Background paper

E-cigarettes and their potential contribution to achieving the Smokefree 2025 goal

Prepared for the National Smokefree Working Group

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Authorship and acknowledgements

This background paper has been prepared for the New Zealand National Smokefree Working Group to consider the role that e- cigarettes could play in reducing smoking prevalence and helping achieve Smokefree 2025.

Professor Richard Edwards, Professor Chris Bullen, Associate Professor Natalie Walker, Professor Janet Hoek, and Emeritus Professor Robert Beaglehole wrote the document. Selected members of the National Smokefree Working Group were consulted following preparation of the first full draft and their comments and feedback have been taken into account in preparing the final document.

National Smokefree Working Group Members' views on e-cigarettes are varied and this document aims, as much as possible, to provide a consensus view. The recommendations and views expressed do not necessarily represent the official views of the member organisations of the NSFWG or of the wider smokefree practitioner community outside of those consulted in the preparation of this document.

Summary

Key messages

- New Zealand (NZ) policy prevents the sale of nicotine containing e-cigarettes (EC) and e-liquids, although it is permissible to import nicotine e-juice for personal use (up to three months' supply). Despite this policy, the illegal sale of nicotine e-juice exists;
- The long-term health effects of EC are unclear, and their role in achieving Smokefree 2025 is uncertain;
- Current evidence suggests EC have a modest effect on reducing smoking prevalence by helping some smokers to quit;
- Current evidence suggests EC help some smokers to cut-down the number of cigarettes they smoke;
- Both maintaining the status quo, or increasing the accessibility of EC through pharmacies and specialist vaping shops, are defensible policy options; and
- Regardless of decisions made about EC, intensifying comprehensive smokefree measures are crucial to achieving the Smokefree 2025 goal in all population groups, and will enhance the impact of EC in reducing smoking prevalence and disparities in smoking.

Introduction

This document reviews the potential contribution of EC (this term is used to refer to all types of EC in this document) to NZ's Smokefree 2025 goal, sets out suggested principles and options for EC related policy, and makes recommendations on how ECs' contribution to the Smokefree 2025 goal could be maximised. The report was prepared by a group of smokefree researchers, following a review of the evidence and following consultation with members of the NZ's smokefree practitioner sector who were members of the National Smokefree Working Group in June 2016. The policy options and recommendations made in this paper are considered apt for the current context in NZ and current state of the evidence. However, this is a rapidly evolving situation and these recommendations may need to change as new evidence emerges about ECs and their potential contribution to achieving Smokefree 2025.

Background

More than half a million New Zealanders still smoke tobacco, contributing to a huge burden of preventable death and disease. In March 2011 the NZ Government adopted the goal of making NZ a smokefree nation by 2025. Progress towards the goal and the 2018 mid-term targets is inadequate, especially for Māori and Pacific peoples. The use of EC has increased in NZ; the role that EC could play in reducing smoking-related harm, smoking prevalence and achieving Smokefree 2025 is debated.

The World Health Organization (WHO) position on the role of EC is cautious. A new WHO Framework Convention on Tobacco Control (FCTC) Conference of Parties (COP) position paper is being prepared, and is likely to be adopted at COP7 in India in November 2016.

The NZ Government has largely followed the WHO FCTC's position on EC. No nicotine-containing EC or e-liquids are currently approved for therapeutic purposes and smoking cessation support, nor are they included on the list of smoking cessation medicines on the Ministry of Health website. EC that do *not* contain nicotine are available for sale in New Zealand. However, it is illegal to sell or advertise nicotine-containing EC or e-liquids in New

Zealand, although up to three months supply can be bought outside of New Zealand (usually through internet sales) and imported for personal use.

There are a number of weaknesses with the current situation: sale of nicotine-containing EC products by NZ retailers occurs despite current legislation; there is no training for smoking cessation staff in the use of EC; no NZ literature is available advising smokers about the use of EC for quitting (other than an information leaflet prepared by End Smoking New Zealand and online information from the New Zealand Vaping Alliance) and there are no quality or health standards applied to imported EC (although some self-regulation by the EC industry does occur). The Ministry of Health has recently released a consultation document on policy options for the regulation of EC. [1]

Principles for addressing EC policy and practice

The following principles should guide the development and implementation of EC-related policy and regulation:

- The primary aim of the EC policy should be to support the achievement of the Smokefree 2025 goal for all population groups in NZ;
- New Zealand's tobacco control efforts should be maintained and intensified;
- E-cigarette policy should minimise the risks initiation of nicotine use by non-smokers' (particularly children and young adults) either through long term EC use and/or via EC use to smoking;
- Regulation of ECs should not be more stringent than regulatory measures in place for smoked tobacco products; and
- The Ministry of Health should continue to monitor emerging evidence on EC and the potential impacts of these products on smoking prevalence in New Zealand. Policy and practice should be updated in light of new evidence.

Evidence Summary

Internationally, EC use has grown rapidly, including use among young people and adults in NZ. The adverse health effects of EC are likely to be much lower than for smoked tobacco, although adverse health impacts of long-term EC use cannot be ruled out.

Evidence about the addictiveness of EC is limited, but it may be similar to the low level of long-term dependence found among ex-smokers who use NRT products. The level of dependence among EC users who are never smokers, particularly children and young adults, is unknown, but again may be similar to the low level of long-term dependence found among the few never smokers who use NRT products. Such dependence would have the greatest potential significance for public health and smoking prevalence, if hypothesized gateway effects to smoked tobacco use were realised. There are therefore strong grounds for prioritising regulatory approaches that minimise the risk of uptake of EC use among never smokers, particularly youth and young adults.

Evidence from around the world about impacts of EC on smoking prevalence must be considered in the context of each country's unique tobacco control policies, programmes and EC regulations. In developed countries there is some suggestion that the increase in EC use may contribute to some (but not all) of the observed declines in smoking prevalence. This evidence suggests that EC use will make a contribution to reducing overall smoking prevalence and achieving Smokefree 2025, but is not the 'magic bullet'.

However, ECs also have the potential to reduce the effectiveness of current smokefree activities by acting as a distraction or creating disunity among smokefree practitioners, and by enhancing the credibility of the tobacco industry through their involvement with EC development and distribution resulting in increased influence on decisions about tobacco control policy. Maintaining unity within the smokefree practitioner community and ensuring continued vigorous advocacy for a comprehensive Smokefree 2025 strategy may be as important as the fine detail of the measures adopted to address EC use.

Recommendations

We identified and evaluated a range of possible policy options for EC in NZ. These recommendations will need to be reviewed and refined as further evidence or authoritative guidance comes to hand.

1. Supply and availability of e-cigarettes

Two preferred options are supported by members of the tobacco control community that were consulted when preparing this document.

Preferred option 1 - Maintain status quo. Sale of nicotine-containing EC or e-liquids within New Zealand is prohibited, but e-liquids are legal to import for personal use (up to three months supply). However, it should be noted that the real status quo is that nicotine-containing EC or e-liquids have been widely available for some time in NZ (due to importation by users and illegal sales by retailers).

Preferred option 2 - **Allow restricted sale of nicotine-containing EC or e-liquids for smokers who want to quit.** Continue to allow the importation of nicotine-containing EC or e-liquids for personal use (up to 3 months supply) but also allow sales of nicotine-containing EC or e-liquids through pharmacies and a limited number of licensed specialist shops (with stipulations about proximity to schools, exclusion of minors from shops, and training/competence for staff in EC use and ABC cessation support); minimum age of purchase 18 years.

2. Smoking cessation advice and support for EC as quitting aids

Preferred option - Cessation service providers receive resources and training in use of EC to support quitting, based, for example, on recent Public Health England advice. Healthcare providers should not recommend or support specific EC products unless these were licensed for cessation through MedSafe.

3. Marketing, packaging and consumer information

Preferred option - marketing and public information. Commercial marketing of nicotine containing EC and e-liquids products sold within NZ (if permitted) to be limited to point of sale displays regulated to avoid exposure to children and young people. Information (e.g. leaflets) giving advice to EC users trying to quit should be provided by cessation services and at point of sale. Consider targeted or mass media information campaigns to provide information about the availability of EC and potential benefits and harms.

Preferred option - packaging. Packaging requirements for EC and e-liquids products sold within NZ (if permitted) to include minimum standards of child safety, safety warnings, health warnings and Quitline information, and list of constituents. No packaging or product names would be permitted that are appealing to children and young people.

4. Product design/standards/additives/flavours

Preferred option –Apply existing consumer protection legislation and explore introducing minimum quality and safety standards and excluded additives/flavours for nicotine-containing EC and e-liquids products sold within New Zealand (if permitted).

5. Use of e-cigarettes in indoor and outdoor workplaces and public places

Preferred option – Use of EC to be banned in all indoor workplaces and public places (consistent with the 1990 SFE Act), all schools, in cars, and in selected outdoor locations (areas where children predominate, e.g. playgrounds, parks) but allowed in other smokefree areas at local discretion and where public consultation suggests this is acceptable. Clear signage should indicate where vaping is permitted, and these areas should be separate to "smoking permitted" areas.

6. Tax and excise for cigarettes

Preferred option – Maintain status quo, i.e. no additional tax or excise applied to nicotine-containing ECs and e-liquids. To be reviewed if there is evidence of substantial uptake of nicotine-containing EC by non-smoking children and young people.

7. Monitoring and research

Preferred option – Ministry of Health develops a framework for monitoring and evaluating emerging evidence on EC, including their evolution and use (internationally and in New Zealand), and for evaluating the impact of EC, especially on smoking prevalence in all population groups and progress towards the Smokefree 2025 goal.

Enhanced and comprehensive tobacco control in New Zealand

The impact of EC in helping achieve the Smokefree 2025 goal will be enhanced by implementing a comprehensive tobacco control strategy and by adhering to the principle that where regulatory measures are applied to EC, equivalent or more stringent regulatory measures should be in place or introduced for smoked tobacco products. Measures to ensure this principle is adhered to are:

Tobacco supply and availability: Introduction of retailer licensing and proximity to schools restrictions for smoked tobacco products, and ideally raising the age of purchase to 21 years for smoked tobacco products.

Tobacco marketing, packaging and consumer information: Intensified and targeted mass media smokefree campaigns. The list of constituents for all smoked tobacco products to be provided on the packaging.

Tobacco product regulation: Regulating the nicotine content of cigarettes to very low levels so that they are no longer addictive (or less addictive), making cigarettes unappealing to children and young people (e.g. changing the pH of the tobacco, or banning particular additives, such as menthol and sugar and banning capsules).

Tobacco use in cars and outdoor spaces: Legislation to ban smoking in cars with children present and national legislation to ban smoking in children-focused outdoor areas such as playgrounds, sports fields and parks.

Tax on tobacco products: Continued and substantial above inflation increases in excise tax on smoked tobacco products.

E-cigarettes and their potential contribution to achieving the Smokefree 2025 goal

Introduction

On August 2 2016 the NZ Ministry of Health announced a consultation on policy options for ECs[1] and invited submissions from interested parties. [1]

The purpose of this report is to review the potential contribution of ECs to promoting or preventing the achievement of NZ's Smokefree 2025 goal, sets out suggested principles and options for EC related policy, and to make recommendations for how their positive contribution, if any, to achieving the goal can be maximised, based on the current evidence and context in NZ. The paper is informed by current data on EC use in NZ and current evidence of the impact of ECs on smoking cessation and smoking prevalence. We encourage use of the paper in the preparation of submissions for the current Ministry of Health consultation on policy options for the regulation of ECs.

The policy options and recommendations made in this paper are considered apt for the current context in NZ and current state of the evidence. However, this is a rapidly evolving situation and these recommendations may need to change as new evidence emerges about ECs and their potential contribution to achieving Smokefree 2025.

The report was prepared by a group of researchers working in the NZ smokefree and EC research sector, following a rapid review of the evidence and informed by consultation with NZ's smokefree practitioner sector who were members of the National Smokefree Working Group in June 2016.

Background

Smoking is a major risk factor for preventable ill health and mortality in New Zealand (NZ), [2] and results in around 4-5000 deaths each year. In 2011 the NZ Government responded to a recommendation of the Māori Affairs Select Committee inquiry into the tobacco industry in Aotearoa and the consequences of tobacco use for Māori [3] and adopted the world-leading goal of *"…reducing smoking prevalence and tobacco availability to minimal levels, thereby making New Zealand essentially a smoke-free nation by 2025*." [4] Since then there has been much debate about how the goal is best achieved, particularly in response to increasing evidence that progress towards the goal is inadequate, especially for Māori and Pacific peoples. [5-8]

An important development in recent years has been the emergence of ECs (for simplicity, this term is used in this document to refer to all types of ECs) as a widely available consumer product in many jurisdictions around the world. E-cigarettes have been proposed as a 'disruptive technology' [9] that may have a major positive influence by reducing tobacco smoking and changing the nature of the market for products that deliver nicotine to users.

E-cigarettes were invented in China in the early 2000s. They are battery-powered electronic devices that deliver an aerosol (commonly called vapor), to users by heating a solution

(commonly called 'e-liquid' or 'juice') typically made up of propylene glycol or glycerol (glycerin), nicotine, and flavouring agents. They are a rapidly evolving technology (and with a growing plethora of associated terminology and jargon) commonly currently categorized into three generations:

- **1st generation products ('cigalikes').** These are often disposable with non-rechargeable batteries (some have rechargeable batteries) and non-refillable liquid supplies. They are usually similar in size and appearance to smoked cigarettes.
- **2nd generation products ('vape pens' or 'eGos').** These are larger devices usually with rechargeable batteries, replaceable liquid cartridges, and can be used with different atomisers. They are larger than cigarettes and dissimilar in appearance – often looking like a pen or laser pointer.
- **3rd generation products ('mods' or 'tanks').** These are usually more sophisticated in design with refillable liquid tanks, rechargeable batteries, ability to variable temperature and voltage and can be paired with a wide range of atomisers. They come in many designs and the appearance and size is highly variable. They do not look like smoked cigarettes and are generally much larger than 1st and 2nd generation products.

The use of ECs (often referred to a 'vaping') has been increasing rapidly in many countries, including in NZ. [10 11, 12] The EC market is commonly characterised by a dynamic independent sector of manufacturers, distributors and retailers and a tobacco-industry controlled sector. There is some evidence of product differentiation, with the tobacco industry focusing to date mainly on 'cigalikes' and the independent sector on later generation products and bespoke 'e-liquids'. Users ('vapers') range from people trying out ECs for the first time, who in many jurisdictions are more likely to use the relatively simple and often heavily marketed 1st generation products, to long-term enthusiastic users who are more likely to use 2nd or 3rd generation products and may be members of a growing vaping sub-culture. [13] In NZ the market is dominated by 2nd and 3rd generation devices, and use of 'cigalikes' is relatively uncommon. For example, 56% of 105 NZ vapers who took part in an online survey in 2015 reported exclusive use of 3rd generation products and another 22% used 2nd and 3rd gen; only 2% used 1st generation exclusively (unpublished data – personal communication Natalie Walker and Chris Bullen).

Some vaping enthusiasts have become vocal and organised proponents for vaping in itself and/or as a means to reduce the use of smoked tobacco. Pro-vaping proponents and groups are often critical of the public health and smokefree (tobacco control) sector, which are commonly viewed as collectively opposed to ECs (for example see http://www.nzvapingalliance.co.nz/). In reality, members of the public health and smokefree practitioner sector have diverse views about ECs, with some supportive, others cautious or opposed, for example due to concerns about the tobacco industry involvement in the ECs market.

In NZ, ECs that do not contain nicotine can be freely sold, unless they look like tobacco products, in which case they cannot be sold to people less than 18 years. It is illegal to sell or advertise nicotine-containing ECs or e-liquids or to advertise an overseas website where people can purchase nicotine-containing EC or e-liquids. However, it is legal to import (usually through internet sales) nicotine-containing ECs or e-liquids for personal use (up to 3 months supply). [14] These imported products cannot be supplied sold or given away to anyone else. There is some illegal sale of nicotine containing products by some NZ retailers.

To date the NZ Ministry of Health has largely adopted the WHO FCTC's cautious position on ECs. No nicotine-containing ECs have been put forward for approval under the Medicines Act

and there are currently no e-ECs (nor any e-liquids) approved for therapeutic purposes and smoking cessation support. Furthermore, ECs and e-liquids are not currently included on the list of smoking cessation medicines on the Ministry of Health website.[15] There is currently no training for smoking cessation staff in the use of ECs and no literature advising smokers about the use of ECs for quitting - other than a leaflet prepared by End Smoking New Zealand[16] and some online information from the New Zealand Vaping Alliance (http://www.nzvapingalliance.co.nz/advice-about-e-cigarettes/). There are no specific NZ quality or health standards applied to imported ECs, although a voluntary New Zealand standard have been prepared by Dr Murray Laugesen of Health New Zealand [17] and another proposed internationally. [18]

In NZ, as in many countries, there has been considerable debate about whether ECs can contribute to reducing smoking prevalence and the enormous harm that tobacco smoking causes to the population's health. Some see ECs as making a major contribution to, or even as being essential for, the achievement of the Smokefree 2025 goal by helping smokers to quit or by being an effective substitute to smoked tobacco products. [19] Others are more cautious and are unconvinced that the benefits of widespread use of ECs will be greater than the harm they might cause, or question will significantly contribute to reducing smoking prevalence. [20]

The current WHO position, adopted in 2014, is cautious about the role of ECs. [21] A new FCTC Conference of Parties (COP) position paper is currently being prepared, and is likely to be adopted at COP7 in India in November 2016.

Potential benefits and harms of e-cigarettes

This section reviews the potential benefits and harms of ECs in terms of their contribution to the achievement of the Smokefree 2025 goal. The emphasis is on documenting a full range of possible benefits and harms for individual users, for overall smoking prevalence and population health, and impacts on the tobacco industry, EC market, and smokefree practitioner community and activity. Inclusion of a particular benefit or harm does not imply that this impact is proven or even considered likely, just that it could potentially occur.

Potential impacts at the individual level

Health and economic benefits at individual level accrue to:

- Smokers who quit, who would not otherwise have quit using other methods.
- Smokers who do not want to quit nicotine use, and who switch to ECs as a complete substitute for smoked cigarettes.
- Smokers who do not want to quit nicotine use (and who otherwise would have continued smoking at the same level), who switch to ECs as a partial substitute for smoking and cut down on smoked cigarettes. [a]
- Children and young adults who otherwise would have started to smoke, who use ECs temporarily or long-term as a substitute for smoking.
- Families/whanau/workmates/others whose exposure to second-hand smoking (SHS) is reduced due to smokers quitting/cutting down or never starting to smoke and instead using ECs.

[a] The health impact of this may be modest as epidemiological evidence suggests that the reduction in risk of adverse health outcomes in the longer term that results from cutting down is much less than quitting completely. [22]

Health and economic harms at individual level accrue to:

- Smokers who use ECs and do not quit completely, who would otherwise have quit if ECs were not available. Possible mechanisms for this outcome to occur include the following scenarios:
    - ECs are less effective as short-term cessation aids than alternatives that smokers would have used if ECs were not available;
    - Smokers who would otherwise have quit instead 'dual-use' e.g. because ECs enable them to get nicotine where smoking is prohibited/discouraged;
    - ECs result in an increase in (less effective) unassisted (without behavioural support e.g. from a smoking cessation counsellor) quitting and a decrease in (more effective) assisted quitting.
- Smokers who switch to using ECs long-term, who would otherwise have quit smoking without on-going use of other nicotine products.
- Children and young adults who use ECs and subsequently take up smoking who would not otherwise have smoked.
- Children and young adults who use ECs short-term or long-term who would not otherwise have smoked.
- Families/whanau/workmates/others who have increased exposure to SHS because ECs result in fewer smokers quitting or more children and young adults starting to smoke, or who are exposed to EC aerosols who would not otherwise have been exposed.

Benefits and harms at population level

The overall impact of ECs at population level will reflect the aggregated benefits and harms to individuals. This will depend on the:

- frequency and distribution of the individual impacts
- relative levels of adverse health effects and economic costs[b] of EC use compared with:
    - smoking or cutting down numbers smoked compared with quitting completely
    - SHS exposure compared to exposure to vaping-related aerosols

A specific proposed (but much disputed) potential harm of EC use at population level is through the 'renormalisation' of smoking. This is proposed to occur by highly visible EC use being mistaken as smoking, resulting in smoking becoming more acceptable as a normal behaviour, and hence increased uptake of smoking among children and young adults, and possible relapse back to smoking among ex-smokers.

The aggregated impacts of ECs could be reflected in the following ways:

- An increase or decrease in the level or rate of change in quit attempts, success of quit attempts, and overall quit rates.
- An increase or decrease in the level or rate of change in uptake of smoking, particularly among children and young adults.
- An increase or decrease in the level or rate of change in smoking prevalence among adults, children, young adults, and key population sub-groups with higher smoking prevalence (e.g. Māori and Pacific people).
- Improved population health due to decreases (or greater rate of decline) in smoking-related diseases and mortality, or worsening of population health due to increases (or reduced declines) in smoking-related diseases and mortality plus any additional adverse health impacts attributable to EC use.

[b] Currently in New Zealand smokers changing over to ECs report savings within a few weeks of purchasing an ECs even with the ongoing cost of e-liquids (unpublished studies – personal communication from Chris Bullen and Natalie Walker and Janet Hoek)

These benefits or harms are only attributable to the impact of ECs if they are additional to what would have occurred due to secular trends and ongoing smokefree efforts.

Benefits and harms through impacts of e-cigarettes on the tobacco industry, development in the e-cigarette market, and impacts on smokefree activity

As well as the direct impacts of ECs on individuals and populations, ECs could also have indirect positive or negative effects on smoking and health, through 1) impacts on the tobacco industry; 2) developments in the EC market, and 3) impacts on smokefree activity [c] and the smokefree practitioner sector.

These impacts could be largely positive for health and reducing smoking prevalence, as in the following scenarios:

- The tobacco industry changes its business model stops attempting to maximise its smoked tobacco product sales (ultimately stopping producing smoked tobacco products altogether) and diversifies more into other products, including ECs.
- The tobacco industry stops opposing smokefree activities aiming to reduce smoked tobacco product use resulting in increased implementation of effective smokefree measures.
- A vibrant EC sector persists with a strong independent (non-tobacco industry) component; this sector develops products that prove increasingly effective smoking cessation aids and smoked tobacco substitutes supports.
- The smokefree practitioner community unites around agreed strategies to achieve the end of smoked tobacco.

However, other scenarios are possible and these would have largely negative effects:

- The tobacco industry adopts a business model of maximising sales and profits from both smoked tobacco and ECs.
- The tobacco industry continues to vigorously oppose smokefree activities.
- The tobacco industry increasingly dominates the EC market and product development, and ensures that ECs do not significantly undermine the smoked tobacco market.
- The independent EC sector declines.
- The tobacco industry uses involvement in ECs to boost its credibility and increase its influence over smokefree policy decisions and enhance its ability to prevent the implementation of effective smokefree measures.
- The smokefree community is rendered less effective due to disagreements about EC policies and strategies to end the use of smoked tobacco.

Principles for addressing e-cigarette related policy and practice

It is unlikely that agreement will be reached on every aspect of policy for ECs among the smokefree practitioner sector. However, agreeing on a set of principles may be feasible, and would help prevent disagreements about policy detail distracting from the broader consensus about over-arching priorities and goals, ensure that debates about EC policy remain

[c] The terms ‘smokefree activities’ or ‘smokefree measures;’ (sometimes called ‘tobacco control’) is used in this document to describe interventions (policy, healthcare, health education etc) that aim to reduce smoking uptake, increase smoking cessation and reduce exposure of non-smokers to second-hand smoke.

constructive, and prevent ECs from undermining the implementation of other smokefree measures and achievement of the Smokefree 2025 goal.

The following principles could guide the development and implementation of EC-related policy and regulation currently, and into the future, as the evidence-base and context for EC use and tobacco use, the nature of the tobacco industry and EC markets, and the smokefree policy agenda changes over time.

- The primary aim of the EC policy should be to support the achievement of the Smokefree 2025 goal for all population groups in New Zealand, especially for high prevalence groups such as Māori and Pacific peoples;
- New Zealand's current smokefree strategies and activities should be maintained and intensified;
- E-cigarette policy should minimise the risks initiation of nicotine use by non-smokers (particularly children and young adults) either through long-term EC use or gateway effects of EC use to smoking;
- Regulation of ECs should not be more stringent than regulatory measures in place for smoked tobacco products; and
- The Ministry of Health should continue to monitor emerging evidence on EC and the potential impacts of these products on smoking prevalence in New Zealand so that policy and practice can be rapidly updated in light of emerging evidence.

Evidence summary

The briefing presents the evidence from some key areas relating to ECs including: patterns of use; impact on users, individual smokers and their smoking-related behaviours; effects on smoking prevalence and population health; as well as wider effects on the tobacco industry and smokefree activity. These reviews are of necessity brief, but are informed by credible recent comprehensive general reviews and position statements. Some prior studies are broadly supportive of ECs, [23 24] some mixed, [25, 26 27] and others very cautious. [28 29 30] The briefing is also informed by topic specific reviews, where available, supplemented by some key recent studies and theoretical considerations (as appropriate).

E-cigarette uptake and patterns of use

Internationally, EC use has grown rapidly, particularly in countries with more liberal policy environments, where intensive marketing campaigns have been undertaken.[31] The rapidly growing (21% increase in 2015) global market is dominated by the US, which has 43% of the global US$8 Billion EC market. [32 33]

Growth in use is apparent among young people as well as adults. For example, data from the Centers for Disease Control (US) show large increases in past 30-day use of ECs among young people from 2011-2015. These data show an increase in high school students' use of ECs from 1.5% to 16%; while among middle school students use increased from 0.6% to 5.3%. [34] Similar increases are evident among US adults, where ever-use grew from 1.8% (2010) to 13.0% (2013), and current use increased from 0.3% to 6.8% over the same period.[35] In 2013 EC use in the US was 30.3% among daily smokers, 5.4% among ex-smokers and 1.4% among never smokers.[35] Variation in the prevalence of EC use between countries with different regulatory regimes is illustrated by data from the International Tobacco Control (ITC) study. This study found awareness, ever-use and current use among smokers and ex-smokers increased rapidly in Canada, USA, UK and Australia countries between 2010 and 2013, but was significantly higher in the UK (where there are few restrictions on the sale and marketing of ECs), compared

with Australia (where there are bans on the sale of nicotine-containing ECs in all States, and the sale of non-nicotine containing ECs in three states). [36]

Data is emerging about how and why people use ECs. For example, in the 2016 ASH UK survey of EC users, about half were smokers (henceforth termed 'dual users') and half ex-smokers.[13] EC use among never smokers in this survey was negligible. The proportion of smokers currently using ECs in the UK had increased from 6.7% (2012) to 17.6% (2014) to 19.4 % (2016). [13] Among ex-smokers the proportion using ECs had increased from 1.1% (2012) to 8.4% (2016). Among current EC users, most dual-users (78%) and ex-smokers (88%) had been using ECs for at least 3 months. Among current EC users who were ex-smokers the most common reason for EC use was to quit (67%). Other common reasons given for use included to: save money (47%), prevent relapse (43%), or as a substitute for smoking (36%). For dual-users, the most commonest reason given for EC use was to cut down but not stop completely (41%), to quit (35%), to save money (32%), or to prevent relapse back to higher rates of smoking (30%). The survey also reported that perceptions of harm from ECs had grown, with only 15% of 2016 respondents believing that ECs were a lot less harmful than smoking (reduced from 21% in 2013), whilst the proportion believing ECs were equally or more harmful as smoking grew from 7% in 2013 to 25% in 2016. [13]

Findings from the 2016 ASH UK survey of EC users, and similar surveys, mostly support a positive interpretation of ECs' role in reducing smoking prevalence. For example, the high proportion of ex-smokers reporting that they used ECs to help them quit smoking entirely. However, some findings suggest possible adverse effects. For example, the high proportion of EC users who were dual users, and the fact that 41% of dual users were using ECs to cut down but not quit, and another 22% reported using ECs because they wanted to continue to smoke but needed something to help them deal with situations where they could not smoke (e.g. bars and workplaces). [13] Some of these dual users may have quit if ECs were not available – emphasizing the importance of research to investigate the net effect of ECs on smoking at population level.

Despite NZ's restrictions on the availability of nicotine-delivering ECs, awareness and use of these devices has increased rapidly over recent years.[11, 12, 37-39] Within NZ, the main youth data come from the biennial Youth Insight Survey, which found reported prevalence of 'ever-use' (i.e. ever tried an EC, even if only once) among adolescents tripled from 7.0% in 2012 to 20.0% in 2014.[38] Ever-use in 2014 was commoner among Māori and students from lower decile schools. Ever-use of ECs was also strongly related to smoking status, varying from 65% among daily smokers, 41% among ex-smokers, 17% among susceptible never-smokers and 6% among non-susceptible never smokers. Data from the 2014 Health Promotion Agency's Health and Lifestyles survey found ever-use of an EC among adults was 13.1%, while current (at least monthly) use was 0.8%. [12] Current smokers in this survey reported the highest rate of EC use (50% reported 'ever-using' and 4% reported they were 'currently using' an EC).[12] Ever-use of an EC was highest among Māori (25% vs. 13% for European/other and 12% for Pacific), younger adults (26% for 18-24 year olds) and people living in the deprived areas of NZ (17.4% vs. 7.9% in least deprived areas). These changes in knowledge and behaviour have occurred concurrently with the opening of 'vapouriums', [40] creation of NZ-hosted websites, [41-43] and increasing advocacy from the vaping community[44, 45] and those promoting harm reduction. [46, 47]

Safety of e-cigarettes

Direct health effects

Evidence from randomised trials has found that short-term EC use is not associated with health risks. [48-50] Population-level data suggests that long-term nicotine use by itself is low in

risk, so it is far more likely that any adverse health effects reported by EC users are due to the non-nicotine constituents of the inhaled vapour.[23, 24]

Toxicants detected to date in a range of EC liquids and vapours/aerosols have included tobacco-specific nitrosamines, aldehydes, metals, volatile organic compounds, phenolic compounds, polycyclic aromatic hydrocarbons, flavours, solvent carriers and tobacco alkaloids.[23, 51, 52] These toxicant levels have, with few exceptions, been at least an order of magnitude lower than those present in tobacco smoke, and are within exposure limits set out by authorities such as the US EPA or IARC. The findings of these reviews highlight a lack of standards in the methods used to analyse EC aerosols. Just as the products differ widely in performance characteristics, so too there is no standardisation of assessment of the toxic potential of ECs. Thus, some of the results found to date could be under- or over-estimating toxicant levels and exposures. Furthermore, while some of these data are now 'historic', they also reveal the lack of standards in the manufacturing processes of much of the EC industry, and lack of governmental quality control standards over EC and e-liquid products.

A new unpublished analysis reviewed the evidence looking at biomarkers for EC use, compared with tobacco smoking.[53] Urinary levels of carcinogens ranged from 1-20% with EC use (compared to the levels observed in tobacco smokers, and expired air carbon monoxide was most often 0% of the levels among tobacco smokers. However, one study in the review found that EC use resulted in four measures of oxidative stress being as high as 65% of those seen in tobacco smokers.[54] Such biomarker studies have the advantage of assessing actual biological exposure through use of ECs, rather than relying on measurements of the constituents of e-liquids and environmental aerosols. Although, many of these studies were preliminary in nature and this analysis has been subject to critique. [55]

Second-hand exposure effects

E-cigarette use produces a visible vapour that is usually odorous, depending on the flavours and other contents of the fluid. Tobacco cigarettes discharge smoke continuously while alight and when the user exhales. E-cigarette vapour is discharged into the air only when the user exhales. There is no side-stream vapour from ECs. The emissions from EC use discharge water, volatile organic compounds (VOCs) and nicotine into indoor air at levels far lower than found with tobacco cigarettes. For example, Schober et al (2013) measured EC pollutants in the air of a ventilated room, while volunteers used ECs with and without nicotine over two hours.[56] There was an adverse change in air quality; polycyclic aromatic hydrocarbons in the indoor air increased by 20% and particulate levels also increased. On this basis, the authors concluded that exposure to EC vapour might be a health concern, as fine and ultrafine particles might be deposited in the lungs of those exposed in enclosed spaces.

There is very limited published research on the health effects of 'second-hand' exposure to EC vapour. McAuley et al. (2012) assessed indoor air concentrations of common tobacco smoke by-products (VOCs, carbonyls, polycyclic aromatic hydrocarbons, nicotine, tobacco-specific nitrosamines, and glycols) emitted by generic ECs using four different high nicotine e-liquids, and compared the results with those from analysis of tobacco cigarette smoke tests. [57] They then undertook risk analyses based on dilution into a 40 m^3 room and standard toxicological data. This assessment revealed no significant risk of harm to human health from EC emissions. In contrast, the tobacco smoke analyses mostly exceeded risk limits. Flouris et al. (2013) exposed healthy volunteers to EC vapour for one hour and found small increases in serum cotinine, but no significant changes in lung function. [58] No studies have been conducted on the impact of longer duration second-hand exposures, exposure in children, or third-hand exposures. On the basis of what was known about constituents of vapour, their toxicity, and

exposure times, Burstyn (2013) asserted that any risks to health from second-hand EC vapour were likely to be far lower than from exposure to tobacco smoke. [59]

In summary, the available evidence supports assertions that the health effects (both direct and indirect) are likely to be much lower than for smoked tobacco. However, emerging data suggests raised levels of some biomarkers following EC use, though at lower level than in tobacco smokers. This information, combined with the lack of any long-term (> 12 months) follow-up studies on EC use, suggests that adverse health impacts of long-term EC use cannot be ruled out.

Evidence for the addictiveness of e-cigarettes

Nicotine is the constituent of cigarettes principally responsible for their addictive potential. However, a number of other factors play a part in the process, [60] namely: 1) the 4,000 plus other substances in tobacco smoke that may work to enhance nicotine's effect; 2) the social environment; and 3) the rituals associated with smoking. [61] The nicotine content of the 22 most popular factory manufactured and roll-your-own cigarettes in New Zealand ranges from 8-18 mg nicotine per gram of tobacco. [62]

The first symptoms of nicotine dependence can appear within days to weeks of the onset of occasional use, often well before the onset of daily smoking. It is hypothesized that people can be grouped into three types, according to their susceptibility to nicotine dependence, namely rapid onset, slower onset, and resistant. However, by the time a person is able to smoke one full cigarette they are considered by some researchers to be addicted. [63] The exact threshold at which nicotine exposure results in addiction in humans is unknown. An indication of the threshold at which tobacco products become addictive comes from research on very low nicotine content cigarettes. This research suggests that the optimal level for a cigarette to be considered of 'reduced addictiveness' is ≤ 0.4 mg of nicotine per gram of tobacco, [64, 65] that is a 95-98% reduction in nicotine content relative to products currently on the market.

Evidence for the addictiveness of other non-smoked nicotine-delivery products may give some indication of the addictiveness of ECs. Nicotine replacement therapies (NRT) deliver nicotine to the user and help reduce nicotine cravings and feelings of nicotine withdrawal following smoking cessation, thereby making it easier to quit. NRT comes in various forms, including slow-release patches (15-24 mg nicotine) and fast-release nicotine gum, inhalers, lozenges, sublingual tablets and mouth sprays (typically 1-4mg nicotine). Addiction to NRT appears to be very rare (1%) in non-smokers and uncommon in ex-smokers, despite the widespread availability of such products.[66] For example, 2-16% of ex-smokers using NRT long-term remain addicted (if use beyond the recommended treatment period is considered an indicator of continued nicotine dependence) [67-69] and 1.4% of ex-smokers using NRT long-term remain addicted. [67]

E-cigarettes are a nicotine delivery device and hence may have a similar addictive potential to NRT. In one of the first studies investigating ECs, the pharmacokinetic profile of a 16mg early 'cig-a-like' EC was similar to that of a nicotine inhaler, with both failing to achieve the pharmacokinetic profile of nicotine levels from a tobacco cigarette. [70] Since this study the design features of ECs have changed dramatically, enabling far better delivery of nicotine to users. However, more recent research indicates that even new generation ECs fail to match the nicotine level delivered by a tobacco cigarette, [71] whilst laboratory-based research suggests they do. [72]

Unlike NRT, ECs also mimic the sensory experience of smoking a cigarette. However, vaping differs from smoking as the average puff duration tends to be longer, and stronger suction is

required than with a cigarette. [73] The designs of ECs and content of e-liquids vary greatly, as do patterns and frequency of use. For example, recent consultation with NZ vapors for the ASCEND-II trial indicates that naïve users of ECs often start with a 2nd generation device and 18mg nicotine/ml, and undertake "mouth to lung vaping", which is similar to the way cigarettes are usually smoked. More experienced vapers tend to undertake "Direct to lung vaping" which involves use of a different type of e-cigarette (eg. a sub-ohm tank) with less nicotine (1-3 mg /ml) (unpublished data – personal communication, Natalie Walker). Some vapors use more than one type of device, and different strengths of nicotine at different times. Some change from episodic to continuous use depending on the setting. Therefore exposure to nicotine is likely to be highly variable, both within and between users. As a result the likelihood of addiction between users and between types of device are likely to vary.

Research into the addictiveness of ECs among users is limited. Evidence is needed about both the absolute level of addictiveness among different types of users, and the degree of addictiveness of ECs relative to other forms of nicotine delivery (i.e. cigarettes, NRT, and snus/smokeless tobacco). A recent investigation of the relative addictiveness of ECs involved three different surveys (n=796-2,623) of smokers and ex-smokers, and used a number of different tests of dependence adapted for ECs and nicotine gum. [74] The key findings were:

- Dependence was slightly higher in users of nicotine-containing ECs than in users of nicotine-free ECs.
- In ex-smokers, those who used ECs for more than three months had lower levels of dependence than those who used nicotine gum for more than three months.
- Subjects who used ECs daily and smoked daily (dual users) were generally less dependent than people who only smoked tobacco cigarettes daily.

In a study of 3,609 ex-smokers who were current users of ECs, dependence (when measured using a specific EC dependence index) increased as the type of device advanced in design and as nicotine concentration increased. Longer term use of an EC was also associated with increased dependence. [75] Even participants who used a nicotine-free EC displayed some degree of dependence, suggesting there is a degree of behavioural dependence to vaping, and not just nicotine dependence. Other studies have also suggested there is a degree of behavioural dependence to EC use. [76]

Dependence on nicotine among EC users who are ex-smokers could be considered to be of less concern, given that their dependence results primarily from their original dependence to smoked tobacco. Addiction to ECs among never-smokers, particularly children and young adults, would be of much greater concern, as this may largely represent nicotine addiction that would not otherwise have occurred, particularly if a significant proportion of never smokers who become dependent on ECs later progress to smoked tobacco products (see next section). Adult never-smokers who became daily users of EC is likely to be rare (and some 'never smokers' may be inaccurately categorised e.g. some may be ex-occasional smokers [77]). An unpublished study of over 20,000 US vapers has found that only around 5% are never smokers. Of these around a fifth were using nicotine-free EC, and most of the remainder vaped with low concentration (1-6 mg/ml) e-liquids (unpublished data, personal communication Natalie Walker). One could hypothesise that if a never-smoker did become a daily user of a nicotine EC it is likely their level of dependence would be similar to the rates reported above for non-smokers using NRT, i.e. <1%. No data are available specifically measuring dependence in adolescent never-smokers who start vaping with nicotine-containing ECs, though it is plausible (e.g. due to evidence that the developing brain of adolescents may be particularly susceptible to nicotine[78]) that dependence could occur.

In summary, evidence about the degree of addictiveness of ECs is currently limited, but it is plausible that it is similar to the low level of long-term dependence found among NRT products. Dependence is likely to vary greatly between different types of users and different types of ECs. Dependence among ex-smokers is likely to be of lesser public health significance, given the likely much lower health risks associated with EC use compared with smoked tobacco products. Levels of dependence among EC users who are never smokers, particularly children and young adults, is largely unknown. However, such dependence is potentially of greatest significance for impacts on public health and smoking prevalence, due to possible (though unproven) gateway effects to smoked tobacco use. Hence this is an area where evidence is most urgently required.

'Gateway' effects

The proposed 'gateway' effect of ECs can be defined as a negative impact that would occur if EC use among non-smokers (mainly minors or young adults) results in increased initiation of tobacco smoking at a later date, over and above the rate of initiation that would have occurred in the same non-smokers without EC use. It is also possible that use of ECs temporarily or longer term has a reverse gateway effect by reducing initiation of tobacco smoking among similar groups of non-smokers compared to initiation that would have occurred in the absence of EC use. Plausible biological mechanisms for gateway effects have been proposed.[78] We are not aware of any comprehensive reviews of the evidence for ECs and gateway effects, so the epidemiological evidence has been summarised in some detail.

Conducting robust studies to investigate gateway effects is extremely difficult. Randomised controlled trials of the impact of EC use vs no EC use on subsequent smoking uptake in groups of adolescents or young adult, never-smokers would be the most robust design, but are highly unlikely to be considered ethical. Therefore observational approaches or natural experiments have to be used.

There are three main types of evidence from observational studies. Cross-sectional designs are common; such designs can demonstrate associations but only provided limited evidence for causality. Many such studies have found that EC use is strongly associated with cigarette smoking. However, this finding provides very limited evidence about possible gateway effects as the temporal relationship (i.e. whether EC use precedes or follows cigarette use) is not clear. Many EC proponents argue that the association between EC use and tobacco smoking is supportive of a 'common liability' hypothesis, i.e. that any association between EC use and smoked tobacco product use is because adolescents and youth who use ECs are the same individuals who were at high risk of smoking. However, some studies are at least suggestive of a possible gateway effect, where associations have been found between EC use and susceptibility to smoking among never smokers. [79-81]

Cohort studies usually follow up groups of adolescents or young adult never smokers who are ever or current EC users, and compare subsequent smoking uptake. Four such studies have been reported (Table 1). [82-85] Each has found strong associations between ever-use of EC and subsequent initiation of smoking of cigarettes and other smoked tobacco products. These associations remain after controlling for potential confounding factors, such as demographic factors, susceptibility to smoking, peer and family smoking and intrapersonal factors such as impulsivity and rebelliousness.

The main criticism of these studies is that the measure used for EC use (namely 'ever-use') in three of the studies is an inadequate measure and a single or very occasional use of an EC may not be a theoretically plausible determinant of smoking initiation. The study by Wills et al

(2016) [85] however found a stronger association between 'weekly or more often' EC use and smoking initiation, suggesting this critique may be misplaced. The other criticism is that EC use may simply be a marker for a general increased risk of experimentation with psychoactive substances – the common liability hypothesis. This remains a possibility, although the adjustment for intrapersonal traits in three of the studies may have at least partially addressed this point.

Table 1: Cohort studies investigating gateway effects of e-cigarettes

Authors, setting, year	Population and follow up period	Comparison groups and outcomes	Confounding adjustment	Findings
Leventhal et al, Los Angeles, 2015 [83]	2530, 14 year old 'never smoker' students, follow up at 6 and 12 months.	EC 'ever users' vs. 'never users'. Outcome = ever smoked cigarettes, cigars or hookah.	Socio-demographics, family and peer smoking, intrapersonal factors such as impulsivity, substance use, smoking susceptibility and smoking expectancies.	2.7x (95%CI 2.0 to 3.7) increased risk (aOR) of being susceptible to smoking, aOR 11.9 (2.1 to 68.7) for using any smoked tobacco product.
Primack et al, US national study, 2015 [84]	694 (imputed sample) 16-26 year old, non-susceptible 'never smokers', follow up at 1 year	EC 'ever users' vs. 'never users'. Outcome = smoking susceptibility and ever smoked cigarettes	Socio-demographics, parental and peer smoking, intrapersonal factors such as sensation seeking.	Increased risk of progressing to becoming susceptible to smoking (aOR 8.5, 95%CI 1.3 to 57.2) or ever smoking cigarettes (aOR 8.3, 1.2 to 58.6). *
Wills et al, Hawaii, 2016 [85]	2338, 14-16 year old 'never smokers' followed for 1 year	EC 'ever use' or categories of frequency of EC of 'use' vs. 'never users'. Outcome = ever smoked at 1 year.	Demographics, family structure, parental support, and rebelliousness	2.9x (95%CI 2.0 to 4.1) increased risk (aOR) of ever smoking if EC 'ever-user' at baseline; aOR 4.1 (2.4 to 6.9) for 'at least weekly' EC user at baseline
Barrington-Trimis, California, 2016 [82]	298 'never smoking' 11th and 12th grade students (mean age 17.4 years), follow up 1-2 years (median 15.6 months) approx.	EC 'ever users' vs. 'never users'. Outcome: ever smoked cigarettes at follow up, past 30 day cigarette use at follow up.	Frequency matched demographics and adjusted for demographics, parental education, use of other tobacco products (hookah, pipe, cigars) at baseline, and social environment characteristics: peer smoking and attitudes to smoking, smoking among others living in home. Susceptibility to smoking addressed through stratified analysis.	5.5x (95% CI 2.7 to 11.2) increased risk (aOR) or smoking initiation if EC 'ever user' at baseline; aOR 9.7 (4.0 to 23.4) for non- susceptible and 2.1 (0.8 to 5.7) for susceptible 'never smokers'.

Key: aOR: adjusted odds ratio CI: confidence interval

* Used imputation to address loss to follow up. Results similar in complete case analysis.

As well as looking at whether EC use is a risk factor for smoking initiation in individuals, it is also possible to look at the overall trends in prevalence of smoking among adolescents and young adults to see if these increase or decrease following changes in EC use. Such analyses are difficult to interpret as there are multiple other possible influences on population smoking prevalence (e.g. price, other smokefree policy measures etc.) and changes may also just be a continuation of longer term trends.

An early study that raised concern came from Poland where increases in current (i.e. use in last 30 days) EC use from 5.5% (2010-11) to 29.9% (2013-14) among 15-19 year olds students, were accompanied by similar increases in current smoking from 23.9% to 38.0%. [86] However, in the US and UK, countries where there are relatively high levels of EC use, it is reassuring that the prevalence of tobacco smoking has continued to fall among schoolchildren. For example, in the US between 2011 and 2015, use of cigarettes in the last 30 days fell from around 16% to 9.3% among Grade 9-13 students, whilst over the same period use of ECs within the last 30 days increased from around 2% to 16%. A possible concern is that cigarette use appears to have plateaued between 2014 and 2015, though it is too early to say if this is a new trend. [34] There have been similar steady declines in smoking prevalence noted among 11-15 year old adolescents in the UK since around 2000. [87]

Some attribute recent smoking prevalence falls to increased use of ECs as a substitute for smoking among this age group. However, such reasoning ignores the fact that youth smoking rates have been declining for some time in the US and UK, even before EC became available. Furthermore very similar decreases in youth smoking have occurred in countries with lower uptake of ECs in this age group, such as NZ and Australia, and declines were most substantial before the widespread uptake of ECs. For example, daily smoking rates in 14-15 year old students NZ declined from 15% (2000) to 4% (2011) to 3% (2014). [88] In Australia 12-15 and 16-17 year old smoking prevalence also fell rapidly between 2000 and 2008, and more slowly from 2008-2014. [89]

The most logical population to monitor for the impact of gateway effects are older youth and young adults. Changes in this age group (positive or negative) due to any potential 'gateway' effects of earlier use of ECs will take some time to become apparent. However, in interpreting future trends in smoking in this group it will be important to note that in many jurisdictions smoking prevalence has been steadily declining in the years prior to widespread EC use. For example, smoking prevalence fell from 24% (2005) to 17% (2014) among 18-24 year olds in the US, from 33% (2001) to 23% (2013) in 16-24 year olds in the UK, and from 25% (2005/6) to 20% (2014/15) in NZ. [90-92]

Most of the position statements reviewed for this document addressed the issue of gateway effects. Neither the Public Health England (PHE) nor Royal College of Physicians (RCP) report provides any description or discussion of the evidence from longitudinal studies described above in Table 1, but both downplayed the risks of a gateway effect through EC use. For example, the PHE report focused on questioning the conceptual basis of the gateway hypothesis.[23] Both reports noted the long-term trends of declining youth smoking prevalence. The RCP report argued that because of the low prevalence of EC use among never–smoking children and adults, the impact of ECs on gateway progression to smoking is likely to be inconsequential. [24] Furthermore, the association between EC use and tobacco cigarette use in youth is likely to be due to a common liability for use of ECs and smoking. [24] Other reviews and position statements are more cautious and express concerns about whether or not ECs will have gateway effects that promote cigarette smoking, but again do not consider the evidence in any detail.[30]

In summary, the existence of gateway effects of ECs on subsequent uptake of smoked tobacco products is uncertain. Distinguishing gateway and common liability effects in cross-sectional and cohort studies is

difficult, but the four cohort studies of never-smoking youth and young adults are at least consistent with EC use increasing subsequent risk of smoking uptake. However, studies of population trends in EC use and smoking prevalence among adolescents and youth do not provide any clear evidence of a gateway effect in most jurisdictions. It is possible that EC use could result in increased uptake later among young adult populations, but there is no clear evidence yet that this is the case.

E-cigarettes and smoking cessation

Some smokers prefer cigarettes compared to other forms of nicotine delivery. [93, 94] This may be because of their superior pharmacokinetics of nicotine delivery, but also may represent positive visual cues and sensory-motor cues from smoking-hand-to-mouth actions, and pleasurable sensations from 'throat feel' of tobacco smoke.

E-cigarettes may have an advantage over other NRT cessation treatments and as substitutes for tobacco smoking, because they approximate smoking visually and behaviourally. [95-98] E-cigarettes may also be superior to NRT products as nicotine delivery devices. Studies with early devices and experienced ECs users found a significant increase in plasma nicotine within five or 10 minutes after the first puff, and salivary levels of cotinine were found to be similar to those of smokers. [98] E-cigarettes have been shown to generate an aerosol that penetrates deep into the respiratory tract, enabling experienced vapers to achieve swift nicotine absorption into the pulmonary venous circulation, equivalent to that observed with tobacco smoking. [99] A group of early studies showed that ECs were capable of reducing tobacco craving and withdrawal symptoms after an overnight period of cigarette abstinence.[70, 100, 101] Several small, early, non-randomised studies reported quit rates from EC use ranging from 22% to 49%. [102, 103]

Together, these studies suggest strong potential for ECs to be effective as a smoking cessation aid. The evidence for whether this potential is realised will now be reviewed in order of strength of evidence.

Evidence from randomised controlled trials

Two randomised controlled trials (RCTs) have found sustained smoking abstinence rates with ECs ranging from 7% to 11%. [48, 49] In 2014, a Cochrane systematic review of ECs for smoking cessation meta-analysed these two randomised controlled trials (RCTs) with a combined sample size of 662 comparing ECs delivering nicotine with placebo (non-nicotine) ECs. [50]

One trial conducted in NZ (ASCEND) included low level telephone support [48] and one from Italy recruited smokers not intending to quit. [49] Both involved first generation products with unreliable batteries and low nicotine content. In the meta-analysis, participants using an EC delivering nicotine were more likely to have ceased smoking for at least six months compared with those using placebo ECs (relative risk [RR] 2.29, 95% confidence intervals [95% CI] 1.05 to 4.96; placebo 4% versus ECs 9%). Only one trial has been published that has compared ECs to nicotine replacement patches, finding no difference in abstinence rates at six months, although a clinically important difference could not be excluded (RR 1.26, 95% CI: 0.68 to 2.34). [48] The ASCEND trial had 213/657 (32%) Maori in the sample. Subgroup analyses stratified by ethnicity (Maori vs. non-Maori) showed no significant differences in primary outcomes, suggesting ECs may be equally effective as cessation aids for Māori. [48]

In both trials, more people using ECs reduced their cigarette consumption by at least half compared with placebo ECs (RR 1.31, 95% CI 1.02 to 1.68, 2 studies; placebo 27% versus EC 36%) and NRT patch (RR 1.41, 95% CI 1.20 to 1.67).

The overall quit rates in the NZ study comparing ECs with NRT were much lower than would be expected for a clinical trial. [48] This could be explained by a range of factors, such as: the pragmatic study design; adherence to the intention-to-treat analysis; early enthusiasm to take part in an EC trial that was tempered by either receiving a poor quality product (although it was among the 'best' ECs available at the time there were several problems with it) or by ending up in the NRT control arm; and limited behavioural support received by participants.

In a recent small trial (n=48) that did not meet the inclusion criteria for the Cochrane review, researchers randomised smokers not interested in quitting to one of two types of second generation ECs or a wait-list control group who received one of the ECs after two months). [98] After two months, 35% of the participants in the two EC groups were abstinent, compared with none in the waitlist group; at 8 months, 19% of the two EC groups were abstinent, compared with 25% in the waitlist control (who by now had been vaping for 6 months).

Further trials are underway and are likely to provide much more comprehensive data on the effectivenss of ECs as cessation aids. These trials include the ASCEND2 trial (run by researchers at the National Institute for Health Innovation [NIHI], University of Auckland). This is the largest EC smoking cessation trial in the world (n=1,809) and will investigate the effectiveness of combined use of NRT and ECs using a three arm trial design (NRT patches vs NRT patches + 3rd generation nicotine-free ECs vs NRT patches + 3rd generation nicotine ECs). All participants will also receive a six-week telephone-based cessation behavioural support programme. Trial findings will be available late 2018. The STATUS trial (also run by researchers at NIHI), will seek to determine whether 737 smokers who do not appear to be benefiting from varenicline (the most effective cessation medication) early on in their quit attempt, are more likely to quit smoking for six months if their treatment is adapted by supplementing with other products (nicotine patch, bupropion, or nicotine-containing ECs), compared to remaining on varenicline alone. The trial will start recruitment in February 2017, with results expected mid-late 2019.

Cohort studies

The Kalkhoran and Glantz (2016) systematic review included 16 cohort studies comparing smoking cessation between cohorts of EC users and non-EC users in real world settings. [104] Their meta-analysis reported an odds ratio for quitting of 0.72 (95%CI 0.57 to 0.91), that is, EC users were less likely to quit smoking than non-users. However, the authors acknowledge a range of limitations in the published studies, including possible selection biases and confounding factors that might have impacted their conclusions. They note that only two of the studies included assessed the frequency or intensity of EC use, so a proportion of the EC users may have been 'once only' or 'very brief users' – a degree of use which will not plausibly result in cessation. They also note that in the context of a rapidly evolving technology, marketing and regulatory environment the relationship between EC use and quitting may change over time.

Three studies have explored the impact of frequency and/or intensity of use of EC on quitting. Biener et al (2015), in a representative sample of 695 smokers from the US, found that vapers classified as 'intensive users' (i.e. used ECs daily for at least one month) were much more likely than non-users/triers (i.e. used ECs at most once or twice) to have quit at one to two year follow-up (aOR 6.07, 95% CI 1.11-33.18). [105] Intermittent EC users (i.e. used ECs regularly, but not daily for more than one month) were not more likely to quit (aOR 0.31, 95% CI 0.04-2.80).

Brose et al (2015) compared quitting outcomes among 1,643 UK smokers of whom 348 were using ECs at baseline and 587 were using ECs at follow up. Frequency of EC use and type of EC was assessed at

follow-up only. [106] The study found a reduced likelihood of quitting among non-daily 'cigalike' users (aOR 0.35, 95%CI 0.2 to 0.6). There were non-statistically significant reductions in quitting among daily cigalike (aOR 0.74, 95%CI 0.39 to 1.42) and non-daily 'tank' users (aOR 0.70, 95%CI 0.29 1.68), and a significant increase in quitting among daily tank users (aOR 2.69, 95%CI 1.48 4.89).

Finally, Hitchman et al reported a one year follow up study of a panel of 1656 smokers and investigated quit attempts and cessation among e-cigarette users and non-users with users divided into daily and non-daily users at baseline. [107] They found that quit attempts were increased in daily (aOR 2.11 1.24–3.58) but not non-daily EC users, but quit rates were non-significantly reduced among non-daily (0.77 0.49–1.21) and daily users (0.62 0.28–1.37).

Cross-sectional studies

As mentioned above cross-sectional designs only provide limited evidence for causality. Therefore interpretation of data from such studies needs to be undertaken with care. Some studies have surveyed smoking behaviour among current vapers, [103, 108] often finding high proportions of ex-smokers. However, these studies have self-selection bias: users with a more favourable experience of ECs are more likely to complete such surveys, than those who did not. It is therefore not possible to tell from such studies the number of smokers who tried ECs but did not find them useful.

The majority of respondents to these studies report being former smokers who had used ECs daily for several months. In by far the largest study (n=19,353) 81% of respondents were former smokers (median duration of abstinence of 1 month). [77] Almost all were vaping daily (97%) and using nicotine-containing e-liquid (96.5%). Duration of EC use was longer in former smokers than current smokers (median of 11 versus 8 months, respectively), whilst a higher proportion of former smokers (56%) than current smokers (41%) were using third generation products. Fewer than 4% of the entire sample used first generation devices. Data on smoking reduction across these studies generally did not quantify the extent of reduction, but vapers who were still smoking reported currently smoking fewer cigarettes since starting vaping.

Some cross sectional studies have assessed recent quit success and previous use of ECs to explore whether e-cigarette use is associated with quitting. For example, in a nationally representative survey of 5,863 adults in the UK who smoked within the last year and tried at least once to quit, those who used an EC to try to quit were more likely to have succeeded than people who either used NRT bought over-the-counter or those who used no aid to quit for up to 6 months (adjusted Odds Ratio [aOR] 1.63, 95% CI 1.17-2.27 and aOR 1.61, 95% CI 1.19-2.18, respectively). [109] Kalkhoran and Glantz (2016) included the UK study together with two other cross-sectional studies in their systematic review and meta-analysis, but the other two studies found the opposite (EC use was associated with less successful quitting), so overall EC use was associated with less quitting in their review. [104]

Smoking reduction

The Cochrane EC review found that ECs may help smokers cut down the number of cigarettes smoked compared with placebo. [50] It is not yet known if 'dual use' (i.e using ECs but also continuing to smoke, albeit fewer cigarettes) is just a step in the process of EC-driven smoking cessation or if it may prolong the duration of what might have otherwise been a short cessation process. What is known is that cutting down the number of cigarettes smoked can be a helpful strategy towards eventually quitting altogether. [110] In a small UK study, smokers who were given an EC as part of specialist stop smoking treatment, and who failed in their attempt to quit smoking but continued to use ECs, were exposed to fewer toxicants, compared to those who continued to smoke only tobacco cigarettes, [111] suggesting short-term 'dual use'

is associated with a reduction in harm. However, epidemiological evidence suggests that the reduction in risk of adverse health outcomes in the longer term that results from cutting down is much less than quitting completely. [22] Therefore, quitting smoking should always be the primary aim in smoking cessation practice, and in outcome measure in studies of effectiveness of potential smoking cessation interventions like ECs. A recent NICE review of the impact of reducing the number of cigarettes smoked, attributed no health benefits from cutting down other than a possible increased likelihood of quitting. [112]

Conclusions on e-cigarette use and smoking cessation

The evidence from the two available clinical trials and from observational studies suggests that ECs may be effective as cessation aids when used as a smoking cessation intervention. Hopefully further trial evidence will be available soon. The evidence for the effectiveness of ECs in supporting cessation in real-world settings (e.g. where use is initiated by the smoker) is uncertain. The overall finding from a recent review[104] that EC use is not associated with increased quitting, and may even be associated with reduced cessation, is concerning though there are methodolgical issues with the evidence and its interpretation is contested. In contrast, the finding that in two out of three prospective studies where it has been examined, more intensive EC use was associated with increased quit rates, and that use of third generation products may be associated with increased quitting, is more encouraging.

Cross-sectional and longitudinal studies have limitations in assessing whether ECs are increasing or decreasing quitting, and therefore their findings must be treated with caution, particularly as the technology changes and social and regulatory context for use changes. As noted above, studies that fail to differentiate between one-off/experimental and regular/sustained vaping are problematic. It is also difficult to ensure that comparisons are not affected by confounding factors that may influence the likelihood of outcome between EC users and non-users. For example, EC users may have a greater proportion of heavily addicted smokers who have tried numerous other measures to quit. Ideally, studies should be prospective, with information on frequency/duration of EC use, type of EC used, and reason for use. There should also be information on a broad range of potential confounding factors, such as heaviness/duration of smoking, previous quitting history, intention and motivation to quit, alcohol use, and smoking among family and friends.

On-going and careful monitoring of emerging evidence around the impact of ECs on smoking prevalence at a population level (see next section) will be important.

Impact of e-cigarettes on smoking prevalence and other population level indicators

Whatever the evidence for gateway effects and the effectiveness of ECs in supporting smoking cessation, the ultimate test for whether ECs will contribute positively to achieving Smokefree 2025 will depend on their impact on smoking prevalence and other key population level indicators. This is undoubtedly one of the most contested areas in the EC debate. Proponents argue that ECs have the potential to make a major contribution to reducing smoking prevalence, [19] and indeed some argue this will be the only effective measure to achieve radical 'endgame' goals like Smokefree 2025 in NZ. [113]

Once again the evidence in this area is limited and there are formidable methodological difficulties in evaluating the impacts of ECs at population level, not least due to the need to take into account pre-existing trends in prevalence and the possibility that findings may be affected by potential confounding factors (e.g. other concurrent smokefree interventions). The debate is unlikely to be settled promptly.

One approach to investigating the impact of ECs is to use sophisticated statistical and computational modelling. Vugrin et al (2015) have developed such a model, [114] and the BODE3 team at the University of Otago, Wellington are working on a NZ version. The Vugrin et al model simulates the effects of initiation, switching, dual use, and cessation using a hypothetical new nicotine-delivery product, on future tobacco use and mortality in a population. The authors conclude that the impacts of a new nicotine delivery product depends critically on level of long-term health risk, degree of complete substitution vs. dual use among smokers using the new product, and degree of initiation and gateway effects among never smokers. [114] Once these parameters become clearer, it should be possible to provide credible estimates of the net impact of ECs on smoking prevalence and population health.

Another recent paper has modelled the impact of EC use on smoking-related mortality, using various scenarios of EC use, transitions between smoking and EC use, and smoking uptake and cessation. The authors concluded that in most plausible scenarios, EC use would result in public health benefits and project a reduction of 21% in smoking-attributable deaths and of 20% in life years lost as a result of EC use in a 1997 US birth cohort, compared to a scenario without ECs. [115]

One approach to investigating the population impact of ECs is to determine trends in population level indicators, like smoking prevalence in relation to the prevalence of EC use. This impact could be analysed (i) within the same country (i.e. does smoking prevalence drop as EC use increases), or (ii) across countries (i.e do countries with the highest EC use have the greatest decline in smoking prevalence).

Addressing the first question, in the US, EC use has increased dramatically in recent years: ever use increasing from 1.8% (2010) to 13.0% (2013) and current use increasing from 0.3% (2010) to 6.8% (2013), with the biggest increase between 2012 and 2013, but then plateauing at 7.4% in 2014. The proportion of smokers and ex-smokers using ECs also increased most rapidly between 2012 and 2013, but was largely unchanged in 2014. [116] US adult current smoking prevalence data changed little between 2005 and 2009, but there has been a steady decline of around 0.7-0.8% per year in absolute prevalence between 2009 and 2014, with no suggestion of an increase in the decline since the big increase in EC use in 2013. [90] However, the most recent data suggest there may have been a substantial fall to 15.1% in 2015 from 16.8% in 2014 [117] Whether this is due to increased EC use is uncertain, but it is one possible explanation.

In the UK, the Smoking Toolkit Survey (available http://www.smokinginengland.info/latest-statistics/) interviews approximately 1800 respondents including around 450 smokers each month and provides excellent data on trends in smoking and EC use, and other relevant indicators from 2007 (since 2011 for ECs). This survey shows that daily EC use increased most rapidly in 2012 and 2013 (from around 3% in the last quarter of 2011 to over 10% by the end of 2013 among smokers and ex-smokers), and has grown more slowly since, to 15.5% in the first quarter of 2016. Current smoking prevalence fell from 24.2% to 20.7% between 2007 and 2011 (0.9% per year) and then from 20.7% to 18.7% between 2011 and 2015 (0.5% per year). [118] There is therefore no evidence of an increase in the rate of decline in smoking prevalence in the UK as EC use has increased. However, other data from the Smoking Toolkit Survey shows that the proportion of smokers who stopped smoking in the last 12 months increased from around 5% between 2009-2011 to over 6% between 2012 and 2015. There was also an observed increase in the proportion of quit attempts reported as successful between 2012-15, compared to previous years. Average daily consumption of cigarettes by current smokers declined steadily from 2007 to 2014, with no evidence the decline accelerating from 2012 onwards.

In Australia and NZ, there are greater constraints on the availability of ECs, and EC use is less than in the UK and US. For example, in the UK in 2014, around 12% of smokers used ECs daily and 20% reported any current use. [119] In comparison, 4% of New Zealand smokers use ECs at least monthly,[12] and current EC use among smokers in Australia is 8.9%. [36] However, recent changes in smoking NZ Zealand Health Survey fell from 18.3% (2006/7) to 16.3% (2011/12) to 15.0% (2014/15) – a decline of about 0.4% per year throughout. In Australia, daily smoking fell from 17.5% (2007) to 15.9% (2010), around 0.5% per year and then to 13.3% in 2013, a fall of around 0.9% per year. [120] These rates of decline are similar to that's seen in the UK (see above).

There are however marked disparities in smoking with far higher smoking prevalence among Aboriginal and Torres Strait Island people in Australia (47% current smokers in 2012/13) [121] and among Māori in NZ (35.5% in 2014/15). [91] Recent rates of decline in prevalence (absolute percentage decrease per year) for Aboriginal and Torres Strait Island people have been similar to the declines in overall prevalence, but trends among Māori are unclear. [7]

Evidence that the impact of ECs on reducing smoking prevalence is modest is supported by a recent analysis estimating the number of smokers who quit in the UK who would not have quit if ECs were not available as between 16,000 and 22,000. Given that there are around 8.5 million smokers in the UK, that represents an additional drop in prevalence of 0.19-0.26%. [122]

In summary, the data from four countries with many similarities in their patterns of cigarette use and smokefree activities, but differences in uptake of ECs, do not suggest that ECs have been followed by a radical acceleration of declines in smoking prevalence. Data also doesn't suggest that ECs are adversely affecting declines in smoking prevalence. There is no evidence yet to suggest that ECs will make any more than a modest (though if present, still useful) contribution to achieving Smokefree 2025.

Impact of e-cigarettes on the tobacco industry and its tactics in relation to smokefree activities and policy

In an ideal scenario for achieving Smokefree 2025, the emergence of ECs would result in the tobacco industry changing its business model to one that accepts the imminent demise of smoked tobacco, ceases smoked tobacco product manufacture, and diversifies into other products, including ECs. This change might be reflected by a change in behaviour so that the industry no longer opposes smokefree activities and policies, such as the introduction or enhancing of pictorial health warnings and increases in tobacco excise tax. The net result would be increased implementation of effective smokefree measures and reductions in smoking prevalence.

Unfortunately, there is no evidence of such a scenario eventuating either in New Zealand or elsewhere in the world. The business model espoused by the industry is to maximise growth in the combustible and non-combustible sector. For example, Imperial Tobacco has targeting growth in brands across different portfolios from premium and discount cigarettes, cigars and 'e-vapour' products. [123] The RCP report notes that although the tobacco industry seems to be embracing the opportunities for growth and profits that ECs represent, they are doing so from the viewpoint of a complementary not competing product to smoked tobacco. [24] Furthermore, tobacco industry leaders continue to emphasise that combustible products are core to profitability and growth. [24]

The tobacco industry continues to oppose smokefree interventions as vigorously as ever, as evidenced internationally by recent legal actions in Australia and the UK to try and block the implementation of plain packaging and in Uruguay to prevent the introduction of large pictorial pack warnings. Similarly in NZ the tobacco industry has made efforts to prevent plain packaging and tobacco excise tax increases. For example, in June 2016, the head of public relations for Imperial Tobacco was in New Zealand to spearhead the industry's response to the plain packaging regulations consultation, and has made threats of possible legal action in press interviews. [124]

Commentators have also questioned the intent of the tobacco industry's actions in the EC market. Since 2012 the tobacco industry has increasingly invested in the EC industry, notably through acquisitions such as blu™ by Lorilland and CN Creative (Intelicig) by BAT in 2012 and Nicocigs by PMI and E-Lites by JTI in 2013. These investments have been accompanied by the development and launch of brands such as 'Vype' (BAT) and 'Puritane' (Imperial). Initially, the tobacco industry focused on developing first generation products, [125] resulting in some questioning if this was a deliberate strategy to invest in products that were likely to be least effective for cessation. [126] However, more recently the tobacco industry has started to diversify into e-liquids used in 2nd and 3rd generation products as well. [24] The industry has aggressively marketed its EC products, often in ways that might appeal to children (e.g. use of cartoons), using highly sexual imagery and emphasising the freedom that ECs give smokers to obtain nicotine when smoking is banned (Figure 1).

Figure 1 Examples of marketing of E-cigarettes by the tobacco industry

In summary, there is no evidence yet that the tobacco industry is changing its core business model to one that focuses on growing the EC market while rapidly phasing out manufacture and sales of smoked tobacco products. The tobacco industry continues to oppose effective smokefree interventions in jurisdictions around the world, including in New Zealand.

Impact of e-cigarettes on the smokefree community and smokefree activities

E-cigarettes and debates about their place in tobacco control are an increasing feature of agenda and discourse within smokefree and tobacco control journals, conferences, and meetings between practitioners, researchers, policy-makers and advocates. This debate is appropriate – a new technology with potentially major implications for smokefree goals and possibly an important contributor to achieving the end of the tobacco epidemic should be prominent in discussions.

However, there are several ways in which ECs represent a potential threat to smokefree activities, regardless of their ultimate impact on increasing or decreasing smoking prevalence and smoking-related harms.

First, ECs could represent a distraction – diverting attention away from other equally or maybe more important smokefree interventions. Indeed, if ECs are viewed as the main or only means to achieve progress in reducing smoking prevalence, then other smokefree measures may be framed as irrelevant or unnecessary.

Second, ECs could result in disunity within the smokefree sector. One of the strengths of the tobacco control movement identified by Philip Morris's strategists in the 1990s was its unity. [127] Philip Morris's 'Project Sunrise' proposed strategies to weaken the tobacco control community by working on areas like youth access and education interventions that created the opportunity to work with 'moderate' elements of tobacco control, thus creating divisions and positioning other tobacco control groups as extreme. [127] From the tobacco industry perspective, ECs could represent an ideal vehicle to split the smokefree movement, undermine its credibility, and impair its effectiveness.

Third, if the tobacco industry is creating and producing 'harm reduction' products like ECs then it may enhance its credibility with the public, media and decision-makers. This enhanced standing may allow it to have input into and influence policy decision-making about ECs, and also smokefree interventions and policies. The RCP report describes several examples of ways in which this influence is evident. [24]

There is evidence that all of the above threats may be eventuating, and if some or all are fully realised, they could potentially have a substantial negative impact on NZ's Smokefree activities and achievement of NZ's Smokefree 2025 goal. In this scenario it seems unlikely that the negative impacts on Smokefree activities would be offset by the positive impacts (assuming the overall impact is positive) of EC use on smoking prevalence. It is therefore very important to identify EC policies and actions that all, or almost all, within the New Zealand Smokefree community can support, and this briefing assumes that this is possible. Whatever position is taken on EC policy and regulation now or in the future, maximising the unity within the Smokefree sector to ensure continued vigorous advocacy for a comprehensive smokefree strategy may be as important as the fine detail of the measures adopted to address EC use.

Potential policy approaches

Table 2 sets out the current situation in New Zealand and a series of potential options in key areas for policy and practice, including some set out in a paper recently published in the New Zealand Medical Journal. [128]

There are several key weaknesses with the current situation in NZ:

- sale of nicotine-containing EC products by NZ retailers occurs despite current legislation (so there is *de facto* availability for many people, but less so for those who are not informed, lack internet access and/or a credit card);
- there is no training for smoking cessation staff in the use of EC;
- no NZ literature is available advising smokers about the use of EC for quitting (other than an information leaflet prepared by End Smoking New Zealand [17] and advice on the New Zealand Vaping Alliance website), and
- there are no quality or health standards applied to imported ECs (although some self-regulation by the EC industry does occur).

The options are set out in Table 2 from the most (option 1) to the least restrictive (option 4) regulation of EC use, supply, and marketing. For each policy area there are many possible options, and those presented in the table could easily be expanded. Note that this table focuses on setting out a range of possible options and is not intended to imply that these are all credible or evidence-based options.

A framework that has been used to assess policy options was set out by Morestin (2012) and suggested policies should be evaluated by assessing their likely effectiveness, unintended effects, impacts on equity, cost/cost-effectiveness, feasibility and acceptability. [129] Effectiveness in this context is the balance of harms and benefits at the individual and population level, and on the tobacco industry and EC market. To this could be added an assessment of likely impact on the NZ smokefree practitioner sector and its activities.

Policy and practice will need to balance the need for bold measures that aim to realise the potential for ECs to help achieve the Smokefree 2025 goal, with the need for caution due to the current high degree of uncertainty and lack of evidence about the balance of the potential benefits and harms at individual and population level and on the tobacco industry, EC market and smokefree activity.

In addition, policy options on ECs should not be viewed in isolation from the equivalent policy for smoked tobacco products. As stated above, an important principle is that where there are regulatory measures applied to ECs, the equivalent regulatory measures for smoked tobacco products should be at least as rigorous, or there should be a commitment to working towards parity where this is not immediately practicable. There are at least three good reasons for adopting this principle.

- The philosophical reason: It seems inherently correct that the most harmful product (smoked tobacco) should be regulated at least as stringently as a less harmful product (ECs).
- By adopting this principle, the introduction or existence of restrictions on ECs may highlight gaps in restrictions for smoked tobacco products and hence help drive progress towards Smokefree 2025.
- The pragmatic reason: In almost every instance having rigorous smokefree measures is likely to increase the benefits that result from EC availability and decrease any harms. Thus the 2014 US Surgeon General's concluded that non-combustible products like ECs are much more likely to

provide public health benefits in an environment where the appeal, accessibility, promotion and use of cigarettes and other smoked tobacco products are being rapidly reduced. [130] For example, assuming that nicotine-containing ECs were eventually made available to some degree in NZ, this approach implies enhancing the appeal of and hence use of ECs as substitutes for those who cannot quit, reducing the risk of relapse from EC use to smoked cigarettes and the likelihood of gateway progression from ECs to smoked tobacco. [131] Similar arguments can be made with regard to other measures such as restrictions on availability (i.e. if restrictions are greater for smoked tobacco than ECs), regulation of marketing, and product modifications like the removal of additives and mandating very low nicotine cigarettes.

Table 2. Current New Zealand e-cigarette policy and proposed policy options

Current New Zealand policy [1]	**Option 1 (Most restrictive)**	**Option 2**	**Option 3**	**Option 4 (Least restrictive)**	**Notes**
Supply and availability					
Nicotine containing ECs and E-liquids cannot legally be sold, but can be imported for personal use. Nicotine-free ECs can be sold with no restrictions e.g. no minimum age of purchase for nicotine-free ECs unless they look like smoked tobacco products or can be used to simulate smoking, no licence required to sell nicotine-free EC.	Allow supply of nicotine containing ECs through pharmacies only. Tighten and police restrictions on internet purchase.	Make nicotine containing ECs available at highly restricted outlets, i.e. through pharmacies and licensed specialist vape shops with all staff trained in smoking cessation ABC, and children excluded. Proximity restrictions to schools. Internet purchase allowed as now.	Make nicotine containing ECs available with limited restrictions (e.g. allowed in all shops but not within 1km of schools). No license required to sell Internet purchase allowed as now.	Fully liberalise and allow nicotine-containing EC availability and sale with minimal restrictions. No license required to sell. Internet purchase allowed as now.	Restrictions for cigarettes and smoked tobacco should be equivalent or ideally more strict. Advantage of making available through pharmacies is that information and advice to support quitting could be easily provided, and policing of restrictions on sales to minors easier. However, pharmacy staff much less skilled in use of ECs. Advantage of using specialist vape shops is that staff are skilled in personalising devices and liquids to needs of users, they could police restrictions on sales to
	Introduce minimum age of purchase of 18 years for all EC sales - exceptions for minors who already smoke, where a health	As for option 1.	As for option 1.	As for options 1-3 but introduce minimum age of purchase of 16 years.	

	professional states use is for quitting under supervision.				minors, and easily be upskilled in ABC. Licensing facilitates monitoring of supply and enforcement of any restrictions (e.g. sales to minors).
Product design/standards/approval/flavours					
No specific standards, but have been proposed in both NZ [17] and internationally [18]	Products only allowed if approved for use by MedSafe as a smoking cessation medicine.	Introduce comprehensive range of compulsory standards for approval for sale of nicotine-containing ECs and E-liquids relating to some or all of: child safety, manufacturing process, lack of contaminants, accuracy of nicotine concentration and content.	Introduce minimal set of compulsory standards for approval sale of nicotine-containing ECs and E-liquids	Treat as consumer product with minimal additional standards &/or voluntary standards	Medsafe approval approach likely to prevent any or very few (tobacco industry supported products are the most likely to be able to have the resources required to navigate the system) from reaching the market and hence may stifle the market and product innovation, and increase costs of ECs. [132] Extensive compulsory standards and approval may not be practicable for the NZ regulatory system due to lack of resources, unless can use assessment from

					overseas processes (e.g. FDA, EU)
	Flavourings not allowed	Partial restrictions e.g. ban flavours that are shown to appeal to children or have demonstrated health risks.		All flavours allowed	Restrictions on flavours should be same or more rigorous for tobacco products. Note, that defining and assessing whether flavours appeal to children may be complex.
Marketing, packaging and consumer information					
Marketing – no regulations apparent for EC marketing	No marketing (advertising, sponsorship etc) allowed of any nicotine-containing EC or e-liquid. Public information campaigns about potential dangers of ECs, including risks relative to smoked tobacco products.	Minimal commercial marketing of nicotine-containing EC or e-liquids e.g. product display and/or advertising allowed at point of sale only. Public information marketing targeted and/or mass media by HPA, leaflets, Quitline etc – e.g. where can	Commercial marketing of nicotine-containing EC or e-liquids allowed with some restrictions e.g. no glamourising content, no marketing that appeals to children, no marketing that claims efficacy in smoking cessation for specific products (unless consensus that	Commercial marketing of nicotine-containing EC or e-liquids allowed with no or minimal restrictions (no more than for other consumer products). Public information marketing as in option 2.	Monitoring and enforcement difficult with partial restrictions on marketing

		purchase EC, how to use to help quitting, any adverse health side-effects, relative health risks compared to smoked tobacco etc)	current trial evidence is definitive). Public information marketing as in option 2.		
Packaging - no regulations that we are aware of currently in NZ.	Rigorous packaging requirements in relation to child safety, listing of ingredients, nicotine content, and safety information. Require health warnings (e.g. regarding possible adverse health effects, no consensus that current trial evidence around effectiveness for smoking cessation is definitive) and plain packaging.	Packaging required to fulfil child safety requirements and to include safety information for use, and list of ingredients and nicotine content. No packaging that appeals to children.		No specific packaging restrictions other than those that apply for any consumer product.	Restrictions for cigarettes and smoked tobacco should be at least as strict for listing ingredients and nicotine content. Note that many NZ vape shops may have self-regulated and already have child proof containers, warnings about keeping out of reach of children and pets, advice not to drink, list ingredients etc.

Advice and support for e-cigarettes for smoking cessation					
No active support for ECs as quitting aids. No official advice to smoking cessation staff/providers about how to support smokers quitting with ECs.	Continue status quo with no support for cessation by ECs, no training of cessation staff, discourage smokers from using ECs.	Passive support for quitting using ECs through cessation services e.g. provide advice and information for smokers and cessation staff about use of ECs to quit (see UK NCSCT advice as example [133]) and training of cessation staff in use.	Active promotion of ECs for quitting, particularly in smokers who have tried and failed with established methods, or who express strong wish to use ECs. Training of cessation staff.	As for active support option, but also promote specific ECs through recommendation or prescription (would require MedSafe approval).	
Use in indoor and outdoor workplaces and public places					
Smokefree Environments Act does not ban or restrict EC use in smokefree places. Local jurisdictions and employers can add restrictions or bans on EC use to local smokefree policies (e.g. Wellington City council propose banning EC use in	ECs to be banned in all indoor workplaces and public places, in cars, and in all outdoor and other public spaces where smoking banned.	ECs to be banned in all schools, all indoor workplaces and public places, in cars, and in selected outdoor locations (areas where children predominate e.g. playgrounds, parks), allowed in other smokefree areas at local	ECs to be banned in all schools, all indoor workplaces and public places but allowed in cars and in all other outdoor areas.	EC use to be allowed in all indoor and outdoor areas at discretion of owner/Council etc).	Restrictions for cigarettes and smoked tobacco should be at least as strict – requires continued progress on SF cars, and various outdoor areas (bars, dining, entrances, malls etc) Clear signage should indicate where vaping is permitted, and these areas should be

smokefree outdoor areas).		discretion and where public consultation suggests this is acceptable.			separate to “smoking permitted” areas.
Tax for e-cigarettes					
No specific tax – GST only.	Add excise tax to nicotine containing ECs and liquids, and possibly devices. Primary aim is to increase price sufficiently to deter most experimentation by youth and young adult never smokers.	Add low rate of excise tax to nicotine containing ECs and liquid to deter use by youth and young adult never smokers, but balance with need to ensure that ECs are cheaper to use than smoked ECs to promote substitution.	Status quo	Lower GST on ECs to provide incentive for use, particularly among lower income smokers.	Accompany measures with continued above inflation increases in tobacco excise.

Recommendations

We have proposed preferred policy options regarding EC availability in NZ. In places, we have outlined more than one acceptable option to reflect varied opinions within the NZ smokefree community .

We note that these recommendations will need to be reviewed and refined as further evidence or authoritative guidance (e.g. the forthcoming FCTC COP position statement) emerges. We also note that the impact of ECs in helping achieve the Smokefree 2025 goal will be enhanced by implementing a comprehensive smokefree strategy and by adhering to the principle that where regulatory measures are applied to ECs, equivalent or more stringent regulatory measures should be in place or introduced for smoked tobacco products. Measures to ensure this principle is adhered to are included within the recommendations where relevant.

1. Supply and availability of e-cigarettes

Two preferred options are proposed drawing on consultations with members of the NZ smokefree practitioner community from the National Smokefree Working Group.

Preferred option 1 - Maintain status quo. Sale of nicotine-containing ECs or e-liquids within NZ prohibited, but legal to import for personal use (up to 3 months supply). However, it should be noted that the real status quo is that nicotine-containing EC or e-liquids have been widely available for some time in New Zealand (due to importation by users and illegal sales by retailers).

Preferre option 2 - A**llow restricted sale of nicotine-containing e-cigarettes or e-liquids.** Continue to allow the importation of nicotine-containing EC or e-liquids for personal use (up to 3 months supply) but also allow sales of nicotine-containing ECs or e-liquids e.g. through pharmacies and/or limited numbers of licensed specialist 'vape' shops (with stipulations about proximity to schools, exclusion of minors from shop, and training/competence for staff in EC technical and ABC cessation support); minimum age of purchase to be same as for smoked tobacco products. [d]

2. Smoking cessation advice and support for e-cigarettes as quitting aids

Preferred option. There is a strong consensus that smokers quitting using ECs should have access to advice and support. Cessation service providers receive resources and training in use of EC to support quitting, based, for example, on recent PHE advice. Healthcare providers should not recommend or support specific EC products unless these were licensed for cessation through MedSafe.

[d] There are precedents for restricted availability of consumer products. For example, for tobacco many jurisdictions require licenses to sell tobacco and Hungary and San Francisco have introduced strict limits on number/density of tobacco retailers. [134] For ECs In NZ the 2013 Psychoactive Substances Act introduced a requirement for a license, powers for Local Authorities to control the location of retailers and stringent on which type of retailers could sell 'party pills'. For ECs, some US jurisdictions have introduced licensing requirments for tobacco and EC retailers, proximity restrictions (e.g. for schools, residential areas) for EC shops and hookah bars, [137] and for retailers selling flavoured tobacco products and ECs. [138]

3. Marketing, packaging and consumer information

Preferred option marketing and public information. Commercial marketing of nicotine containing ECs and e-liquids products sold within NZ (if permitted) to be limited to point of sale displays regulated to avoid exposure to children and young people. Information (e.g. leaflets) giving advice to EC users trying to quit should be provided by cessation services and at point of sale. Consider mass media or targeted information campaigns to inform about availability of ECs and potential benefits and harms.

Preferred option packaging. Packaging requirements for ECs and e-liquids sold within NZ (if permitted) to include minimum standards of child safety, safety warnings (e.g. dangerous to ingest, keep away from children and pets), health warnings and Quitline information, and list of constituents. No packaging or product names would be permitted that are appealing to children and young people

4. Product design/ standards/flavours

Preferred option – Apply existing consumer protection legislation and explore introducing minimum quality and safety standards and excluding additives/flavours (e.g. those shown to be toxic or that make products appealing or palatable for children and young adults) to nicotine containing ECs and e-liquids products sold within NZ (if permitted). To be identified from review of international standards and best practice.

5. Use of e-cigarettes in indoor and outdoor workplaces and public places

Preferred option – Use of ECs to be banned in all indoor workplaces and public places (consistent with the 1990 SFE Act), all schools, in cars, and in selected outdoor locations (areas where children predominate e.g. playgrounds, parks) but allowed in other smokefree areas at local discretion and where public consultation suggests this is acceptable. Clear signage should indicate where vaping is permitted, and these areas should be separate to “smoking permitted” areas.

6. Tax and excise for cigarettes

Preferred option – Maintain status quo i.e. no additional tax or excise applied to nicotine-containing ECs and e-liquids. To be reviewed if there is evidence of substantial uptake of nicotine-containing ECs by children and young people.

7. Monitoring and research

Preferred option – Ministry of Health develops a framework for monitoring and evaluating emerging evidence on ECs, including their technological evolution and use (internationally and in NZ), and for evaluating the impact of ECs, especially on smoking prevalence in all population groups and progress towards the Smokefree 2025 goal. Use consistent, international best practice methods for measuring and monitoring EC use.

Enhanced and comprehensive smokefree activity in New Zealand

The impact of EC in helping achieve the Smokefree 2025 goal will be enhanced by implementing a comprehensive tobacco control strategy and by adhering to the principle that where regulatory measures are applied to EC, equivalent or more stringent regulatory measures should be in place or introduced for smoked tobacco products. Measures to ensure this principle is adhered to are:

Standardised Packaging: Passing of the Standardised (Plain) Packaging amendment to the Smokefree Environments Act currently before parliament.

Tobacco supply and availability: Introduction of retailer licensing and proximity to schools restrictions for smoked tobacco products, and ideally raising the age of purchase to 21 years for smoked tobacco products.

Tobacco marketing and consumer information: Intensified and targeted mass media smokefree campaigns. The list of constituents for all smoked tobacco products to be provided on the packaging.

Tobacco product regulation: Regulating the nicotine content of cigarettes to very low levels so that they are no longer addictive (or less addictive), making cigarettes unappealing to children and young people (e.g. changing the pH of the tobacco, or banning particular additives, such as menthol and sugar, and banning capsules).

Tobacco use in cars and outdoor spaces: Legislation to ban smoking in cars with children present and national legislation to ban smoking in children-focused outdoor areas such as playgrounds, sports fields and parks.

Tax on tobacco products: Continued and substantial above inflation increases in excise tax on smoked tobacco products.

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