were randomized to three groups (patches, e-cigarettes with nicotine, e-cigarettes without nicotine). This study found that at 2, 4 and 12 weeks, there was a statistically significant difference between the two groups with e-cigarettes containing nicotine and the group with non-nicotine containing devices. However, there was no difference between the groups with regard to the overall reduction in the number cigarettes smoked at 24 or 52 weeks.⁴ In addition to these, there are many other small-scale trials, some of which show positive and some of which have negative results which may be considered inconclusive. These studies often address particular aspects of efficacy which are of concern (e.g. efficacy in key sub-populations), but they do not resolve the overall question of the efficacy of e-cigarettes for cessation. An interesting 'real world' study which was part of the continuing English Smoking Toolkit Study found that e-cigarette users had a better quit rate than those who used 'over

the counter' nicotine replacement products, or than those who succeeded in quitting without any form of nicotine.⁵ The survey reports high e-cigarette use among ex-smokers, which raises questions regarding the role of e-cigarettes in maintaining abstinence or as a gateway to relapse.

The approach to establishing safety has included demands for accurate information on e-cigarette contents and basic ingredients, which was initially very limited but is now increasing thanks to labelling by makers and analysis by independent scientists. However, the wide range of available devices (some estimates exceed 500 variants) reduces confidence that the contents are reliably known. For the purpose of this article, only nicotine containing devices are relevant to this discussion. Within these products, the main constituents are reported to be nicotine, propylene glycol, glycerine and flavours which of course when vaporized are released as particles of varying sizes which have not been well characterized. Particle size may be a consideration in itself, distinct from the actual composition of the particles. All of these substances have toxicity and when vaporized are inhaled into the lungs and released into the atmosphere. The relevance of animal studies showing potential toxicity from e-cigarettes are uncertain but to date, they are thought to be low.⁶ At least two human-based studies show acute but mild toxicity on lung function: one demonstrates an increase in airway resistance with active e-cigarette usage⁷ and one indicates a decrease in FEV1/FVC ratio, but only in passive exposure to e-cigarettes.⁸ It is too soon to be confident about long-term toxicity. A knowledge of the constituents indicates that the effects may not be severe, with one estimate suggesting that in comparative terms it may be as little as 5% that due to cigarette smoking.⁹ However, this estimate is based on a modelling study where the inputs for the effects of e-cigarettes are reported to be largely unknown for these relatively new devices.

The possible long-term effects on tobacco control are also largely unknown. Prevalence studies referred to earlier suggest that adolescences and young adults are using e-cigarettes in increasing numbers.¹⁰ Most studies find that young people who use e-cigarettes also use tobacco products, though there are instances where young people try e-cigarettes without having tried tobacco.¹¹ The possible gateway effect to cigarette smoking is not resolved. Studies conducted in the UK have not shown a link to date but research from the USA is starting to indicate that e-cigarettes may serve as a gateway in some circumstances.^{12, 13}

The effects that e-cigarette use may have on smokefree laws are no less complex. Many purport that the vapour released from e-cigarettes is harmless and therefore should not be banned in indoor/public places. However, the possibility that the vapour may be confused with smoke has led some authorities to ban 'vaping' where smoking is banned with the aim of ensuring continued support for Article 8 of the WHO FCTC and avoiding the confusion that e-cigarette use in public may affect attitudes and implementation of smokefree laws. Countries contemplating policies towards the tobacco 'endgame' (e.g. Ireland, Finland, Scotland, New Zealand and Singapore) are also grappling with the policy implications that e-cigarettes may have on smokefree legislation.¹⁴

Perhaps the greatest challenge that e-cigarettes may pose for tobacco control would be the actions and reactions of the tobacco industry. With the e-cigarette market, we see a revival of the difficulties that marketing, advertising, sponsorship and promotion of cigarettes posed for tobacco control and that were

subsequently reflected in WHO FCTC Article 13. Perhaps even more concerning is the threat posed by the consequences of ownership of a large and seemingly increasing proportion of the e-cigarette industry by the tobacco industry, which directly challenges implementation of WHO Article 5.3, requiring governments to refuse the tobacco industry access to policy formation in public health and is regarded among the most important of tobacco control measures. It seems possible that the proposed provisions of the Transatlantic Trade and Investment Partnership (TTIP) may also be used to threaten TC. In the European Union, multinational corporations may try to use TTIP to challenge the EU Tobacco Products Directive regulations on e-cigarettes, further muddling the already unclear circumstances surrounding the right of Member States to legislate for public health of their citizens.

Data to support or refute these growing hopes for, or concerns regarding, e-cigarettes are yet not available and will likely not become available during this rapidly evolving situation. History, however, suggests caution. Both in Europe and the USA, efforts by scientists to collaborate with the tobacco industry in the 1950s, 1960s and 1970s to find safer nicotine delivery devices had the net effect of only delaying the inevitable conclusion that the tobacco industry's aims are incompatible with public health.^{15, 16} Will history repeat itself with this new, sophisticated, less toxic device or will public health learn the lessons from history and reject the extravagant hopes placed in a technology which, at its most benign can be seen as another nicotine replacement therapy with unpredictable prospects of success?

Funding

The authors, Prof Luke Clancy and Dr Kate Babineau were employed and funded by Tobacco Free Research Institute Ireland (TFRI), Dublin.

Conflict of interest: None declared.

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