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Electronic cigarettes: an update on products, regulation, public health approaches and oral health

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Background: Electronic cigarettes remain a divisive topic amongst public health experts and researchers. The division hinges on the the role of e-cigarettes in public health, i.e., whether e-cigarettes represent a potential to compromise decades of public health efforts by driving smoking rates up, or an effective tool to drive smoking rates down. Dental settings are a strategic place for stop smoking interventions, with large proportions of the population attending regularly and harms of smoking often presenting early in the mouth. Dental professionals should be equipped with the necessary information to provide evidence-based advice and recommendations to their patients. ***Objective***: To update dental professionals and researchers on the current regulations, public health approaches, and oral health effects of prevailing novel nicotine products, with a focus on e-cigarettes. ***Methods***: Narrative literature review. ***Principle findings***: Regulatory approaches vary considerably around the world but in the UK and Europe, e-cigarettes are regulated as consumer or medicinal product, and their use is permitted. In the UK, e-cigarettes have increasingly been supported by public health institutions for smoking cessation as part of a Tobacco Harm Reduction strategy. The potential harms (including to oral health) from e-cigarette use are likely to be much less than from tobacco cigarettes.

Keywords*: Nicotine, Tobacco, Smoking, Electronic Nicotine Delivery Systems, Oral Health, Smoking Cessation*

Introduction

Electronic cigarettes (e-cigarettes) are not as new as some might think, with a patent from 1965 describing a product not too dissimilar to the modern-day phenomenon, and the term ‘vaping’ being coined in 1979. However, a Chinese inventor is generally cited as a source of the modern e-cigarette, which was introduced into the EU market in 2005/2006. Early products often had technical issues and were a niche product with relatively few users. Use grew and in 2011 surveys started to enquire about e-cigarettes. For example, in England the Smoking Toolkit Study (a survey tracking national smoking patterns and cessation-related behaviours since 2006) started collecting data on e-cigarette use (West *et al*., 2021). Daily e-cigarette use in smokers and recent ex-smokers was reported at 2% the first time it was measured (2011), rising to 15.5% in 2016 and reducing slightly to 12% in 2021.

E-cigarettes are probably the most hotly debated public health topic of the last decade. Numerous guidance documents and hundreds of scientific papers have been published, often with conflicting opinions and conclusions. In this review we aim to summarise the novel nicotine product category, reviewing the range of public health approaches employed, exploring the general and oral health evidence base and reflect on where we may be in another ten years’ time.

Products

E-cigarettes are part of a wider product category, sometimes referred to as novel nicotine products. This category also includes nicotine patches, gels, and tooth pics, but e-cigarettes are by far the biggest player. Estimates suggest that current e-cigarette use among the general adult and young populations in Europe ranges from 0.2% to 27%, being 7.4% in England (Kapan *et al*., 2020). E-cigarettes are also known as Alternative Nicotine Delivery System (ANDS) or Electronic Nicotine Delivery System (ENDS) in the scientific literature, and as Vapes or Vaporisers by retailers and users. They come in many different formats, but the basic concept is that a battery-powered device produces an aerosol that the user inhales. This aerosol is usually created by heating a liquid containing a carrier solution (propylene glycol, vegetable glycerine), nicotine and flavourings (e.g., tobacco, mint, fruit). Originally, free-base nicotine was used but then nicotine salts were utilised, providing higher nicotine delivery from a smaller volume, and allowing innovation in product design. For example, the JUUL device, which was launched in the US in 2015, uses nicotine salt, allowing a small size and an appearance similar to a USB stick. Products can be single use but are more commonly rechargeable devices in a range of shapes and sizes (Figure 1). Some designs allow the user to fill up the devices themselves whilst others use pre-filled ‘pods’. An important clarification is that e-cigarettes are not tobacco products; they do not contain tobacco. Confusingly, in some jurisdictions they

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Figure 1. E-cigarette and heated tobacco devices in a range of designs. From right, two early devices that resemble a tobacco cigarette, so called 'cigalikes'; three 'tank' device which are refillable with e-liquids and rechargeable; a much smaller device that resembles an USB drive and uses nicotine salt technology; finally, a heated tobacco product with the tobacco stick in place.

are classed as tobacco products for regulatory reasons. Advice to researchers is to describe the products as 'nicotine-containing products' because the term can be applied to both tobacco and non-tobacco products such as e-cigarettes and nicotine-replacement therapies (Munafò, 2018). Even so, there are some e-cigarettes that do not contain nicotine (Non-Nicotine Delivery Systems) and so do not fit into the broad description of 'nicotine-containing products'.

Apparently similar, but fundamentally different, is the heated tobacco product, commercially known as 'heat-not-burn' with products including 'IQOS', 'Pax' and 'Glo'. This design involves a mini-tobacco cigarette/stick, which is heated inside an electrical device to just below the temperature of combustion, reportedly exposing the user to less harmful toxicants than seen in tobacco cigarettes.

Another product worthy of discussion in a paper about tobacco harm-reduction is Swedish-style snus. Snus is a form of heat-treated and pouched smokeless tobacco (placed between the upper lip and gum) commonly used in Scandinavian countries (Sweden, Norway, Denmark), but illegal in European Union (EU) countries other than Sweden, under the Tobacco Products Directive (TPD). A review of the potential of snus as an alternative to cigarettes concluded that health risks associated with snus are considerably lower than those associated with cigarette smoking (Clarke *et al*., 2019). Sweden has the lowest rate (5%) of tobacco-related mortality and the lowest incidence of male lung cancer in Europe, and this is associated with the use of snus (Clarke *et al*., 2019). However, the rest of this review will focus on e-cigarettes.

Public Health Approaches

Public health has adopted a range of regulatory strategies to tackle tobacco smoking; the leading preventable cause of premature mortality and morbidity in the world. Initial measures recommended by the World Health Organisation (WHO) included tobacco taxation, packaging, labelling and restrictions on promotion, sponsorship, and advertisement. Public health approaches to e-cigarettes have varied wildly between accepting them as a harm-reduction tool to banning them completely. In a recent worldwide analysis, six countries do not have regulations on sales of e-cigarettes beyond age limitation, six countries prohibit sales of nicotine-containing e-cigarettes, 45 countries regulate sale or require marketing authorisation before sale, and 29 countries have banned the sale of all types of e-cigarettes (Global Tobacco Control, 2020). To illustrate different approaches, we will compare the situations in three countries.

United Kingdom

A common misperception is that e-cigarettes are not regulated in the UK. Before 2014 the regulatory status of e-cigarettes was unclear, with them generally being regarded as a consumer product. E-cigarettes are currently regulated under the Tobacco and Related Products Regulations (TRPR), which is the UK's law derived from the EU's Tobacco Products Directive (TPD); an EU directive that came into force on 19 May 2014. The TRPR regulates several aspects of the e-cigarette (Figure 2).

The UK has a history of adopting harm-reduction approaches to public health issues e.g., needle exchanges for HIV prevention in injecting drug users. A Tobacco Harm Reduction (THR) strategy is policy in the UK for four groups: those stopping smoking but using a harm-reduction product to prevent relapse, those cutting down before stopping smoking, for smoking reduction and for temporary abstinence. Traditionally, THR involves smokers obtaining their nicotine from medically licenced Nicotine Replacement Therapies (patches, gums, lozenges), but e-cigarettes have also played an increasing role in this approach. The NICE (2021) draft guidelines on 'Tobacco: preventing uptake, promoting quitting and treating dependence', include nicotine containing e-cigarettes as a stop smoking intervention for adults.

English data reported a positive association between the prevalence of e-cigarette use and the overall quit and success rates (but not with the number of quit attempts or mean cigarette consumption) (Beard *et al*., 2020).

United States

In the United States (US), when e-cigarettes first entered the market around 2005, the product was not uniquely regulated. However, the Federal Food, Drug, and Cosmetic Act 1938 (FDCA) was the active regulation for tobacco products at the time. In 2009, the Family Smoking Prevention and Tobacco Control Act 2009 (FSP&TCA) was enacted to amend the FDCA, giving the FDA authority to regulate tobacco products under the FDCA. In May 2016, the FDA enacted the 'Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act' (DTP). The FDA in the DTP clarified that the FDCA classifies any product that consists wholly or in part, tobacco or any of its derivatives as a 'Tobacco product'. Therefore, the FDA deems nicotine containing e-cigarette as a tobacco product because nicotine is a derivative of tobacco. In effect, e-cigarettes are regulated as tobacco products. The FSP&TCA regulation requires registration/ notifications, health warning labels

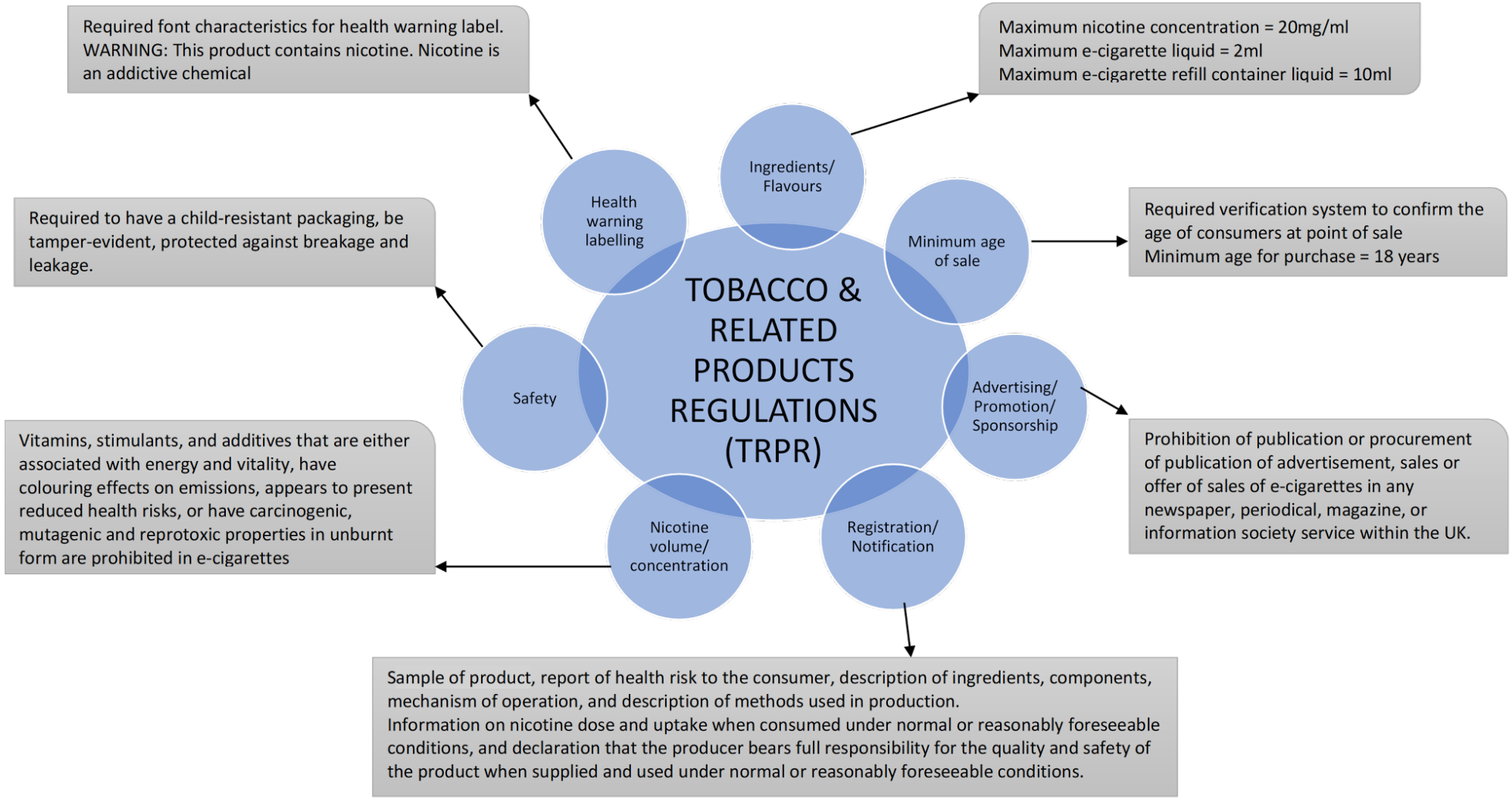

Figure 2. Summary of regulatory domains in the Tobacco and Related Products Regulations (TRPR)

and age of sale verifications. There are also other local and state government e-cigarette policies. For example, some regional, state, local governments and commonwealth territories have indoor vaping bans, and some others restrict vaping in 100% smoke-free and other venues. The US has generally focused e-cigarette regulation and policies on concerns that e-cigarettes may pose a risk to non-smoking children and young people. The US Centre for Disease Control and Prevention (CDC, 2019) regards e-cigarettes as unsafe and claims that they can harm adolescent brain development. On 29th December 2019, the US enacted the 'Tobacco 21 Act' raising the minimum age for purchase of tobacco products (including e-cigarettes) from 18 years to 21 years.

Australia

Australia has no specific regulation of e-cigarettes. Non-nicotine e-cigarettes are classified as legal consumer products, whereas those containing nicotine are inherently banned by the prohibition of sale of nicotine, though import for personal reasons is permitted under certain instances. Nicotine is classified by law in Australia as a dangerous poison. Although states and territories are responsible for regulating dangerous poisons, none permits the retail sale of nicotine-containing e-cigarettes. In most states and territories, manufacturing (including mixing), storage, labelling and packaging of dangerous poisons are prohibited. In addition, some states and territories prohibit obtaining, purchasing, possessing and/or using nicotine without a permit. E-cigarettes marketed as smoking cessation aids are treated as therapeutic goods. The importation and supply (including sale) of therapeutic goods are illegal in Australia unless authorised by the Therapeutic Goods Administration (TGA). The Australian Government has stated that 'unlike Nicotine Replacement Therapy (NRT) products, which have been rigorously assessed for efficacy and safety and, therefore, approved by the Therapeutic Goods Administration for use as aids in withdrawal from smoking, no assessment of electronic cigarettes has been undertaken and, therefore, the quality and safety of electronic cigarettes is not known.'

General Health and Epidemiology

Research and discussions of e-cigarettes and general health have focused on two main topics: the role of e-cigarettes in modifying smoking rates, and the health risk of e-cigarettes.

Science and public health experts are divided in their findings and opinions of the role of e-cigarettes in modifying smoking rates. Some argue that e-cigarettes are instrumental in driving down smoking rates, as many smokers have used them to quit smoking completely, with estimates of at least 50,000 additional (smoking) quitters each year in England as a consequence of e-cigarette use (Beard *et al*., 2020). A (living) Cochrane Review currently concludes that e-cigarettes are more effective than NRT for smoking cessation (Hartmann-Boyce *et al*., 2020). Others say e-cigarettes have the potential to drive smoking rates up by leading non-smokers (particularly children and adolescents) to tobacco smoking via the 'gateway theory' or by hampering quit attempts (Glantz and Bareham, 2018). A WHO (2019) report associated experimental use of e-cigarettes with subsequent experimental smoking. Other than direct causal links a common liability theory could explain this association; that is, risk taking individuals are likely to experiment with both e-cigarettes and tobacco cigarettes.

Two aspects of the health risk from e-cigarettes warrant consideration: the risks from e-cigarettes alone in a non-smoker and the relative risk from e-cigarettes compared to tobacco cigarettes. In terms of the specific risks from e-cigarettes alone, some studies have found harmful effects of e-cigarettes on different body systems, while others have found no harmful effect. For example, some incidents of respiratory injury involving lipoid pneumonia and hypersensitivity pneumonitis have been associated with the use of e-cigarettes (Viswam *et al*., 2018, Nair *et al*., 2019). As most e-cigarette users are former or current tobacco users, studies often struggle to determine the specific role of e-cigarettes over and above current or previous tobacco use. Studies on tobacco naive e-cigarette users are rare and often struggle to recruit participants. A small 3.5-year prospective study reviewed users with high-resolution computation tomography and concluded no pathological changes could be identified after this relatively short time period (Polosa *et al*., 2017).

With regards to relative risks, a longitudinal study (2013 – 2016) found vaping to be an independent risk factor for respiratory disease when used in addition to tobacco smoking (Bhatta and Glantz, 2020). In contrast, a randomised control trial found that smokers who switch completely to vaping, experience respiratory health improvements (Veldheer *et al*., 2019). One study suggested that nicotine (a constituent of e-cigarettes) can have detrimental effects on the cardiovascular system and potentially disrupt the central nervous system (Benowitz, 2010). Another study showed that nicotine does not cause serious adverse health effects such as acute cardiac events, coronary heart disease or cerebrovascular disease (Hubbard *et al*., 2005). A more recent study did not find any association between e-cigarette use and myocardial infarction or coronary heart disease (Farsalinos *et al*., 2019). Another study revealed that tobacco smokers (particularly females) who switch to vaping, experience significant improvement in vascular health within 1 month of switching (George *et al*., 2019).

WHO (2019) has stated that 'e-cigarettes are harmful to health and are not safe', but the studies on which conclusions about the toxicity of e-cigarettes were based, are mainly *in vitro* chemical and toxicological studies and, to a lesser degree, clinical studies such as human trials. A review of the safety of e-cigarette use concluded that the long-term health effects of e-cigarette use are not yet known but are likely to be much less, if at all, harmful to users or bystanders as compared to cigarettes (McNeill, 2015). In reality, due to the novelty of e-cigarettes, it will take years of research to determine the true absolute risk of e-cigarettes. As discussed by Gotts et al. (2019) it took decades of chronic smoking for development of lung diseases such as lung cancer or chronic obstructive pulmonary disease, it may take up to the middle of this century before the population effects of e-cigarette use becomes apparent. This is perhaps why most public health experts and health organisations tend to now focus on the relative risk of electronic compared to tobacco cigarettes. Reviews and reports from health authorities such

as the National Academies of Sciences, Engineering, and Medicine (NASEM) (St. Helen and Eaton, 2018), Public Health England (PHE) (McNeill, 2015), Royal College of Physicians (RCP) (Royal College of Physicians, 2016), US Surgeon General (The Surgeon General, 2020) and WHO (World Health Organization, 2019), indicate that while there is currently little evidence of long-term effects, e-cigarettes are likely to pose significantly less risk to an individual compared to tobacco cigarettes.

Oral Health

Given the well-known oral health consequences of tobacco smoking and the fact that the oral tissues are the first to be contacted by e-cigarette aerosol, it is no surprise that the potential oral health consequences of e-cigarette use have been the subject of much research. Two recent reviews (Holliday *et al*., 2021, Yang *et al*., 2020) have summarised the evidence in this area. Many of the studies are *in vitro*. Cells or tissues are exposed to e-liquid or e-cigarette aerosol, sometimes in an unrealistic way. In their entirety these studies report a wide range of cellular effects, but they are much less pronounced when compared to tobacco cigarette smoke. Data from clinical trials is limited and no firm conclusions can be drawn. Epidemiological studies have so far mainly been cross-sectional and self-reported, limiting conclusions. However, oral dryness, irritation and gingival diseases are the areas that have drawn most concern. Finally, microbiological studies have identified that e-cigarette users have a distinct microbiome and indicate that this could be more pathogenic. This area is the most robust to date of potential oral health harms from e-cigarettes.

A systematic review of the specific role of nicotine on oral cells included 42 *in vitro* studies and showed that nicotine, at levels found in tobacco smokers, NRT users and e-cigarette users, is unlikely to be cytotoxic to human gingival and periodontal cells but may have impacts on other cellular processes, although evidence was conflicting (Holliday *et al*., 2019).

A large multi-centre randomised controlled trial has recently been funded in the UK and will be investigating e-cigarettes as a cessation aid in dental settings and any impacts on oral health, particularly the response to periodontal therapy in those with periodontitis (Holliday, 2021).

Reflections

In summary, e-cigarettes are a complex and dynamic public health issue that have caused much controversy for public health researchers and practitioners. There is now a fairly clear consensus that the potential harms of e-cigarette use are likely to be much less than from tobacco cigarettes and this appears to hold true for oral health. Regulatory approaches vary considerably around the world but in the UK and Europe a clear regulatory framework allows their use as a consumer or medicinal product. Whilst there is a route to regulate e-cigarettes as medicinal products in the UK, none are licensed in this way. This route is far more restrictive than the consumer route, which has probably contributed to the abundance of products and choices.

Given the artificial nature of e-cigarettes, some would argue that researchers are in a fairly unique position to be able to influence the composition of future products if certain ingredients were found to be harmful. Others may argue that this is not the role of the research community, rather manufacturers. We think such changes are likely going to be a function of both. Manufacturers will initiate new ingredients in future products, possibly in their interest, but the research community could influence how those products are regulated, based on their knowledge of those or similar ingredients.

As with other new or developing research areas, there have been issues with the quality of the research conducted and the data available. 'Hot stuff bias' has likely played a role, whereby investigators are less robust in their methods and journal editors are less strict, keen to publish trendy results when a subject is new or fashionable. Readers should be aware of this when reviewing studies in this area. There is a range of specific challenges in e-cigarette research, including: tobacco smoking being a confounding factor (the vast majority of e-cigarette users are current or former tobacco smokers), rapid product development (products used in clinical trials are often discontinued before the end of the trial) and the wide range of products (studies can only use a limited number of products and translating results to the wider product category can be challenging).

To finish, what about our predictions for the next 10 years? We anticipate that ongoing research and that e-cigarettes will have been used for another 10 years, will provide more definitive answers to the important questions in this area. For example, what role, if any, e-cigarettes should play in healthcare and whether they have oral health effects. The level of existing controversy is likely to remain for some time, although the COVID-19 pandemic may have increased public and researcher understanding and appreciation of relative risks. For the public, smokers, and practitioners in a position to recommend best practice to their patients, the current evidence and consensus, recommends that getting expert support combined with using an e-cigarette doubles ones chances of successfully quitting smoking.

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