

VAPING: *Degrees of harm*

E-cigarette and smokeless tobacco products

A narrative review of evidence



Cancer Society Auckland Northland, July 2019

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Contents

Acknowledgements.....	2
Contents.....	3
Executive Summary.....	4
Summary of key findings.....	6
Background	23
Review methods	26
Levels of evidence.....	26
Methods.....	27
Limitations.....	27
Terminology	27
Strength of evidence on key issues.....	29
How much is known about the health risks associated with vaping?	29
Vaping is less harmful than tobacco smoking.....	29
Health impacts of vaping	30
Is vaping effective in smoking cessation?	44
Effectiveness of e-cigarettes in smoking cessation.....	44
Vaping as a smoking cessation tool for Māori and Pacific.....	51
What is known about vaping among children and young people?	54
Youth tobacco smoking prevalence trends.....	54
Youth vaping prevalence and trends	56
Gateway effect of vaping to smoking	66
What are the risks and benefits of promoting vaping as a harm reduction strategy?.....	71
Vaping as a harm reduction strategy for achieving Smokefree Aotearoa 2025	71
Regulation	80
How can these findings inform responses to proposed amendments to the SFEA 1990?.....	80
Supporting smokers to switch to significantly less harmful alternatives	80
International studies discussing vaping regulation.....	81
New Zealand research and debate on e-cigarette regulation	85
Will liberalising access to ‘safer’ nicotine increase quitting?	Error! Bookmark not defined.
Ministry of Health Regulatory Impact Statement.....	90
Improving publicly available information on vaping and smokeless tobacco	96
References	99

Executive Summary

Introduction

This report of the Cancer Society Auckland Northland, reviews and summarises research evidence and policy issues on the use of vaping and smokeless tobacco products as at July 2019.

The Ministry of Health is currently reviewing the Smoke-free Environments Act 1990 (SFEA) to regulate these products. Draft legislation is expected to have its first reading during 2019.

Consultation will take place via select committee hearings. The process will result in an amendment to the SFEA.

Purpose of this report

The findings from this review are intended to inform Cancer Society and other submissions in response to the draft SFEA amendments and other related policy.

Review structure

The findings are structured in response to five questions

1. How much is known about the health risks associated with vaping?
2. Is vaping effective in smoking cessation?
3. What is known about vaping among children and young people?
4. What are the risks and benefits of promoting vaping as a harm reduction strategy (at individual and population levels)?
5. How can these findings inform responses to proposed amendments to the Smoke-free Environments Act 1990?

Context

During the last 20 years, smoking prevalence in New Zealand has been reduced from 20.1 per cent in 2006/7 to 14.9 per cent in 2017/18², but on current projections we are unlikely to meet the Smokefree 2025 goal of reducing tobacco smoking prevalence to minimal levels. Smoking continues to be the major preventable cause of cancer and cardiovascular disease in New Zealand and globally, and is known to exacerbate longstanding inequalities in health outcomes between different population groups – specifically Māori and non-Māori³; and low-income and high-income New Zealanders.

While the focus of the current regulatory review of vaping and smokeless tobacco products is on supporting adult smokers to switch to less harmful smokeless tobacco alternatives, it is important to retain a focus on all effective policy options for reducing the great harm caused by tobacco smoking. There is a need to strengthen the Smoke-free Environments Act 1990 by reducing the supply of all tobacco products. Restricting access would send a clear message that tobacco is no ordinary product. Because of its uniquely harmful and addictive nature, it should be subject to rigorous policy and regulatory approaches aiming to minimise its use and support current users to quit.

² MoH data retrieved from https://minhealthnz.shinyapps.io/nz-health-survey-2017-18-annual-data-explorer/_w_fc9a88f6/#!/explore-topics on 5 March, 2019.

³ By comparison to overall prevalence, NZHS data shows that Māori current smoking prevalence reduced from 42.1% to 33.5% between 2006/07 and 2017/08.

The Cancer Society supports strengthening the Smokefree Environments Act and investing in effective strategies to make progress on Smokefree Aotearoa 2025 goals and aspirations. These include

- **A substantial reduction in the number of retail outlets selling tobacco products**
- **Reductions in nicotine levels in cigarettes and tobacco**
- **A sinking lid on tobacco supply**
- **Tobacco-free generation policies**
- **Extending smokefree areas.**

The Ministry's review provides an opportunity to consider the place of a harm reduction approach to achieving the Smokefree 2025 goal, and within that the potential contribution of ECs to supporting smokers to quit or transition to lower harm nicotine delivery products.

Proposed principles for vaping and smokeless tobacco product regulation/policy

The following proposed principles have been developed from various sources, including a 2016 background report of the National Smokefree Working Group, and those developed by the Australian Department of Health⁴.

1. Regulation/policy should be evidence-based

- Policy and regulation should be informed by interpretations of evidence and conclusions reached by credible health and scientific agencies.
- Decisions should be consistent with good quality research evidence on the potential benefits and harms of ECs and on effective strategies for reducing smoking prevalence.
- Health claims for ECs should be rejected by health authorities in the absence of robust supporting scientific evidence to substantiate these claims.

2. Regulation/policy should contribute to achieving Smokefree Aotearoa 2025

- Policy on e-cigarettes should support the achievement of the Smokefree 2025 goal of reducing tobacco prevalence to minimal levels for all New Zealanders.
- Priority should be given to reducing smoking in Māori, Pacific, low-income and other high-prevalence groups.
- Policy should aim to maximise the benefits of supporting smokers to quit, while minimising the health risks from their use due to initiation of EC use by non-smokers (particularly children and young people) or possible gateway effects leading to smoking.
- Regulation of ECs should not be more stringent than regulatory measures in place for smoked tobacco products.
- New Zealand's current smokefree strategies and activities should be maintained, continuously improved, and intensified.

3. Precautionary approach.

- The precautionary approach acknowledges the potential risks associated with the long-term use of ECs, particularly among non-smokers, and most importantly among adolescents and young adults.
- This approach requires that regulation and policy concerning the sale and marketing of ECs should seek to minimise the risk of their uptake among non-smokers, particularly adolescents and young adults.

⁴ Retrieved from <https://beta.health.gov.au/resources/publications/principles-that-underpin-the-current-policy-and-regulatory-approach-to-e-cigarettes-in-australia> on 10 July 2019.

4. Protecting public health gains.

- Regulations and policy for ECs should be consistent with the best available evidence for how to maximise the degree to which ECs support smokers to successfully quit or transition to using them as complete substitutes for smoked tobacco products, while minimising use of ECs among non-smokers.
- The Ministry of Health should continue to monitor evidence from New Zealand and internationally on the impacts of ECs and regulatory and policy frameworks on smoking prevalence so that policy and practice can be rapidly updated in light of emerging evidence.

5. Protecting public health policy from all commercial and other vested interests related to e-cigarettes

- Parties with a commercial interest in the sale and marketing of ECs ought not to be placed in advisory positions to New Zealand Government policy or programme development in this area.

6. Complementary with jurisdictional regulation and existing health and social policy frameworks.

- Any action taken at a national or local government level for ECs supports existing health and social policy frameworks.

Summary of key findings

Preventing cancer, reducing the harm caused by tobacco smoking, and reducing inequalities in health outcomes are priorities for the Cancer Society in New Zealand. The organisation is very interested in the potential for vaping and associated products to help adult smokers to quit smoking.

While smoking prevalence among Māori and Pacific has been dropping since 2006, it remains unacceptably high, and Māori women in particular are unfairly impacted by tobacco smoking.

The Cancer Society acknowledges the commitment of many individuals and organisations who are exploring the potential of ECs to help Māori to quit, and the anecdotal reports that it can be helpful. However, this review was unable to find published evidence for effectiveness in this area.

Investment is needed in research to enable a better understanding of the potential of ECs as cessation tools for Māori. This knowledge could then be applied to improve all stop smoking services.

The findings of this review provide cause for reflection, balancing the potential benefits in helping individuals who smoke to switch to vaping, against the potential risk of increasing smoking in the population of children and young people.

Based on the findings of our review, the Cancer Society supports a precautionary approach to legislation and argues against the widespread promotion of, and access to ECs. There is emerging evidence that supports ECs being made available in a controlled manner for smokers wanting to use them for smoking cessation or as a substitute for smoking. But there is also emerging evidence that raises serious concerns about the risks to non-smokers and young people, our rangatahi. These include the potential for nicotine addiction, the impact of nicotine itself on cognitive development, and the need to protect young people's health and wellbeing from the as-yet-unknown long-term impacts of these products.

The Cancer Society has concluded that EC sales should be restricted, for example to specialist vape shops and pharmacies. The Society supports a planned process to substantially reduce the availability of smoked tobacco products by gradually removing all tobacco products from most retail outlets such as dairies, petrol stations and supermarkets.

It is a priority for the Cancer Society that children and young people are protected from online and other marketing of e-cigarette and smokeless tobacco products. There is strong international evidence that young people who start vaping are more likely to start smoking, although a causal relationship has not yet been established. Minimising access to all tobacco and vaping products for children and young people is a necessary step to protect young people from becoming smokers, and from nicotine addiction.

How much is known about the health risks associated with vaping?

Key findings

- E-cigarettes and smokeless tobacco products are less harmful than tobacco smoking
- Lack of long-term clinical data, together with rapid commercial development and product variation makes it difficult to assess health risk
- E-cigarettes deliver known carcinogens and other toxic compounds at relatively low levels
- New research suggests potential for harm to cardiovascular health
- New research has found strong associations between e-cigarette use and respiratory disorders, significant for both asthma and chronic pulmonary diseases

There is broad agreement within the tobacco control sector in New Zealand and internationally, that vaping is less harmful than smoking tobacco, but disagreement about the potential health risks and social harm associated with e-cigarettes and other smokeless tobacco products. Vaping is a recent phenomenon, and there is a lack of long-term clinical data that can be used to accurately assess population health risk.

The US National Academies of Sciences, Engineering, and Medicine (2018) concluded that

Conclusion 5-1. There is *conclusive evidence* that in addition to nicotine, most e-cigarette products contain and emit numerous potentially toxic substances.

Conclusion 5-3. There is *substantial evidence* that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible tobacco cigarettes.

Conclusion 7-1. There is *substantial evidence* that e-cigarette aerosols can induce acute endothelial cell dysfunction, although the long-term consequences and outcomes on these parameters with long-term exposure to e-cigarette aerosol are uncertain.

Conclusion 7-2. There is *substantial evidence* that components of e-cigarette aerosols can promote formation of reactive oxygen species/oxidative stress. Although this supports the biological plausibility of tissue injury and disease from long-term exposure to e-cigarette aerosols, generation of reactive oxygen species and oxidative stress induction is generally lower from e-cigarettes than from combustible tobacco cigarette smoke.

Studies investigating health risks are complicated by a wide variation in vaping products in terms of delivery mechanisms, constituents and levels of nicotine. New products are rapidly being developed and marketed. In addition, there can be considerable variation in vaping behaviour between individuals, which may increase or decrease the risk that individuals are exposed to (Goniewicz et al., 2014).

Several international review studies have raised concerns about potential health risks associated with vaping (Middlekauff, 2019). The most serious of these are related to the intake of vapour carrying ultrafine particles deep into the lungs (Glanz & Bareham, 2018). Ultrafine particles have

been implicated in **cardiovascular disease** (Pope et al., 2009). E-cigarette use has been found to be an independent risk factor for myocardial infarction (Bhatta & Glanz, 2019).

While e-cigarettes appear to be much less likely than conventional cigarettes to cause cancer, it may take years to establish whether they increase the risk of cancer. There is evidence that some products can deliver low levels of known carcinogens, including nicotine-derived nitrosamine ketone, which may increase risk of **lung cancer** even at low doses, and formaldehyde (Goniewicz et al., 2014), suggesting there may be some risk from their long-term use. E-cigarette users were found to be exposed to “toxicologically significant levels of carbonyl compounds, especially formaldehyde” by EL-Hellani and colleagues (2016).

E-cigarette use in adults has been found to be associated with **respiratory disorders**, independent of cigarette smoking, age and various physical and psychological covariates in a recent cross-sectional study. The association was described as significant for both **asthma** and **chronic pulmonary disorders** (Wills et al., 2019). Prospective studies are required to investigate this issue further.

Vaping and smoking cessation

Key findings

- The available evidence base does not definitively answer the question of whether e-cigarettes help smokers to quit
- A new clinical trial showed that e-cigarettes were more effective than some nicotine replacement products, when provided in comprehensive stop smoking programmes that included face-to-face behavioural counselling
- No evidence was found that vaping promotes smoking cessation among young people
- The majority of smokers who use ECs in New Zealand and overseas are dual users (people who both vape and smoke) who may begin vaping to quit smoking
- Qualitative research indicates that dual use enables smokers to navigate smoking restrictions and manage social norms, providing a disincentive for some smokers to quit.

Systematic reviews have found that the available evidence base is insufficient to definitively answer the question of whether e-cigarettes helped smokers to quit. Until recently, only one well-designed RCT had tested the efficacy of e-cigarettes for smoking cessation compared with other nicotine replacement therapy (NRT), and this New Zealand study found no significant difference between the two options (Bullen et al., 2013). A Cochrane review (McRobbie et al., 2014) found evidence from two trials that ECs help smokers to stop smoking long-term compared with placebo ECs, but confidence in the result was rated ‘low’ by GRADE standards. This review was later updated (Hartmann-Boyce et al., 2016). The authors’ confidence in the results was still rated ‘low’, and they noted that the long-term safety of ECs was unknown.

The US National Academies of Sciences, Engineering, and Medicine (NASEM, 2018) made the following conclusions

Conclusion 17-1. Overall, there is *limited evidence* that e-cigarettes may be effective aids to promote smoking cessation.

Conclusion 17-2. There is *moderate evidence* from randomized controlled trials that e-cigarettes with nicotine are more effective than e-cigarettes without nicotine for smoking cessation.

Conclusion 17-3. There is *insufficient evidence* from randomized controlled trials about the effectiveness of e-cigarettes as cessation aids compared with no treatment or to Food and Drug Administration–approved smoking cessation treatments.

Conclusion 17-4. While the overall evidence from observational trials is mixed, there is *moderate evidence* from observational studies that more frequent use of e-cigarettes is associated with increased likelihood of cessation.

Public Health England examined 14 systematic reviews of e-cigarettes in smoking cessation and/or reduction, all of which concluded that further RCTs are needed. Of those reviews that included a meta-analysis, two found a positive effect, four found an inconclusive effect and one found a negative effect for e-cigarette use on cessation (McNeill et al, 2018).

A review of longitudinal studies of young people (Chatterjee et al., 2016) found no evidence that vaping promotes smoking cessation among adolescents. The authors suggest that most adolescents use ECs for experimentation with tobacco rather than as a smoking cessation tool.

A recent RCT from the UK (Hajek et al., 2019) found that when e-cigarettes are used by smokers who are motivated to quit (i.e. using smoking cessation services), alongside a programme of behavioural counselling, the one-year abstinence rate was 18%, compared with 9.9% in the NRT group. Hajek and colleagues found that e-cigarette use continued for much longer than NRT in those who had quit smoking (at one year 39.5% of EC users were still vaping, compared with 4.3% of the NRT group still using the NRT product).

Qualitative research undertaken by the Health Promotion Agency⁵ on young Māori women's attitudes towards vaping, their vaping behaviour, and the relationship between smoking and vaping supported other research indicating that switching to vaping can be challenging, it takes time, and requires personal support and better information to overcome barriers.

Dual use

There is good evidence that most dual users (people who vape and smoke) begin vaping to quit smoking. As is the case with smokers attempting to quit using other methods, only a subset who use e-cigarettes succeed in quitting (Brandon et al., 2019). It is important to understand the relative frequencies with which dual use results in (i) a transition to quitting smoking; (ii) a transition back to exclusive smoking or (iii) a prolonged state of dual use. If outcome (i) predominates then dual use is not a concern. If outcome (ii) &/or (iii) predominates then a high prevalence of dual use is concerning, particularly as there is emerging evidence that ongoing dual use may not reduce exposure to smoking, or health risk (Wang et al., 2018, Osei et al., 2019).

Recent data from the New Zealand Healthy Lifestyle Survey provides an overall prevalence of current e-cigarette use (defined as those who reported using ECs 'less often than once a month' or more often) of 2.7 per cent, and among smokers or dual users, of 10.6 per cent (Oakly & Martin, 2019). Of those respondents who currently used ECs, 63.9 per cent also currently smoked tobacco.

New Zealand survey data indicate very high rates of dual use (Oakley et al., 2019), and qualitative research investigating dual use found that it enabled smokers to navigate smoking restrictions and manage social norms (Robertson et al., 2019), reducing the incentives for EC users to quit.

Monitoring the outcomes among dual users will be an important component of monitoring smoking and vaping behaviours in New Zealand.

⁵ Retrieved from <https://www.hpa.org.nz/research-library/research-publications/māori-womens-perspectives-and-experiences-with-smoking-and-vaping> on 20 June 2019.

What is known about vaping among children and young people?

Key findings

- Young people start vaping because of curiosity, peer endorsement, novelty, flavourings, industry marketing, the perception it is relatively harmless, to manage smoking restrictions and to stop smoking
- In 2017, 4% of NZ youth aged 15-17 were current smokers, and 20% of young adults aged 18-24 were regular smokers. Smoking prevalence has declined among all subgroups of Year 10 students since 2006/07, except for the years 2017 and 2018, which show a levelling off
- 2018 ASH data showed that Māori students were around five times as likely to report daily smoking as non-Māori non-Pacific students, a drop from 2017 when they were six times more likely to report daily smoking
- Young New Zealanders (14 to 15-year olds) who had ever tried vaping more than tripled between 2012 and 2016, with 27.7% of young people having ever tried vaping in 2016. Just under 2% of Year 10 students reported using e-cigarettes daily in 2018
- Data from the US and Canada indicates that 'current e-cigarette use' increased very rapidly between 2017 and 2018, associated with the introduction of high-nicotine 'podvapes' (JUUL). This coincided with an overall increase in the use of all tobacco products in school children, indicating a reversal of the long-term trend of reducing smoking prevalence
- There is strong evidence from international longitudinal studies that shows young people who use e-cigarettes are up to four times more likely to smoke tobacco within 12 months
- Canadian and US longitudinal studies suggest that vaping may be expanding the youth nicotine use market by attracting low-risk youth who would otherwise be unlikely to initiate using cigarettes

Why young people start vaping

Analysis of New Zealand Youth Insights Survey (YIS) data on e-cigarettes found that in 2014, being a current or ex-smoker was the most important predictor of ever-use of e-cigarettes in adolescents, and that young New Zealanders have been exposed to industry marketing and have responded to it. Almost two-thirds of YIS respondents cited curiosity, and about one-quarter reported peer endorsement as their motivation for first trying an e-cigarette. Among adolescent smokers, 17% cited smoking cessation, and 18% cited reduction in smoking as their motivation for trying vaping (Merry & Bullen, 2018).

International research indicates that both adults and young people are attracted to vaping by industry marketing, the prospect of reducing or quitting smoking, the novelty, the perception that it's relatively harmless and the flavourings. Vaping is used by some youth to reduce the social stigma associated with smoking, and to manage smoking restrictions (Glantz & Bareham, 2018).

New Zealand smoking prevalence in children and young people

Smoking prevalence has declined among all subgroups of youth since 2006/07, except for the years 2017 and 2018, for which ASH Year 10 data shows a levelling off in overall daily (1.9%) and regular (5%) smoking prevalence.

The Health Promotion Agency reported that in 2017, 4 per cent of youth aged 15-17 years were current smokers, and 20 per cent of young adults aged 18-24 were regular smokers.

Among male youth, daily smoking prevalence declined over the nine-year period by 8.2% among Māori and 3.6% among non-Māori youth (NZ Health Survey, 2015/16⁶).

The ASH Year 10 snapshot results for 2018 showed that Māori students were around five times as likely to report daily smoking as non-Māori non-Pacific students. This was a reduction since 2017 survey results which showed that Māori students were around six times as likely to report daily smoking.

New Zealand data on e-cigarette use in children and young people

The Ministry of Health (2018) reported that the number of young people (14- to 15-year olds) who had ever tried vaping more than tripled between 2012 and 2016, with 27.7% of young people having ever tried vaping in 2016. Among young Māori, 45.8% had ever tried vaping in 2016, compared with 22.2% of non-Māori. In 2016, 33.4% of young males, and 21.8% of young females had ever tried vaping.

In the 2018 ASH Year 10 Survey one-third of the students reported having tried an EC, but fewer than 1% of Year 10 students who never smoked reported using ECs daily. Just under 2% of Year 10 students reported using ECs daily.

Possible harms from children and adolescents using e-cigarettes and smokeless tobacco.

There are three main potential harms: (i) the potential for nicotine addiction occurs, resulting in possible long-term use of nicotine products with potential adverse effects (uncertain in extent) (II) the potential for prolonged duration use of vaping products and smokeless tobacco resulting in possible uncertain in extent) long term health effects and (iii) gateway effect to smoking.

Vaping as a gateway to tobacco smoking

The evidence from longitudinal studies clearly indicates that young people who start vaping are more likely to start smoking. This has two main proposed explanations. The first is that it may be due to a 'gateway effect' – the theory that initiation with one substance/product (in this case e-cigarettes) can increase the subsequent use of another substance/product (in this case smoked tobacco). Such an effect could occur through initial nicotine addiction with vaping progressing to smoking through positive relationships with smoking peers, reducing the perceived harm of smoking, and prompting smoking behaviours. The alternative explanation is the 'common liability' theory, whereby young people transition from vaping to tobacco smoking due to other factors that make them susceptible to both behaviours (Siddiqi et al., 2019).

The US National Academies of Sciences, Engineering, and Medicine review (2018) concluded that

Conclusion 16-1. There is *substantial evidence* that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.

Conclusion 16-2. Among youth and young adult e-cigarette users who ever use combustible tobacco cigarettes, there is *moderate evidence* that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking.

Data from the US indicates that 'current e-cigarette use' increased very rapidly between 2017 and 2018 in middle- and high-school children from 11.7 per cent to 20.8 per cent (Cullen et al., 2018). A

⁶ Ministry of Health data retrieved on 22 January 2019 from <https://minhealthnz.shinyapps.io/nz-health-survey-2015-16-annual-update/>

similar rapid increase in EC use appears to have occurred in Canada (Hammond et al., 2019) where teenage vaping rates were reported in the press⁷ as having increased substantially.

Longitudinal studies can contribute to the understanding of causal pathways, and these studies show consistent, strong associations between vaping and tobacco smoking uptake in young people. Chatterjee and colleagues (2016) reviewed four longitudinal studies that investigated the effects of e-cigarette use on the onset of tobacco smoking among adolescents and young adults (total sample $n=10,690$) and concluded that e-cigarette use in young people leads to a higher incidence of combustible cigarette smoking.

A Canadian longitudinal study (Hammond et al., 2017) investigated e-cigarette use and smoking initiation among Canadian youth using survey data from secondary school students aged 14-18 years ($n=19,130$) at baseline (2013/4) and one-year follow-up (2014/15). Youth who reported e-cigarette use in the previous 30 days at baseline were found to be more likely to initiate cigarette smoking and more likely to report having smoked daily at follow-up, even after adjustment for a range of other factors at baseline.

Another Canadian longitudinal study examined whether baseline use of e-cigarettes among a sample of never-smoking high school students ($n=9501$) predicted cigarette smoking initiation over a two-year period (Aleyan et al., 2018). The authors concluded that vaping may contribute to a new population of cigarette smokers, and is expanding the tobacco market by attracting low-risk youth who would otherwise be unlikely to initiate using cigarettes.

In their systematic review and meta-analysis of nine longitudinal studies Soneji et al., (2017) found strong and consistent evidence of an association between initial e-cigarette use and subsequent cigarette smoking initiation, as well as between past 30-day e-cigarette use and subsequent past 30-day cigarette smoking. The odds of subsequent cigarette smoking within 12 months were found to be quadrupled among e-cigarette users, after adjusting for demographic, psychosocial, and behavioural risk factors for cigarette smoking.

Serious concerns regarding the potential for non-smoking children and young people to become addicted to nicotine through vaping, and transition to smoking cigarettes, were raised by the US Surgeon General (US Department of Health and Human Services, 2018). The US Centre for Disease Control and Prevention (CDC) reported that e-cigarette use had increased exponentially in the US over the seven years to 2018 from 1.5% (220,000 students) in 2011 to 20.8% (3.05 million students) in 2018. A particularly large increase in e-cigarette use occurred in 2018, coinciding with the introduction of the podvape JUUL to the market. This increase in 2018 occurred alongside the first increase in overall tobacco product use among young people for many years, possibly representing a reversal of the decline observed in recent years (Cullen et al., 2018).

A more regulated tobacco environment and differences in how EC prevalence is reported between countries may explain why vaping in children and young people appears to be much lower in the UK (less than 2%) than in North America. Public Health England (2018) reported that e-cigarettes were attracting very few young people who had never smoked into regular use, and that they did not appear to be undermining the long-term decline in cigarette smoking among young people (McNeill et al., 2018).

⁷ Press article titled Teen vaping in Canada has taken a 'worrisome' turn – New data suggests teen smoking rates in Canada are also rising, retrieved on 16 April 2019 from <https://www.cbc.ca/news/health/health-canada-youth-teenage-vaping-smoking-hammond-1.4937593>

This conclusion is similar to the ASH interpretation of 2017 and 2018 Year 10 survey findings. However, evidence presented in this report suggests that it may be premature to equate low daily use in Year 10 students with the absence of a gateway effect. Data from these two Year 10 surveys show a levelling off of the long-term decline in youth smoking prevalence between 2017 and 2018. The research was not able to take into account the impact of mid-2018 liberalisation of sales and point-of-sale and online marketing of EC products containing nicotine (prior to this it was illegal to sell these products if they contained nicotine), or the introduction of high-nicotine podvapes to the New Zealand market in late 2018.

What are the risks and benefits of promoting vaping as a harm reduction strategy?

Key findings

- Risks and benefits can occur at both individual and population levels. At an individual level, smokers who fully switch to ECs or quit will undoubtedly benefit.
- At a population level, increasing access to ECs may be positive or negative on smoking prevalence, reducing inequalities in health outcomes, and on population health, depending on the degree of their direct adverse health impacts and the extent to which they result in increased quitting/substitution among smokers and increased smoking uptake among young people and non-smokers.
- Modelling studies that find net benefit from ECs assume that they have positive benefits on quitting and that high levels of substitution from smoking to ECs occurs, and this outweighs the potential risks of any health effects in non-smokers who use ECs and increased smoking prevalence in young people due to gateway effects.

Modelling studies investigating benefits and harms of e-cigarettes

There is a body of research investigating the benefits and harms of introducing ECs through modelling different scenarios. The assumptions underpinning current modelling scenarios, and conclusions reached, can quickly become outdated. For example, none of the modelling studies discussed in this section have accounted for the impact of relatively new, user-friendly podvapes. These and other product developments, new information about health impact, policy and other contextual changes need to be considered in reading the research.

A key New Zealand study (Petrovic-van der Deen, et al., 2019) used a computer simulation model to estimate the likely net health impact of liberalising access to e-cigarettes in New Zealand. Note, the authors used the term 'liberalising access' to mean a scenario where ECs could be purchased only from pharmacies and specialist shops, because the study began before it became legal to sell nicotine-containing ECs in NZ. It did not consider the impact of a public education campaign promoting the use of ECs for smoking cessation or the advent of podvapes. The study did take into account various known benefits of vaping as well as the known risks and based on this information concluded that the NZ population alive in 2011 was estimated to gain 236,000 extra years of healthy life over the remainder of the population's lifespan through making e-cigarettes available in specialist stores and pharmacies. The authors noted that e-cigarettes were modelled to have a much greater impact than some interventions, but that some other tobacco control interventions (the most effective being a sinking lid policy on tobacco sales) were likely to reduce smoking prevalence more than improving access to e-cigarettes.

Key to all the modelling papers that find net benefit from e-cigarettes is the assumption that they have positive benefits on quitting and that ECs are substantially less harmful to health than smoking and that high levels of substitution from smoking to ECs occurs.

What did this review find about assumptions underpinning harm reduction?

Little evidence was found that adult tobacco smokers in New Zealand are using vaping effectively as a smoking cessation tool or as a substitute for smoking, although many smokers state they intend to use vaping to quit and many vapers report that they have quit smoking successfully through vaping. Population survey data show that the great majority of vapers are dual users both in New Zealand (Oakley & Martin, 2019) and elsewhere (Lee et al., 2018). However, it is not yet clear whether dual users subsequently quit, relapse to smoking or continue to dual use long-term.

Systematic reviews of observational studies have reported mixed results on whether e-cigarette use increases quitting among smokers in the general population. There are only a small number of randomised controlled trials, but a recent UK study that ECs more effective than NRT in the context of structured, comprehensive smoking cessation services.

The published research on the health impacts of vaping is largely restricted to studies of constituents of EC vs smoked tobacco emissions and some biomarker and short-term health impact studies. These suggest that ECs will not be completely safe, but the harms of exclusive vaping are likely to be much less than continued smoking. There is no evidence available on the long-term health effects of EC use, though these are likely to be much less than for smoking tobacco products. Some recent evidence has caused concerns about long-term harms, particularly to respiratory health, especially studies suggesting ECs can adversely affect human airway cells and lungs.⁸

How can these findings inform responses to proposed amendments to the SFEA?

Key findings

- Current evidence on the long-term health impacts of vaping is insufficient to properly inform regulation in this area, and many countries are taking a more precautionary approach to regulation than is currently being proposed in New Zealand
- The Ministry of Health proposed approach has identified, but not yet addressed concerns about the need to protect children and young people from the promotion of and access to e-cigarettes and smokeless tobacco products. Specifically:
 1. The proposed approach allows for the products to be sold in dairies, supermarkets, petrol stations and other places where tobacco products are sold. Many of these venues have a poor record of restricting sales of tobacco products to under 18-year-olds.
 2. E-cigarettes and smokeless tobacco products are being successfully marketed and sold online, and are easily accessed by minors. There appear to be no proposed restrictions or monitoring of online advertising and sales, and minimal obligations placed on vaping and tobacco industries to demonstrate compliance with age restrictions.
 3. Realistic investment is needed to provide for ongoing monitoring and compliance with regulations to protect young people.
- The evidence in this report supports a very targeted approach to public information provision encouraging smokers to consider using e-cigarettes to support quitting smoking. Public campaign messages need to be assessed to ensure that they do not promote use among non-smokers, particularly children and young people.

⁸ Radio NZ interview with Dr Stuart Jones of 11 December 2018 retrieved on 19 December 2018 from <https://www.radionz.co.nz/national/programmes/ninetoon/audio/2018675067/too-many-young-people-vaping-respiratory-specialist>

E-cigarette regulations in other countries

A review of e-cigarette regulations in 68 countries (Kennedy et al., 2017) found that the most common forms of regulation were

- complete sale bans
- place of use restrictions (eg. vape-free public places)
- age-of-purchase requirements
- warning labels
- regulation of constituents of ECs/e-liquids
- advertising and promotion bans.

E-cigarette use is banned in enclosed public spaces such as bars, restaurants and other workplaces in 25 countries; 14 countries required health warning labels; and 13 regulate e-cigarette constituents and flavours. Six countries, including the UK, apply a tax to e-cigarettes. Safety standards are required in 26 countries.

Of the above components, many will be considered when the SFEA 1990 is amended to extend current coverage to vaping and smokeless tobacco products (advertising and promotion, vape-free public places, and age-of-purchase requirements). The proposed changes include the establishment of minimum safety requirements under the Hazardous Substances and New Organisms Act (HSNO).

Protections for young people

At a public forum in early April 2019, Associate Minister of Health Jenny Salesa stated that Government was taking a precautionary approach with regulation, and particularly wanted to ensure children and non-smokers did not start vaping – while supporting a switch to vaping for current smokers. Key components announced regarding the proposed legislation and approved by Cabinet at this stage were:

- Regulate like tobacco
- No sales to under 18-year-olds
- No vaping in legislated smoke-free areas
- No promotion, advertising at point of sale
- Will require annual sales data reporting
- Product safety requirements
- Regulate flavours and colours.

At the time of writing this report, no further detail was available. There seems to be very little in the Ministry's Regulatory Impact Statement (2019) that addresses the issue of protecting children and young people from the risk of becoming addicted to nicotine through experimenting with vaping. Extending coverage of the SFEA to include all vaping and smokeless tobacco products will make it illegal to sell these products to young people under the age of 18 years, but the products can easily be accessed online or in other retail outlets such as dairies, which have a poor record of restricting tobacco product sales to minors and are difficult to monitor.

A key issue relating to the promotion of ECs and smokeless tobacco products to children and young people is that of online marketing. It is clear that many New Zealanders are both impacted by online advertising, and purchase products online. Monitoring and regulation in this area does not yet appear to have been addressed.

The US Food and Drug Administration (FDA)⁹ has taken the following steps to protect children and young people from vaping. Similar measures could be considered for New Zealand.

- Measures were taken to foreclose the sale of products to minors online by working with online distributors
- Warning letters were issued to manufacturers, distributors and retailers for selling kid-friendly vape products
- Nationwide undercover investigations were carried out on vaping shops and online stores resulting in over 1300 warning letters to retailers who illegally sold products to minors
- Required manufacturers and retailers to submit plans describing how they would address the issue of minors' access to their products
- Provided guidance to the industry signalling a move to strengthen regulations and enforcement on the sale of flavoured vaping products to minors.

Improving publicly available information on vaping and smokeless tobacco

Improving publicly available information is the second of the two key aims in the Ministry's Cabinet paper on vaping and smokeless tobacco (2018), and progress has been made in this area during the time of writing this report. The Health Promotion Agency is undertaking a public campaign to provide information about vaping to quit smoking.

The evidence in this report supports a very targeted approach to public information provision, in recognition of the two very different audiences for such messages – adult smokers, and young people. Public campaign messages conveying that a product is 'relatively harmless' are important for communicating to smokers, but can easily be interpreted as 'harmless' by both young people and non-smoking adults (including parents).

Issues that are not addressed in the Ministry's preferred approach

The Ministry's preferred approach as summarised on page 35 of the 2019 Regulatory Impact Statement does not include the following measures that have been adopted in other countries:

Restrictions on sale: The Ministry's preferred approach will enable vaping and other smokeless tobacco products to be sold in any retail store; that will include dairies, service stations, and supermarkets. This approach would maximise access of smokers to vaping products and may encourage their use. However, this approach could also be problematic for several reasons, most notably because:

- Qualitative research indicates that many smokers find vaping unsatisfying (Robertson et al., 2019, Hoek et al., 2017) or difficult to master and hence require advice, support and encouragement – particularly when first start to vape. Specialist vape stores and pharmacies could provide smokers with advice and support on how to use vaping more effectively to quit or reduce smoking.
- A qualitative study¹⁰ investigating Māori women's perspectives and experiences with smoking and vaping identified a number of barriers to vaping with this group. Those who tried vaping and returned to smoking tended to do so within two weeks.

⁹US Food and Drug Administration (2019). Modifications to Compliance Policy for Certain Deemed Tobacco Products. Retrieved on 28 March 2019 from <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM633281.pdf>

¹⁰ Retrieved from <https://www.hpa.org.nz/research-library/research-publications/māori-womens-perspectives-and-experiences-with-smoking-and-vaping> on 11 June 2019.

- It is not consistent with limited evidence in this area, which suggests that vaping is most effective when used with support in the context of structured quit programmes (as are most NRT products).
- The liberalisation of access to smokeless tobacco products may normalise these products and increase use among non-smokers and young people by making them more accessible and appealing to both non-smokers and young people.

Hence, there is a strong case that to maximise the benefits of making ECs more widely available they should be sold in places which are more able to support smokers and are less likely to sell to minors. A complementary measure which could encourage smokers who can't quit to switch to vaping would be to greatly restrict the places allowed to sell smoked tobacco products to ensure that e-cigarettes are relatively more easily available to smokers than cigarettes.

Promotion and advertising: The Ministry's preference is to allow R18 stores to give away free samples, rewards and the co-packaging of products (presumably existing SFEA restrictions on marketing and sponsorship will also apply to vaping and smokeless tobacco products). Allowing product giveaways is discussed by some researchers, who argue that free sampling should be prohibited (Bhatnagar, 2017) as it could be used to promote vaping among non-smokers.

Regulation of constituents and flavours: The Ministry suggests providing for "flavours and/or colours to be prohibited in future should evidence come to light that they are being used to attract young people to vaping..." (MoH 2019, p. 35). While it could be argued that flavours are important to make the products attractive to adult smokers, there is good evidence that children and young people are attracted by flavourings such as fruit, chocolate, and bubble gum (Glantz & Bareham, 2018, Patel et al., 2016). A regulatory framework is needed to ensure that the appeal of ECs and e-liquids to children is minimised.

Restrictions on some smokeless tobacco constituents known to be toxic may be covered by HSNO requirements.

Restricting nicotine levels will be necessary in light of evidence about both the addictiveness of nicotine, data on the high levels of nicotine in some e-cigarettes and smokeless tobacco products, and evidence on its impact on cognitive development in children and young people (US Surgeon General, 2019). The European Union's Tobacco Products Directive states that nicotine-containing liquid can only be sold if the nicotine concentration does not exceed 20mg/mL.

Smoke-free environments: The SFEA allows for smoking restrictions in some public places, but there are many outdoor public places that are not yet covered. The Ministry has suggested that vaping not be allowed in legislated smokefree areas, and that guidelines will be developed for business owners, employers and local authorities to develop and implement their own policies in relation to vaping in those areas not yet covered by the Act. Placing the onus on these parties to be proactive about vaping will create public confusion. There is an opportunity to extend the coverage of the SFEA to additional public places, which will further reduce the social acceptability of tobacco smoking, and the risk that addiction to vaping becomes normalised amongst children and young people.

The Cancer Society supports making all areas designated smoke-free, vape-free, for the following reasons

1. Allowing vaping in indoor smokefree environments will expose non-users to possible health risks from exposure to vaping-related emissions. Non-users may also dislike being exposed to vapour, creating a nuisance effect.
2. Allowing vaping in these areas contributes to the 'normalisation' of nicotine product use at a societal level.
3. Allowing vaping to take place in smokefree areas may reinforce the notion that alternative nicotine product use is both acceptable and 'safe', rather than less harmful than tobacco.
4. Individuals (children, young people and non-smokers) who are curious about vaping may have their interest reinforced by seeing people vaping more frequently than at present.
5. Finally, smokers may be able to manage their nicotine addiction more easily if they are able to vape in smokefree areas, and this could undermine their motivation to quit smoking.

On the positive side, allowing vaping in some or all smokefree areas may make vaping products more attractive to smokers and therefore encourage their use for quitting or as a substitute for smoked tobacco.

Health Warning Labelling: Health warning labelling does not seem to be included in the proposed approach, but it is a feature of the e-cigarette regulation in many OECD countries including the European Union, the UK, and the US. Careful consideration of appropriate warnings and messaging on packaging is needed, consistent with messaging in public education campaigns, messaging from health professionals, Quitline and other smoking cessation services. This needs to strike a balance between educating smokers/public about the relative harms of ECs compared to smoking, the addictiveness of nicotine and the need to keep products out of the hands of children.

Consideration ought to be given to health warnings/advice about vaping in pregnancy. There is evidence from animal studies that vaping during pregnancy may be harmful to the foetus. It has been suggested that if the mother uses vaping as a way of reducing smoking during pregnancy and mistakenly increases her intake of nicotine this could be very damaging to the child (Spindel & McEvoy 2015).

Marketing of vaping as a smoking cessation aid: The Ministry notes that the Medicines Act 1981 regulates products that make a therapeutic claim (eg to support smoking cessation) and also the importation of nicotine (MoH 2019, p. 13). It is unclear how/whether this Act is being used or considered as a vehicle for placing the onus on the vaping/tobacco industry to restrict nicotine levels or meet requirements for demonstrating cessation effectiveness.

Conclusions

Health risk

The lack of long-term clinical data to enable clarity on the risks to human health caused by vaping is contributing to divided opinions about its potential harm, both in New Zealand and internationally (Gornall, 2015). It is a concern that in the absence of a solid research base, we may be inadvertently exposing New Zealanders to health risk.

There is new evidence that vaping is associated with respiratory problems and can damage the lungs; and may contribute to cardiovascular disease. E-cigarettes contain low levels of carcinogens, including formaldehyde and nicotine-derived nitrosamine ketone which may increase the risk of lung cancer even at low doses and especially with long-term EC use.

Nicotine itself is not harmless; it is highly addictive and has been found to have detrimental impacts on cognitive development in children and young people (US Surgeon General, 2018). Cardiovascular

tissue is very sensitive to nicotine and it has been found to cause an increase in blood pressure and heart rate (Bhatnagar, 2019).

There is sufficient emerging evidence of harm presented in this review to justify a precautionary approach in making these products available.

Smoking cessation

There is reason for optimism about the potential role of e-cigarettes in helping smokers to quit and reducing smoking prevalence, and hence contributing to achieving the Smokefree 2025 goal.

There is some randomised controlled trial evidence that e-cigarettes support smokers to quit, and one good quality randomised controlled trial has demonstrated vaping to be more effective than nicotine replacement therapies in the context of supported smoking cessation (Hajek et al., 2019). Population evidence of impact on quitting is less clear.

There are anecdotal reports that ECs are more acceptable to and effective for Māori smokers than other cessation tools. However, vaping is not supported by all providers of Māori smoking cessation services, and this review was unable to find evidence supporting the anecdotal reports. These claims underline the need for investment in well-designed studies that investigate the potential of vaping for reducing smoking prevalence among Māori and other priority populations, and to inform the design of cessation services.

The research brought together in this report suggests that vaping is likely to be most effective in smoking cessation when it is made available in the context of smoking cessation services or when smokers are supported by trained professionals. However, most smokers wanting to do not quit do not receive support from such services. The evidence that many smokers have difficulties with using e-cigarettes suggests that the most effective approach may be to make e-cigarettes available through specialised shops, pharmacies and smoking cessation services, where training can be provided to staff on advising smokers how to best use the products for smoking cessation. This may result in more effective use of EC products among smokers than making them widely available in dairies, supermarkets and petrol stations. It should also help minimise the use of these product by children.

Population surveys indicate that most smokers who vape continue to smoke ('dual use'). Qualitative research indicates that vaping is often used to manage nicotine addiction and navigate smoke-free restrictions. Recent research raises concerns about the potential for 're-normalising' nicotine addiction, thus creating a social environment that is not conducive to quitting smoking and may actually provide disincentives for smokers to quit. These findings support the need to restrict vaping in all smokefree areas.

Children and young people

While e-cigarettes have potential to help existing smokers to quit, there also needs to be a balance in regulation and legislation to ensure that children and non-smokers are protected.

There is widespread agreement within the tobacco control sector that e-cigarettes are not harmless, and that regulation is needed to protect children and young people from becoming addicted to nicotine through 'playing around' with these and other smokeless tobacco products. The US Surgeon General warns that nicotine exposure can disrupt the growth of brain circuits that control attention, learning and susceptibility to addiction during periods of significant brain development, such as adolescence. There is evidence that managing vaping behaviour and addiction in school children has become problematic for schools in New Zealand (Kidd, 2019) and overseas.

While ASH NZ Year 10 data shows that 'daily' e-cigarette use in 2018 was below two per cent, it is concerning that four per cent were already using e-cigarettes 'daily or weekly' at a time when the sale of nicotine-containing e-cigarettes was illegal, and high-nicotine JUUL had not yet been introduced into the New Zealand market. Furthermore, smoking prevalence in 14- to 15-year-old students actually levelled off during 2017 and 2018 after declining for many years. The Year 10 data will not have picked up any effect of the recent liberalisation of sales and point-of-sale promotion in dairies and petrol stations. Without effective regulation, monitoring and enforcement, the trend of declining smoking prevalence in young New Zealanders could be reversed, as appears to be happening in the US and Canada.

There is evidence that young people are being targeted globally with online marketing of vaping and smokeless tobacco products, which has been shown to be effective with young people even in countries where there are advertising and marketing bans. Many vaping flavourings are known to appeal to children and young people. Since the ban on sales of nicotine-containing ECs was lifted in mid-2018, there are documented instances of vaping products being given away at youth music concerts¹¹, and reports that youth radio stations in Auckland are providing vaping products as competition prizes¹². JUUL and other nicotine-containing EC products are easily available now from New Zealand outlets, and being aggressively promoted online and by specialist shops, in dairies, liquor outlets and petrol stations, while regulation of the products is still being developed.

There is growing evidence from many large, longitudinal cohort studies North America and Europe that indicate young non-smokers who vape, are three to four times more likely to go on to smoke tobacco within 12 months. Longitudinal studies are providing strong, consistent associations between e-cigarette use and subsequent smoking, though whether this is a causal link or represents 'common liability' is uncertain.

It took decades to prove causality for tobacco smoking, so inability to prove causality at this early stage is not a reason to risk a generation of young people starting smoking as a result of vaping. The potential for children and young people to become addicted to nicotine through vaping – whether or not they go on to become smokers – provides a key argument for restricting access to e-cigarettes and non-combustible tobacco products to specialist outlets, pharmacies and smoking cessation programmes. This would enable the monitoring and enforcement of regulations to protect children and young people.

Harm minimisation

There are obvious benefits for individual smokers in reducing the health risks associated with tobacco smoking. Vaping may be more appealing than nicotine replacement therapy (NRT) products and could be a more effective way of helping adult smokers to quit than other options. But the risks associated with promoting these products (as a less harmful alternative to smoking) to the whole population are likely to outweigh the benefits at a population level.

There is sufficient emerging evidence of potential long-term health risks to justify caution and a very targeted approach to promoting vaping to smokers.

¹¹ Interview with Professor Janet Hoek's on RNZ 20 Dec 2018, discussing vape giveaways at youth music concerts: <https://www.radionz.co.nz/national/programmes/ninetoon/audio/2018676434/vape-giveaways-despicable-public-health-academic>

¹² Personal communication with Health Promoter Leitu Tufuga, who has heard the promotions on youth radio (Flavour and Mai FM).

The main risk is that the message of ECs being much less harmful than smoking intended for adult smokers could be interpreted by children, young people and non-smokers as 'harmless' and their curiosity about vaping will be reinforced, further encouraging experimentation among these groups. Global tobacco and vaping industry marketing of EC products has been very effective in reaching school children through multiple platforms including social media for many years. Strong regulation, monitoring and enforcement of restrictions on marketing ECs is required to maximise protection of children and adolescents, while acknowledging the limitations of what can be achieved. The recent experience of rapid increases in JUUL use among school children following extensive marketing in the US and Canada provides a cautionary tale.

Research shows that many people who had never thought about smoking are curious about trying vaping and there is a risk that many children and non-smoking young people in New Zealand could become addicted to nicotine in a liberalised sales environment. Making ECs widely available with largely unrestricted access (allowing sales in retail settings including dairies, petrol stations and supermarkets) would improve access for smokers as an aid to quitting. However, it would also maximise youth access to ECs, risking the prospect of a new cohort of children and young people becoming addicted to nicotine, and potentially starting to smoke.

An alternative approach would be to make e-cigarettes available, but with some restrictions. This would allow sales only in specialist vape shops and pharmacies, as both stores have (or could have) staff trained in using e-cigarettes and smoking cessation. This approach could enhance the successful use of e-cigarettes by ensuring that smokers buy them at locations where they will receive expert advice about their use (which device, which strength of e-liquid etc) and support for quitting smoking. This option would greatly reduce the risk of children and young people experimenting with, becoming regular users of e-cigarettes or going on to smoke conventional cigarettes.

While the findings of this review support more restricted access to EC and smokeless tobacco products, it must be acknowledged that the New Zealand tobacco control sector is divided on these matters. There are many who believe that ECs and other smokeless tobacco products ought to be made as widely available as possible and marketed comprehensively. They argue that ECs save lives, that youth uptake is not a problem here, and that EC use in young people has not been proven to lead to tobacco smoking. Arguments are made that ECs have the potential to reduce health inequalities, based largely on anecdotal reports that Māori smokers prefer vaping to other smoking cessation approaches, and that it is more effective for them.

These claims and reports are deserving of investment in well-designed research – to test their validity and to inform the design and improve the effectiveness of stop smoking services for Māori and other priority groups.

Meanwhile, serious consideration must be given to how New Zealand protects children and young people from the risk of exposure to nicotine addiction, in any form.

E-cigarette regulation and the context of Smokefree 2025

E-cigarette regulation should not be seen as an issue in isolation. It is potentially part of the means to help achieve the Smokefree 2025 goal. As such, it is important that measures to make e-cigarettes more available for smokers to help them quit or transition away from smoking are supported by comprehensive measures to make smoked tobacco products less affordable, appealing and addictive, as was laid out in the Achieving Smokefree Aotearoa Action Plan (<https://aspire2025.org.nz/hot-topics/smokefree-action-plan/>) developed by the tobacco control

sector in 2017. Such an approach will maximise the positive impacts of e-cigarettes and accelerate progress towards achieving the Smokefree 2025 goal.

The Ministry's regulatory review provides an opportunity to strengthen the Smokefree Environments Act 1990 (SFEA), based on sound evidence. The time has come to seriously consider 'endgame strategies' such as a substantial reduction in tobacco sales outlets over time, reducing levels of nicotine in cigarettes, a sinking lid on tobacco supply, and tobacco-free generation policies to be included in amendments to the Smokefree Environments Act 1990.

Further restricting the sale of all tobacco products would enable a more supportive environment for helping smokers to switch to vaping. Specialist vape stores, pharmacies and smoking cessation services could provide smokers with advice on how to use vaping to quit or reduce smoking.

The debate on the pros and cons of vaping needs to be seen in the context of interventions known to be effective in reducing smoking prevalence, and especially among Māori. In this respect, tobacco taxation appears to be the most effective tool we have at present, as confirmed by Ernst and Young (2018) findings.

More emphasis on protecting children and young people is needed in New Zealand regulation. There is an urgent need for regulating, monitoring and enforcing restrictions on online marketing and sales that encourage children and young people to try vaping and purchase products online. This will require additional investment.

Findings from ASH Year 10 and other New Zealand surveys show low levels of current vaping in young people, but this could change very quickly unless we get the regulation and messaging right.

Background

“We have to locate, with clarity, where e-cigarettes are within the current tobacco landscape and we have to agree on larger, more profound questions regarding the social acceptance of nicotine addiction and its potential health effects. Whatever we choose to do, we have to proceed urgently, but with care, caution and responsibility, because over the next decades, our actions could impact over a billion lives.”

(Bhatnagar, 2017)

As a result of a long-term comprehensive tobacco control programme in New Zealand that began getting traction with the Smokefree Environments Act 1990, population smoking prevalence has more than halved in this country – from approximately 35 per cent in 1970 (Tobias, Cavana, & Bloomfield, 2010) to less than 15 per cent in 2017/18.¹³

New Zealand Health Survey data¹⁴ for 2016/17 shows that adult smoking rates had been declining since 2006/07 as follows:

- About 600,000 adults (15.7%) were current smokers, down from 20.1% in 2006/07.
- 35% of Māori adults were current smokers, down from 42% in 2006/07.
- 24% of Pacific adults were current smokers (not a significant change from previous years – 27% in 2006/07).

Smoking prevalence in young people has also been falling, with the Health Promotion Agency reporting that four per cent of youth aged 15-17 years are current smokers, and 20 per cent of young adults aged 18-24 are regular smokers.¹⁵

While it is encouraging that smoking prevalence continues to decline, based on current projections (van der Deen, Wilson, Blakely et al., 2016) there are real concerns within the tobacco control sector about the likelihood of reaching the Smoke-free Aotearoa 2025 target of below five per cent prevalence by 2025. There are also concerns that Māori prevalence remains much higher than non-Māori, and that longstanding inequities also remain between Pacific and other low- income groups, and high-income New Zealanders. This has fuelled support for making e-cigarettes and smokeless tobacco products more widely used as a harm reduction strategy and smoking cessation tool.

This is consistent with the *Achieving Smokefree Aotearoa by 2025* plan¹⁶ (Aspire, 2017) which identifies as a planned action “Ensure access to safe alternative nicotine-delivery products, along with complementary information and smoking cessation support”.

Patents for nicotine inhaler devices were filed throughout the 20th century starting in 1930, but early models were unlike modern e-cigarettes. Modern e-cigarettes began to be commercialised during the 1990s, and the first commercially successful e-cigarette was created in China in 2003 by

¹³ Retrieved from <https://www.health.govt.nz/publication/tier-1-statistics-2017-18-new-zealand-health-survey> on 7 February 2019.

¹⁴ Ministry of Health data retrieved on 22 January 2019 from <https://www.health.govt.nz/publication/annual-update-key-results-2016-17-new-zealand-health-survey>

¹⁵ Retrieved from <https://www.smokefree.org.nz/smoking-its-effects/facts-figures> on 7 February 2019.

¹⁶ Retrieved on 22 January 2019 from <https://aspire2025.files.wordpress.com/2017/07/asap-report-cover.jpg> Logic model is on p. 33.

Hon Lik, a 52-year-old pharmacist, inventor and smoker. E-cigarettes were introduced to Europe in 2006, and slightly later in the U.S.¹⁷

In 2008 the World Health Organization (WHO) proclaimed that it did not consider the e-cigarette to be a legitimate smoking cessation aid¹⁸ (see WHO September 19, 2008 press release [here](#).)

Philip Morris further developed e-cigarette technology during the 1990s “as part of a larger policy to keep people using recreational nicotine” and by 2014, all the major tobacco companies had entered the market (Glantz & Bareham, 2018, p. 217). Vaping is now a well-established component of the industry. The Ministry of Health (2018) has identified a lack of information about the local market for vaping, but in the USA, where the industry has been relatively free to advertise and promote their products, it was projected to reach \$10 billion by 2017 (Bhatnagar, 2016) and has grown exponentially in many countries since then. A large proportion of e-cigarette business is conducted on the internet – internationally estimated to be about 30–50 per cent of total e-cigarettes sold (Zhu et al., 2014).

The products are still relatively new to New Zealand, and vaping is a controversial issue within the New Zealand tobacco control sector and amongst academic researchers. While some believe that vaping is a key strategy in smoking cessation and harm reduction in heavily addicted populations, there is also concern about lack of solid evidence for its effectiveness in these activities. There is also concern internationally about the tobacco industry’s targeting of children and young people in some jurisdictions by using flavourings, clever packaging, and effective marketing, including online and through social media. A particular concern has been the growth in ‘podvape’ systems such as JUUL and their aggressive marketing and subsequent high-use rate among youth and young adults in the US. There is growing concern, based on data from the US and elsewhere, about the potential for this population to become nicotine-addicted, resulting in long-term use and transition from vaping to smoking.

Until recently, nicotine-containing e-cigarettes (NECs) and e-liquids were not legal for sale in New Zealand, though they could be bought online and imported for personal use. In practice, from around 2017 this restriction was not enforced, and NECs were widely available through specialist vape stores. The situation in New Zealand changed following the District Court decision (Philip Morris (NZ) Ltd v Ministry of Health [2018] NZDC4478) which determined that Philip Morris’ tobacco stick (HEETS), a Heat Not Burn (HNB) could be lawfully imported for sale, sold and distributed in New Zealand. As a result, NECs and HNBS can be legally sold here by all retailers with the same restrictions as smoked tobacco products on advertising and sales to minors. However, restrictions on marketing of NECs are difficult to enforce as determining whether they are a tobacco product can be complex.

The health impact of such products is, like vaping, not well understood, and the Ministry argues for regulatory controls to mitigate potential harm, especially in young people.

Consultation undertaken by the Ministry during 2016/17 through an online survey of 250 individuals and organisations, including 29 from vaping and tobacco industries, confirmed general agreement

¹⁷ Information on the history of e-cigarette development retrieved on 3 April 2019 from <http://www.casaa.org/historical-timeline-of-electronic-cigarettes/>

¹⁸ WHO media release dated September 19, 2008, retrieved on 3 April 2019 from <https://www.who.int/mediacentre/news/releases/2008/pr34/en/>

that vaping is less harmful than smoking tobacco, and that it may be a helpful aid in quitting smoking.

The Ministry also established the E-Cig Technical Advisory group¹⁹ (as yet no report has been issued); issued a statement on vaping and advice to cessation workers²⁰; and has a commitment to introduce a risk-proportionate regulatory framework for all nicotine/tobacco products²¹.

Cancer Society has taken a precautionary approach in its previous submissions on e-cigarettes /vaping²², and is working collaboratively with the tobacco control sector, in preparation for consultation on the draft amendment to the Smoke-free Environments Act 1990. This is expected to take place during the 2019 calendar year²³.

On 23 November 2018, Associate Minister of Health Jenny Salesa outlined changes to the SFEA in a media release and Cabinet paper *Supporting smokers to switch to significantly less harmful alternatives*. The paper outlines her proposal to better support smokers to switch to significantly less harmful alternative products through:

1. amending the Smokefree-free Environments Act 1990 to improve smokers' access to quality vaping and smokeless tobacco products, while protecting children and young people from the risks associated with them
2. improving publicly available information on vaping.

The Ministry of Health then released a Regulatory Impact Statement with the same title *Supporting smokers to switch to significantly less harmful alternatives*, in December 2018, which was revised and replaced in January 2019. This paper canvasses arguments and recommendations for the regulation of vaping and smokeless tobacco products. The Ministry argued that that improved regulation is necessary to:

- Improve the safety of vaping and smokeless tobacco products on the New Zealand market and manage any adverse effects that occur with the use of these products
- Reduce the likelihood that vaping and smokeless tobacco products, which have associated health risks (including the potential for addiction) can be accessed by children and young people.

¹⁹ Minutes of the advisory group are available here <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-and-smokeless-tobacco/electronic-cigarette-technical-expert-advisory-group>

²⁰ Advice to smoking cessation workers is available at <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-and-smokeless-tobacco>

²¹ Risk-proportionate regulatory framework commitment is available at <https://www.health.govt.nz/news-media/news-items/ministry-consider-risk-proportionate-regulation-vaping-and-heated-tobacco-products>

²² Cancer Society's 2018 position statement on e-cigarettes can be found at: <https://auckland-northland.cancernz.org.nz/assets/Positions-Statements/Position-statement-E-CIGARETTES-2018-ID-15984-230718-ID-20120.pdf>

²³ Personal communication from Leigh Sturgess, Ministry of Health, of 16 January 2019.

Review methods

The purpose of this narrative review is to summarise and critically assess the quality of research evidence on the use of vaping and smokeless tobacco products. The review is intended to inform Cancer Society and other stakeholder responses to proposed changes to the regulatory controls in the Smoke-free Environments (SFE) Act 1990. It attempts to answer the following questions.

1. How much is known about the health risks associated with vaping?
2. Is vaping effective in smoking cessation?
3. What is known about vaping among children and young people?
4. What are the risks and benefits of promoting vaping as a harm reduction strategy at both individual and population levels?
5. How can these findings inform responses to proposed amendments to the SFEA 1990?

Levels of evidence

In bringing together a range of studies to answer research questions, it is helpful to understand the strengths and weaknesses of the different types of research included. There are many different evidence hierarchies that are used, and some flexibility in the ranking of information between these hierarchies. The diagram below provides an indication of the strength of different research methodologies.

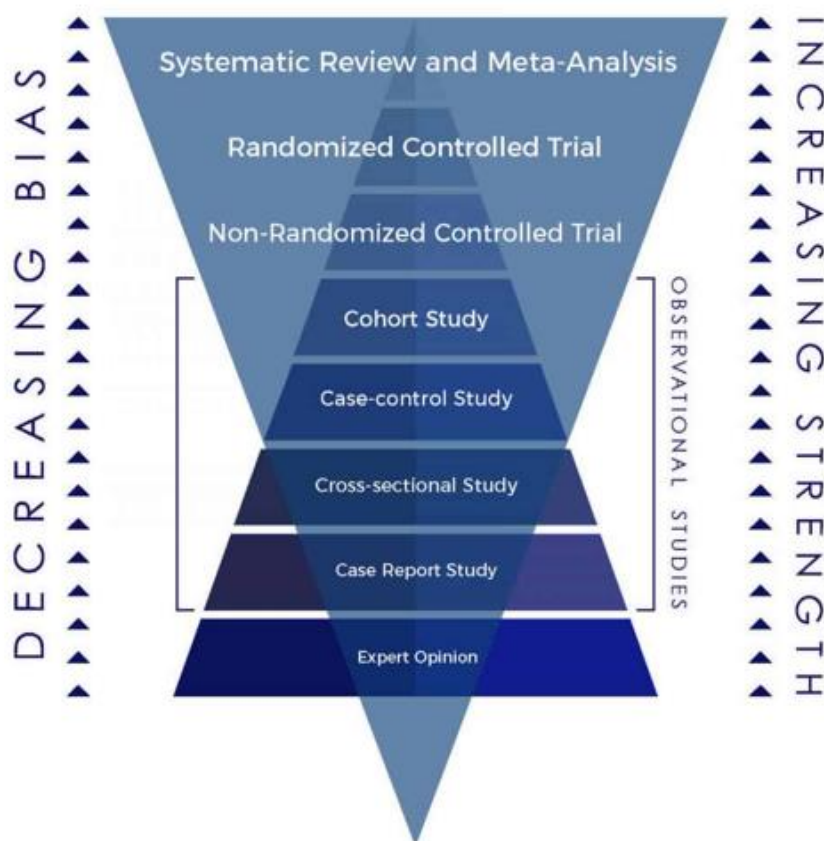


Figure 1: Hierarchy of evidence ⁽²⁴⁾.

²⁴ Developed by the International Food Information Council Foundation; retrieved on 28 May 2019 from <https://foodinsight.org/evaluating-scientific-evidence/>

Generally speaking, the higher up the hierarchy the study design is positioned, the more rigorous the methodology and hence the more likely it is that the study design can minimise the effect of bias on the results. In most evidence hierarchies current, well-designed systematic reviews and meta-analyses are at the top of the pyramid, and expert opinion and anecdotal experience are at the bottom.

This review relies primarily on the findings of systematic reviews and meta-analyses that are relevant to the five research questions. Of these the 2018 publication by the US National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes* is currently recognised as the most authoritative and thorough summary of research evidence in this area.

Methods

In this report, several major evidence reviews, systematic reviews and meta-analyses that were published since 2015 were identified from personal collections and knowledge of the review team, suggestions of experts in the field and through Google Scholar searches (a total of 13 systematic reviews of which six included meta-analyses). High-quality New Zealand and international studies including randomised controlled trials ($n=3$), longitudinal cohort ($n=7$) and cross-sectional studies ($n=19$) are the primary sources of information. Qualitative studies ($n=8$) that provide insights to the views and behaviour of adult smokers, vapers and young people are drawn from. Relevant New Zealand studies, particularly a small number investigating priority populations such as Māori and low-income groups are also discussed.

A body of material – research papers, peer-reviewed journal editorials, blogs, media reports and other written material – had already been identified through previous Cancer Society Auckland Northland Health Promotion Team searches investigating the many complex issues surrounding the production, marketing and safety of e-cigarettes. A small number of communications with stakeholders and media reports were included to provide ‘on-the-ground’ (anecdotal) information where no published material was available. Additional material was found through hand searches of review study references, and reports that are identified as significant in the 2018 Ministry of Health Cabinet Paper and 2019 Regulatory Impact Statement both titled “Supporting smokers to switch to significantly less harmful alternatives”.

Limitations

The use of Google Scholar provides somewhat limited access to research databases, and the author relied on personal contacts to access some papers. New papers relevant to this review are frequently being published. Important new work may not have been included.

Terminology

The terminology used in this report is not necessarily consistent. Researchers use a number of terms to describe smokeless tobacco products, including e-cigarettes (EC), ENDS, nicotine vaping products (NVP), vaping, smokeless tobacco, heat-not-burn (HNB) and so on.

Public Health England (2019) advises that as the technology has changed there are discussions going on in the UK and internationally to develop common terminology. A consensus had not yet been reached when the 2019 PHE report was published.

Population surveys ask different questions and use definitions particular to the survey, making it difficult to compare findings. For example, ASH Year 10 survey data collects information from NZ students on Never smoking; Regular smoking (daily, weekly, or monthly smoking); and Daily smoking (smoking at least once a day). The NZ Youth Insights Survey collects data on smoking from Year 10

students using the terms Never smoker (answered 'no' when asked if they had ever smoked); and Current smoker (smoked at least once a day, at least once a week, or at least once a month when asked how often they smoked).

Acronyms

ANDS: Alternative Nicotine Delivery Systems

AOD: Adjusted Odds Ratios

ASH: Action on Smoking and Health

CDC: Communicable Diseases Centre (US)

CI: Confidence Interval

COMPASS: COMprehensive Post-Acute Stroke Services Study

COPD: Chronic Obstructive Pulmonary Disorder

CVD: Cardiovascular Disease

EC: Electronic Cigarettes

ENDS: Electronic Nicotine Delivery Systems

EU: European Union

FDA: United States Food and Drug Administration

HNB: Heat Not Burn tobacco products such as IQOS (I Quit Ordinary Smoking)

HPA: Health Promotion Agency

HSNO: Hazardous Substances and New Organisms Act

NASEM: National Academies of Sciences, Engineering, and Medicine (US)

NEC: Nicotine-containing Electronic Cigarettes

NRT: Nicotine Replacement Therapy

NVP: Nicotine Vaping Products

NZHS: New Zealand Health Survey

NZSMS: New Zealand Smoking Monitor Survey

OR: Odds Ratio

PHE: Public Health England

RCT: Randomised Controlled Trial

RIS: Regulatory Impact Statement (Ministry of Health internal document)

SAE: Serious Adverse Events

SFEA: Smoke-Free Environments Act 1990

WHO: World Health Organisation

YIS: Youth Insights Survey (NZ)

Strength of evidence on key issues

“The field has become increasingly polarized and e-cigarettes have been the subject of many sharp, and sharply contested, debates among public health advocates. ... in the absence of relevant evidence, we cannot abandon our commitment to evidence-based policy making or offer opinions at odds with extant knowledge. Hence, for now, it might be more prudent to acknowledge ignorance...”

Bhatnagar, 2017

How much is known about the health risks associated with vaping?

Vaping is a relatively new phenomenon, and information about health effects is still emerging. In the absence of a solid evidence base, there is broad agreement that e-cigarettes are less harmful than conventional cigarettes, but disagreement between researchers and tobacco control advocates about how much safer it actually is, and whether the risks such as adverse health effects of long-term vaping and of ‘re-normalising’ nicotine addiction are outweighed by the potential benefits of helping some cigarette smokers to quit.

Evidence about what is known about health risk has been summarised in the international review studies that inform this report. Evidence from these reports has been supplemented by high-quality single studies published since those reviews were completed.

Vaping is less harmful than tobacco smoking

“It is possible/likely that e-cigarettes are safer than tobacco cigarettes but that does not mean they are without risk. The discussion as to whether e-cigarettes should be available as a commercial or regulated product needs to be based on available evidence of potential harm.”

(Larcombe et al., 2017 b.)

The evidence summarised in this report suggests widespread agreement among researchers that vaping is considerably less harmful than tobacco smoking. There is less agreement about how much less harmful it is, or rather, how safe it is, given lack of data about the longer-term impacts of vaping on human health. There is even less evidence about the health impacts of smokeless tobacco such as ‘heat-not-burn’ (HNB) products.

The 2018 Ministry of Health Cabinet paper on the topic states that “there is scientific consensus that vaping is significantly less harmful than smoking (around 95%)”.

The ‘95% less harmful’ statement originated from a 2015 report by Public Health England (PHE), and immediately became contentious, as the report (McNeill et al., 2015a) was described in print and television media at the time as a ‘landmark review’ and the 95% claim was widely reported.

A Lancet editorial the following week criticised the evidence cited in support of the claim as methodologically weak, and “made all the more perilous by the declared conflicts of interest surrounding its funding, (which) raises serious questions not only about the conclusions of the PHE report, but also about the quality of the agency’s peer review process.” (Lancet, 2015, p. 829.) In response, the PHE authors rejected any significant conflicts of interest and justified the 95% less harmful figure by arguing the importance of communicating the relative safety of e-cigarettes to the public, noting that “undermining this message will keep smokers smoking and dying as a result.” (McNeill et al., 2015b, p. 1237.)

The findings of this report were later challenged by Glantz & Bareham (2018) who reported that the 95% claim was made on the basis of a consensus meeting of 12 individuals, who reached the conclusion without citing any specific evidence, and with the caveat: “A limitation of this study is the lack of hard evidence for the harms of most products on most of the criteria...” a caveat which “has generally been ignored by those quoting this report” (Glantz & Bareham, 2018 p. 223).

The debate over the quality of evidence underpinning the 95% claim illustrates a divided research sector on both the safety of vaping, and how to responsibly communicate risk. One BMJ article discussing the PHE’s 2015 report stated that “although British organisations such as the Royal College of Physicians of London and ASH UK, have endorsed some of the report’s conclusions, albeit with caveats, many others have come to the opposite opinion. These include the British Medical Association, the UK Faculty of Public Health, the US Centers for Disease Control and Prevention, the American Lung Association, the World Health Organization, the European Commission, and other leading international health bodies. The available evidence about e-cigarettes suggests that the debate is far from over and questions remain about their benefits and harms.” (McKee & Capewell, 2015.)

Health impacts of vaping

“Widespread acceptance of these devices could renormalize the use of tobacco products and recruit a new generation of users to nicotine addiction. Therefore, further toxicological, clinical, economic, and marketing research is required to chart a clear, evidence-based pathway for alleviating the cardiovascular disease burden of tobacco products.”

(Bhatnagar, 2017.)

Introduction

In summarising the evidence on health impacts, there are two key issues.

Firstly, it is important to understand adverse health effects from vaping in relation to smoked tobacco products. Assessing relative harm is relevant for assessing the harm reduction potential of vaping. The lack of long-term health outcome data on vaping suggests it is far too early to communicate a definite figure on the safety of e-cigarettes relative to smoking tobacco.

Secondly, an understanding of how much more harmful vaping is than not vaping is important for assessing the potential for harm due to vaping uptake among non-smokers, particularly youth and young adults. Again, lack of long-term data makes this problematic. However, this section attempts to shed some light on this issue by summarising evidence that is emerging quite rapidly in response to concerns about the increasing popularity of e-cigarettes and other smokeless tobacco products especially among young people.

Review summaries

Since 2015, several good quality systematic reviews have been published that have investigated health risks associated with vaping. The most comprehensive of these recent reviews was undertaken in the US by an expert committee of the National Academies of Sciences, Engineering, and Medicine (NASEM) and published in 2018, in book form. The NASEM committee examined over 800 peer-reviewed studies, reaching 47 structured conclusions on the strength of evidence about a range of health impacts. In relation to health impact, the review found:

Constituents of e-cigarettes

Conclusion 3-1. There is *conclusive evidence* that e-cigarette use increases airborne concentrations of particulate matter and nicotine in indoor environments compared with background levels.

Conclusion 4-1. There is *conclusive evidence* that exposure to nicotine from e-cigarettes is highly variable and depends on product characteristics (including device and e-liquid characteristics) and how the device is operated.

Conclusion 5-1. There is *conclusive evidence* that in addition to nicotine, most e-cigarette products contain and emit numerous potentially toxic substances.

Conclusion 5-3. There is *substantial evidence* that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible tobacco cigarettes.

Conclusion 5-4. There is *substantial evidence* that the e-cigarette aerosol contains metals. The origin of the metals could be the metallic coil used to heat the e-liquid, other parts of the e-cigarette device, or e-liquids. Product characteristics and use patterns may contribute to differences in the actual metals and metal concentrations measured in e-cigarette aerosols.

Health effects of e-cigarettes

Conclusion 7-1. There is *substantial evidence* that e-cigarette aerosols can induce acute endothelial cell dysfunction, although the long-term consequences and outcomes on these parameters with long-term exposure to e-cigarette aerosol are uncertain.

Conclusion 7-2. There is *substantial evidence* that components of e-cigarette aerosols can promote formation of reactive oxygen species/oxidative stress. Although this supports the biological plausibility of tissue injury and disease from long-term exposure to e-cigarette aerosols, generation of reactive oxygen species and oxidative stress induction is generally lower from e-cigarettes than from combustible tobacco cigarette smoke.

Conclusion 8-1. There is *substantial evidence* that e-cigarette use results in symptoms of dependence on e-cigarettes.

Conclusion 8-2. There is *moderate evidence* that risk and severity of dependence are lower for e-cigarettes than combustible tobacco cigarettes.

Conclusion 8-3. There is *moderate evidence* that variability in e-cigarette product characteristics (nicotine concentration, flavouring, device type, and brand) is an important determinant of risk and severity of e-cigarette dependence.

Conclusion 9-1. There is *no available evidence* whether or not e-cigarette use is associated with clinical cardiovascular outcomes (coronary heart disease, stroke, and peripheral artery disease) and subclinical atherosclerosis (carotid intima-media thickness and coronary artery calcification).

Conclusion 9-2. There is *substantial evidence* that heart rate increases shortly after nicotine intake from e-cigarettes.

Conclusion 9-3. There is *moderate evidence* that diastolic blood pressure increases shortly after nicotine intake from e-cigarettes.

Conclusion 9-4. There is *limited evidence* that e-cigarette use is associated with a short-term increase in systolic blood pressure, changes in biomarkers of oxidative stress, increased endothelial dysfunction and arterial stiffness, and autonomic control.

Conclusion 10-1. There is *no available evidence* whether or not e-cigarette use is associated with intermediate cancer endpoints in humans. This holds true for comparisons of e-cigarette use compared with combustible tobacco cigarettes and e-cigarette use compared with no use of tobacco products. **Conclusion 10-1.** There is no available evidence whether or not e-cigarette use is associated with intermediate cancer endpoints in humans. This holds true for e-cigarette use compared with use of combustible tobacco cigarettes and e-cigarette use compared with no use of tobacco products.

Conclusion 10-2. There is *limited evidence* from in vivo animal studies using intermediate biomarkers of cancer to support the hypothesis that long-term e-cigarette use could increase the risk of cancer; there is no available evidence from adequate long-term animal bioassays of e-cigarette aerosol exposures to inform cancer risk.

Conclusion 10-3. There is *limited evidence* that e-cigarette aerosol can be mutagenic or cause DNA damage in humans, animal models, and human cells in culture.

Conclusion 10-4. There is *substantial evidence* that some chemicals present in e-cigarette aerosols (e.g., formaldehyde, acrolein) are capable of causing DNA damage and mutagenesis. This supports the biological plausibility that long-term exposure to e-cigarette aerosols could increase risk of cancer and adverse reproductive outcomes. Whether or not the levels of exposure are high enough to contribute to human carcinogenesis remains to be determined.

Conclusion 11-1. There is *no available evidence* whether or not e-cigarettes cause respiratory diseases in humans.

Conclusion 11-2. There is *limited evidence* for improvement in lung function and respiratory symptoms among adult smokers with asthma who switch to e-cigarettes completely or in part (dual use).

Conclusion 11-3. There is *limited evidence* for reduction of chronic obstructive pulmonary disease (COPD) exacerbations among adult smokers with COPD who switch to e-cigarettes completely or in part (dual use).

Conclusion 11-4. There is *moderate evidence* for increased cough and wheeze in adolescents who use e-cigarettes and an association with e-cigarette use and an increase in asthma exacerbations.

Conclusion 11-5. There is *limited evidence* of adverse effects of e-cigarette exposure on the respiratory system from animal and in vitro studies.

Conclusion 12-1. There is *limited evidence* suggesting that switching to e-cigarettes will improve periodontal disease in smokers.

Conclusion 12-2. There is *limited evidence* suggesting that nicotine- and non-nicotine-containing e-cigarette aerosol can adversely affect cell viability and cause cell damage of oral tissue in non-smokers.

Conclusion 13-1. There is *no available evidence* whether or not e-cigarettes affect pregnancy outcomes.

Conclusion 13-2. There is *insufficient evidence* whether or not maternal e-cigarette use affects foetal development.

Conclusion 14-1. There is *conclusive evidence* that e-cigarette devices can explode and cause burns and projectile injuries. Such risk is significantly increased when batteries are of poor quality, stored improperly or are being modified by users.

Conclusion 14-2. There is *conclusive evidence* that intentional or accidental exposure to e-liquids (from drinking, eye contact, or dermal contact) can result in adverse health effects including but not limited to seizures, anoxic brain injury, vomiting, and lactic acidosis.

Conclusion 14-3. There is *conclusive evidence* that intentionally or unintentionally drinking or injecting e-liquids can be fatal.

In their 2018 review, Public Health England (PHE) focused more on a comparison between e-cigarette and conventional tobacco smoking risk and found relatively little evidence of concern. The following is a summary of the PHE findings on e-cigarette (EC) data on health risks (McNeill et al., 2018, p. 19).

- One assessment of the published data on emissions from cigarettes and EC calculated the lifetime cancer risks. It concluded that the cancer potencies of EC were largely under 0.5% of the risk of smoking.
- Comparative risks of cardiovascular disease and lung disease have not been quantified but are likely to be also substantially below the risks of smoking. Among EC users, two studies of biomarker data for acrolein, a potent respiratory irritant, found levels consistent with non-smoking levels.
- There have been some studies with adolescents suggesting respiratory symptoms among EC experimenters. However, small scale or uncontrolled switching studies from smoking to vaping have demonstrated some respiratory improvements.
- EC can release aldehydes if e-liquids are overheated, but the overheating generates an aversive taste.
- To date, there is no clear evidence that specific flavourings pose health risks but there are suggestions that inhalation of some could be a source of preventable risks.
- To date, the levels of metals identified in EC aerosol do not give rise to any significant safety concerns, but metal emissions, however small, are unnecessary.
- Biomarkers of exposure assessed to date are consistent with significant reductions in harmful constituents and for a few biomarkers assessed in this chapter, similar levels to smokers abstaining from smoking or non-smokers were observed.
- One study showed no reductions across a range of biomarkers for dual users (either for nicotine replacement therapy or EC dual users).
- To date, there have been no identified health risks of passive vaping to bystanders.
- Reporting of some academic studies has been misleading.

The European Union (EU) commissioned a report on health risks associated with refillable e-cigarettes in 2016²⁵ which included advice on how to mitigate these risks. The report noted that

- Refillable e-cigarettes allow users to determine the e-liquid in their devices, and some blend their own e-liquid at home and may customise it. This creates risks for users and others if high concentrations of nicotine liquid are stored at home and handled inappropriately.

²⁵ Retrieved on 7 March 2019 from <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0269&qid=1551905901571&from=EN>

- Many of the flavours in use in e-liquids have not been tested for use in e-liquids and it is not known if they are safe for inhalation. There is evidence emerging that some flavours are not safe when used in e-cigarettes.
- The health risks of second-hand exposure of vapour from such self-mixed e-liquids are unknown.
- Refillable e-cigarettes may be used with illegal substances such as tetrahydrocannabinol (THC). As study of 3,847 students in the United States showed that 5.4% had used e-cigarettes to vaporise cannabis. Of those that had ever used e-cigarettes, 18% had used them to vaporise cannabis.
- In order to mitigate the risks associated with home blending or e-liquid customisation, Member States should ensure that manufacturers and importers respect the limits on nicotine concentration set by the TPD. The TPD does not allow e-liquids of concentrations higher than 20 mg/ml or in containers larger than 10 ml.
- Authorities should ensure that oils or liquids with THC or other illicit substances are not sold to consumers in Member States where they are not allowed.
- Member States should monitor notifications and conduct research on the toxicological profile of e-liquids and emissions as regards flavours and the mixing of flavours in notified products. Member States should carefully monitor evidence on the health risks of flavours, as it may be justified for Member States to prohibit certain flavours for use in e-liquids.

How harmless is nicotine?

Nicotine is a highly addictive substance that is critical in maintaining the habits of cigarette smoking and smokeless tobacco products including e-cigarettes. Public education about the relative safety of vaping needs to take account of the addictiveness of nicotine, and its impact on cognitive development in young people, and not assume that nicotine itself is harmless to health.

The 2018 NASEM report concludes the following in relation to nicotine.

Conclusion 8-3. There is *moderate evidence* that variability in e-cigarette product characteristics (nicotine concentration, flavouring, device type, and brand) is an important determinant of risk and severity of e-cigarette dependence.

Conclusion 9-2. There is *substantial evidence* that heart rate increases shortly after nicotine intake from e-cigarettes.

Conclusion 9-3. There is *moderate evidence* that diastolic blood pressure increases shortly after nicotine intake from e-cigarettes.

The 2018 Public Health England (PHE) report provides some information about nicotine and its role in maintaining dependence on tobacco smoking, but less on its potential harm in smokeless tobacco products. The report discusses the addictiveness of nicotine, which “depends on a number of factors including presence of other chemicals, speed of delivery, pH, rate of absorption, the dose, and other aspects of the nicotine delivery system, environment and behaviour. Tobacco smoking with rapid delivery of nicotine to the lungs and absorption, has been demonstrated to be highly addictive, compared with the NRT patch, for example, which has much lower dependence potential and long-term use.” (McNeill et al., 2018, p. 57.)

Concerns regarding the potential for non-smoking children and young people to become addicted to nicotine through vaping, and transition to smoking cigarettes, were raised in a 2018 US Surgeon

General Advisory report²⁶. The report described e-cigarette use among young people in the US as an ‘epidemic’ and called for immediate action to protect them. The Surgeon General concluded that e-cigarette use among young adults is of public health concern, as exposure to nicotine during adolescence can cause addiction and “nicotine exposure during adolescence can harm the developing brain ... (and) impact learning, memory and attention” (see Figure 2 below).

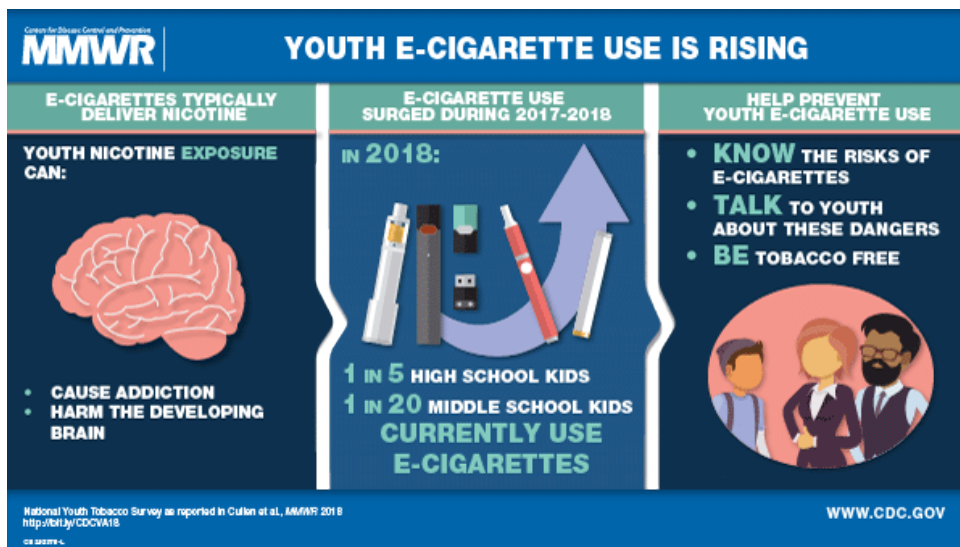


Figure 2: Youth e-cigarette use is rising. Centre for Disease Control and Prevention, 2018

The addiction of an estimated 3.6 million middle- and high-school students to vaping was discussed in a December 2018 New York Times article²⁷, which outlined parental and clinical difficulties in withdrawing children from vaping-based nicotine addiction and managing related behaviours at school.

Health impacts of Heat-Not-Burn (HNB)

Limited evidence of health impacts of HNB tobacco products was found in this review.

The 2018 Public Health England evidence review included both e-cigarettes and heated tobacco products (McNeill, Brose, Calder et al., 2018). Evidence on the ‘heat-not-burn’ (HNB) tobacco products had not been covered in previous PHE reports, and a systematic review was undertaken and summarised in the 2018 report. The report recommends that “regulations for heated tobacco products should be made at least as stringent as for e-cigarettes” (p. 11).

The PHE review included 20 studies of which 11 were funded by the manufacturer of IQOS. Key findings were reported as follows:

- In mid-2017 heated tobacco products were commercially available in 27 countries and further country launches were planned. Three tobacco manufacturers were promoting heated tobacco products: ‘IQOS’ was promoted by PMI, ‘glo’ by BAT, and ‘Ploom TECH’ by Japan Tobacco International.
- Out of 20 studies that were included in this review, 12 were funded by manufacturing companies so there is a lack of independent research.

²⁶ Retrieved on 8 January 2019 from <https://www.surgeongeneral.gov/news/2018/09/statement-on-fda-youth>

²⁷ Retrieved on 8 January 2019 from <https://www.nytimes.com/.../18/health/vaping-nicotine-teenagers.html>

- There is a variety of heated tobacco products, including some that deliver via both vapour and combustion.
- Most studies published at the time of the search for this review evaluated IQOS, none evaluated glo or Ploom TECH. An updated version of the review including later publications is in preparation to be published separately.
- In Great Britain, in 2017, awareness and ever use of heated tobacco products were very rare.
- Nicotine in mainstream aerosol from heated tobacco products reached 70%–84% of the nicotine detected in smoke from reference cigarettes.
- The tested heated tobacco products delivered more nicotine in aerosol than a cigalike EC and less nicotine than tank style EC.
- Pharmacokinetics and delivery of nicotine after single use of a heated tobacco product were generally comparable with smoking a cigarette. However, studies that compared *ad libitum* use of heated tobacco products with smoking cigarettes consistently reported lower nicotine levels in heated tobacco product users compared with smokers. Probably to compensate, smokers who were switched to using heated tobacco products adjusted their puffing behaviour.
- Heated tobacco product use reduced urges to smoke, but smokers consistently reported heated tobacco product use to be less rewarding compared with smoking a cigarette.
- Compared with cigarettes, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds (HPHC). The extent of the reduction found varies between studies.
- The limited evidence on environmental emissions from use of heated tobacco products suggests that harmful exposure from heated tobacco products is higher than from EC, but further evidence is needed to be able to compare products.
- Japan, where EC are not available, has the most diverse heated tobacco product market with three tobacco manufacturers participating. Past 30 day use for the most frequently used product increased from 0.3% in 2015 to 3.7% in 2017, suggesting rapid penetration of heated tobacco products. (McNeill et al., 2018, pp 218-219.)

A another systematic review investigating evidence on heat-not-burn tobacco products (HNB), their second-hand emissions and use by humans (Simonavicius, McNeill, Shahab, & Brose, 2018) found 31 publications on HNB second-hand emissions ($n=16$) or use by humans ($n=15$), of which 20 studies were affiliated to the tobacco industry. It was hard to draw conclusions due to study heterogeneity and affiliation with the manufacturers. The authors found that the available evidence suggested that nicotine levels in mainstream heated tobacco product aerosol are lower than those in cigarette smoke. They concluded that HNB exposed users and bystanders to toxicants, although at substantially lower levels than cigarettes.

Concerns about respiratory issues associated with vaping have been further investigated in Australian research comparing the impact of traditional and e-cigarettes with heat-not-burn (HNB) tobacco products marketed as IQOS (I Quit Ordinary Smoking), in relation to the impairment of human airway cell homeostasis (Sohal, Eapen, Naidu et al., 2019).

IQOS is available in New Zealand and since it was launched in Japan and Italy in 2014, has become the market leader for HNBs. As Philip Morris International (PMI) explains “At the heart of IQOS are sophisticated electronics that heat specially designed heated tobacco units. IQOS heats the tobacco

just enough to release a flavourful nicotine-containing tobacco vapor but without burning the tobacco.”²⁸

Sohal and colleagues (2019) exposed human lung cells *in vitro* to substances released by smoked cigarettes, EC, and IQOS, and compared the effects. They concluded that all three options were toxic to lung cells, and that the new heated tobacco devices (HNBs) were as harmful to the lungs as smoking traditional cigarettes. They acknowledged the limitations of their methodology, but suggest that “persistent allergic, smoke or environmental-triggered inflammation leads to airway remodelling/scarring through re-organisation of extra-cellular matrix and airway cell proliferation, and mitochondrial dysfunction plays a pivotal role in this process.” (Sohal et al., 2019, p. 3.) The authors note that prospective clinical studies are needed to verify their cell-based findings.

Dual Use

There is growing interest in the research literature on the dual use of e-cigarettes and tobacco smoking, as the majority of smokers who use ECs continue to smoke (Lee et al., 2018; Oakley & Martin, 2019). Dual use could be related to the quit process, as ECs can be used by smokers to reduce smoking with the intention of quitting altogether. However, there are concerns about long-term dual use, as this is likely to undermine the potential health benefits of quitting. There is a body of research that shows very limited health benefits of cutting down on smoking rather than quitting altogether, and that even smoking small numbers of cigarettes per day can increase the risk of tobacco-related disease (Oakley & Martin, 2019). There is also some evidence that ongoing dual use may be more harmful than tobacco smoking alone (Wang, Olgin, Nah et al., 2018).

In their study of dual use and risk of cardiopulmonary symptoms, Wang and colleagues (2018) performed cross-sectional analysis using baseline data from the US Health eHeart Study. Of the 39,747 adult participants, 573 (1.4%) reported e-cigarette only use, 1,693 (4.3%) reported cigarette only use, and 514 (1.3%) dual use.

Dual users, compared to cigarette-only users, reported a greater median number of cigarettes per day, a lower (worse) median general health score, and a higher (worse) median breathing difficulty score in the past month. Of the 19 cardiopulmonary symptoms/conditions, having a history of arrhythmia was significantly different between cigarette-only users (14.2%) and dual users (17.8%). In this sample, dual use was not associated with reduced exposure to either (i) cigarettes, compared to cigarette-only users or (ii) e-cigarettes, compared to e-cigarette only users. E-cigarette-only use, compared to no product use, was associated with lower general health scores, higher breathing difficulty scores (typically and past month), and greater proportions of those who responded ‘yes’ to having chest pain, palpitations, coronary heart disease, arrhythmia, COPD, and asthma.

The authors concluded that these data suggest the added use of e-cigarettes alone may have contributed to cardiopulmonary health risks; particularly respiratory health risks, and recommended that dual users are encouraged to stop using both products (Wang et al., 2018).

These findings were supported by those of Osei and colleagues (2019) who investigated the association between e-cigarette use and cardiovascular disease among never and current combustible cigarette smokers using 2016 and 2017 data from the US Behavioral Risk Factor Surveillance System, a large, nationally representative, cross-sectional telephone survey ($n=449,092$). The main exposure, e-cigarette use, was further divided into daily or occasional use,

²⁸ Retrieved from <https://www.pmi.com/smoke-free-products/iqos-our-tobacco-heating-system> on 20 February, 2019. IQOS was recently launched in New Zealand.

and stratified by combustible cigarette use (never and current). Cardiovascular disease, the main outcome, was defined as a composite of self-reported coronary heart disease, myocardial infarction, or stroke.

No significant association between e-cigarette use and cardiovascular disease was found among never combustible cigarette smokers. However, compared to current combustible cigarette smokers who never used e-cigarettes, dual use of e-cigarettes and conventional cigarettes was associated with 36% higher odds of cardiovascular disease.

Cancer risk

In their analysis of health effects of e-cigarettes, Glanz and Bareham (2018) note that discussion on this topic has mainly focused on agreement among researchers that cancer risk is likely to be significantly lower for vapers than tobacco smokers. Review studies (National Academies of Sciences, 2018; McNeill et al., 2018) support the proposition that the vapour from e-cigarettes is significantly less harmful to health than the smoke from cigarettes, and that therefore if a person switched from conventional cigarettes to e-cigarettes, exposure to toxic chemicals and related adverse health effects would be reduced.

Yet while it seems that e-cigarettes are less likely than conventional cigarettes to be carcinogenic, there is evidence that they do deliver known carcinogens, including nicotine-derived nitrosamine ketone, which may increase risk of lung cancer even at low doses. Hence, e-cigarettes could increase the risk of cancer among non-smokers.

Vapours generated from 12 models of e-cigarettes were tested for the presence of four groups of toxic compounds found in tobacco smoke by Goniewicz and colleagues (2014) who confirmed earlier findings of several toxic substances, including three carbonyls compounds – formaldehyde, acetaldehyde (in vapor exhaled) and acrolein, which have been shown to be toxic in numerous studies. Formaldehyde is classified as carcinogenic to humans; acetaldehyde as possibly carcinogenic to humans. Acrolein has been found to cause irritation to the nasal cavity, damage to the lining of the lungs and may contribute to cardiovascular disease in cigarette smokers.

The authors found that levels of toxic compounds found in the smoke from a conventional cigarette were considerably higher than those in the vapour of an EC. However, they noted that smoking an EC could result in comparable exposure to carcinogenic formaldehyde as that received from cigarette smoking. Lack of certainty about this was partly due to the difficulty of replicating the actual vaping behaviour of EC users in studies of this kind. The authors referred to studies indicating that “actual doses of toxicants inhaled by e-cigarette users might be higher than measured in our study” (Goniewicz et al., 2014, p. 8).

Exposure to toxic substances was further investigated in a population-based cohort study ($n=5,105$) comparing known tobacco-related toxicant exposure in e-cigarette (EC) users and tobacco smokers (Goniewicz, Smith, Edwards et al., 2018). This study examined 50 biomarkers associated with tobacco exposure in four current tobacco user groups: e-cigarette-only users; cigarette-only users; dual users; and never tobacco product users (reference group). Participants were mostly aged between 35 and 54 years.

Goniewicz and colleagues (2018) found that compared with exclusive EC users, never users had 19% to 81% significantly lower concentrations of biomarkers of exposure to nicotine, tobacco-specific nitrosamines (TSNAs), metals and some volatile organic compounds (VOCs). Exclusive EC users showed 10% to 98% significantly lower concentrations of biomarkers of exposure, including TSNAs, polycyclic aromatic hydrocarbons (PAHs) and nicotine compared with exclusive cigarette smokers.

Exclusive cigarette users showed 10% to 36% lower concentrations of several biomarkers than dual users. An important finding was that toxicant exposure to nearly all biomarkers was greatest among dual users, 82% of whom reported daily cigarette smoking.

The authors noted that first-generation EC products were mainly used during the timeframe covered by this research, and that their findings were consistent with these products being inefficient nicotine-delivery systems. Advances in device technology suggest that the results presented may be conservative. An example provided was that later-generation ECs had been linked to “greater yields of carbonyl compounds, including acrolein, ... formaldehyde, and acetaldehyde ...” (Goniewicz et al., 2018, p. 11).

In a study measuring nicotine concentration and other constituents from 27 e-cigarette products, EL-Hellani and colleagues (2018) found that nicotine yields varied considerably between products – a range that corresponded to the nicotine yield of less than one to more than three combustible cigarettes). Carbonyls, including the carcinogen formaldehyde, were detected in all the EC aerosols. In 15 puffs, some e-cigarette devices were found to exceed the nicotine quantities of tobacco cigarettes. Nicotine emissions varied widely across products, but carbonyl emissions showed little variations. E-cigarette users were found to be exposed to “toxicologically significant levels of carbonyl compounds, especially formaldehyde” (EL-Hellani, Salman, El-Hage et al., 2018, p. 215).

Rubenstein and colleagues (2018) investigated the presence of chemical toxicants associated with e-cigarette use among adolescents (aged 16.1 years on average): e-cigarette-only users (no cigarettes in the past 30 days; $n = 67$), dual users (use of cigarettes in the past 30 days in addition to e-cigarettes; $n = 16$), and never-using controls ($n = 20$). They found that urine excretion of metabolites of benzene, ethylene oxide, acrylonitrile, acrolein, and acrylamide was significantly higher in dual users versus e-cigarette-only users, and that excretion of metabolites of acrylonitrile, acrolein, propylene oxide, acrylamide, and crotonaldehyde were significantly higher in e-cigarette-only users compared with controls.

Many of the volatile organic compounds identified in this study are known to be carcinogenic. The authors advised that messaging to teenagers should include warnings about the potential risk from toxic exposure to carcinogenic compounds generated by vaping products (Rubenstein, Delucchi, Benowitz & Ramo, 2018).

Cardiovascular disease

No substantive evidence of an association between e-cigarette use and clinical cardiovascular outcomes was found by the US National Academies of Sciences, Engineering, and Medicine review study (2018) as summarised in their recommendation 9.1 which states “There is *no available evidence* whether or not e-cigarette use is associated with clinical cardiovascular outcomes (coronary heart disease, stroke, and peripheral artery disease) and subclinical atherosclerosis (carotid intima-media thickness and coronary artery calcification)”.

However, a more recent review of the cardiovascular impact of EC use (Middlekauffe, 2019) discussed the finding that many potentially adverse cardiovascular effects of ECs were attributable to the nicotine being inhaled. This finding was described as ‘potentially ominous’ because traditional nicotine replacement therapies are available in the form of gum and patches, and their safety profiles have suggested that nicotine itself is relatively safe even though it is addictive. Middlekauffe noted that the few inhaled NRTs available carry warnings that inhaled nicotine can cause bronchospastic disease – a warning that is not provided on patches or gum. Unlike NRTs, ECs can

become a lifelong addiction. Prolonged exposure to inhaled nicotine could expose the person to potentially dangerous cardiovascular problems.

Concern has been voiced about the specific role of nicotine in cardiovascular disease (CVD), as well as the way e-cigarettes work by “creating an aerosol of ultrafine particles to carry nicotine deep into the lungs” (Glanz & Bareham, 2018, p. 224). These particles may be smaller than those in conventional cigarettes and have themselves been implicated in CVD (Pope et al., 2009).

The emergence of e-cigarettes has revealed a gap in our knowledge about the mechanisms by which smoking affects cardiovascular health, which some argue is limiting our understanding of the potential risks associated with vaping. “We do not know how smoking accelerates atherogenesis, promotes negative tissue remodelling or triggers plaque rupture. And we have not yet identified specific cardiovascular targets of smoking or individual constituents of tobacco smoke, responsible for cardiovascular injury in smokers.” (Bhatnagar, 2017, p. 1872.)

A study of US cross-sectional data from 2014 ($n=36,697$) and 2016 ($n=33,028$) National Health Interview Surveys (Alzahrani, Pena, Temesgen, & Glantz, 2018) found that daily e-cigarette use was independently associated with increased odds of having suffered a myocardial infarction (OR = 1.79, 95% CI 1.20-2.66; $p=0.004$) after controlling for conventional cigarette smoking, demographic characteristics (age, gender, BMI, family income) and health characteristics. It should be noted that a limitation of such cross-sectional analyses is that many vapers are ex-smokers, so it is difficult to know if any observed increase in risk is due to e-cigarette use or tobacco smoking.

A more recent study based on cross-sectional analysis of US data from a nationally representative population-based longitudinal cohort study (PATH Waves 1 and 2) investigated the association between EC use and having had a myocardial infarction (MI), and whether reverse causality can explain the observed cross-sectional association between EC use and MI (Bhatta & Glantz, 2019). The study found that 69 per cent of current EC users were also smoking cigarettes, and that

- Both ECs and combustible cigarettes were independently associated with increased MI risk
- Dual use of ECs and combustible cigarettes is riskier than using either product alone and switching from combustible cigarettes to e-cigarettes is not associated with lower risk of MI than continuing to smoke; complete cessation is the only way to reduce risk of MI
- These results are unlikely because of reverse causality, where smokers who had myocardial infarctions started using ECs in an effort to quit smoking.

The authors noted the limitations of using cross-sectional (rather than longitudinal) data but concluded that ECs should not be promoted as a less risky alternative to combustible cigarettes or recommended to people with or at risk of MI for smoking cessation (Bhatta & Glantz, 2019).

Respiratory conditions

“It took us nearly five decades to understand the damaging effects of cigarette smoke and we don’t yet know the long-term impact of using e-cigarettes. These devices that heat solid tobacco are relatively new and it will be decades before we will fully understand their effects on human health.”²⁹

Dr. Sukhwinder Sohal

²⁹ Retrieved on 20 February 2019 from <https://www.unreservedmedia.com/new-research-says-e-cigarettes-still-damage-lungs/>

Neither of the two main review studies discussed in this report (Academy of Sciences 2018; McNeill et al., 2018) identified serious concerns about respiratory conditions associated with vaping. The PHE report found some studies with adolescents suggesting respiratory symptoms among EC experimenters. But they also noted that other studies had shown tobacco smokers who switched from smoking to vaping had demonstrated respiratory improvements.

However, a position statement of the Forum of International Respiratory Societies (Ferkol, Farber, La Grutta et al., 2018) identifies serious concerns about the potential impact of e-cigarettes on the respiratory systems of young people. Electronic aerosols are known to contain ultrafine particulates, volatile compounds and heavy metals including nickel, tin and lead, that can lead to lung injury and chronic respiratory symptoms in users. The authors note that flavourings that are safe to eat may be toxic when inhaled. Evidence was cited that e-cigarette inhalation leads to “pulmonary inflammation, impaired innate immunity, reduced lung function and changes consistent with chronic obstructive lung disease (emphysema) in pre-clinical animal models” (Ferkol et al., 2018, p. 3).

A 2019 position statement from the European Respiratory Society on smokeless tobacco products (such as heat-not-burn) concluded that ERS could not recommend any product damaging the lungs and human health. The paper noted that

- Two to three out of four smokers want to quit and that many smokers want to quit because they want to regain control of their life and not be addicted to nicotine
- Ex-smokers and never-smokers might be tempted to start using this ‘harmless’ product and a renormalisation of smoking in the public might occur
- Heated tobacco products, regular tobacco smoking and smokeless tobacco for oral or nasal use are all addictive and carcinogenic to humans
- We should not allow debate around the new tobacco products to distract us from the main job at hand – promoting regulatory measures that we know are effective at reducing smoking and continue to support those who wish to quit smoking.

Respiratory conditions related to vaping were investigated in a cross-sectional survey of adults ($n=8087$) using data from the Hawaii Behavioural Risk Factor Surveillance Survey (Wills, Pagano, Williams & Tam, 2019). Wills and colleagues (2019) tested “whether e-cigarette use is associated with items indexing asthma and pulmonary disorder in a representative sample aged 18 years and over, and whether e-cigarette use and combustible cigarette smoking could have synergistic effects for respiratory symptomology” (Wills et al., 2019, p. 364). E-cigarette use in adults was found to be associated with respiratory disorder, independent of cigarette smoking, age and various physical and psychological covariates. The association was described as significant for both asthma and chronic obstructive pulmonary disorder (COPD).

The data showed that significant associations between vaping and respiratory problems occurred primarily among non-smokers. Wills and colleagues argued that where e-cigarette use had begun in adolescence respiratory problems had developed from an early age. However, they noted that longitudinal research was needed to study the extent to which vaping is related to onset of symptomatology or maintenance of existing symptoms.

As noted in the 2018 PHE report, evidence has been emerging from many countries of respiratory issues among adolescents who were vaping. An example was a Hawaiian study of adolescent e-cigarette smokers which provided evidence of an elevated risk of respiratory problems, independent of cigarette smoking, marijuana use, and other covariates (Schweitzer, Wills, Tam, Pagano & Choi, 2017).

In an earlier study using results from laboratory, observational, and clinical studies, Ratajczak and colleagues (2018) synthesized data on potential respiratory health effects related to inhalation of e-cigarette aerosols. This included chemical analyses showing that e-cigarette aerosols contain numerous respiratory irritants and toxicants, and documented cytotoxic effects of e-cigarette constituents on lung tissue. Not surprisingly, studies among ex-smokers who switched to e-cigarettes found reduced exposure to respiratory toxicants, reduced asthma exacerbations and COPD symptoms. But regular exposure to e-cigarette aerosols was found to be associated with impaired respiratory functioning, and the authors argued for prospective studies and randomized controlled trials to examine the impact of e-cigarette use on lung health (Ratajczak, Feleszko, Smith, & Goniewicz, 2018).

Inflammation is considered an important factor in the development of both lung cancer and COPD. In their review of pulmonary toxicity of e-cigarettes Shields and colleagues (2017) summarized current data on pulmonary inflammation related to both smoking and vaping. They concluded that there is sufficient data about the toxicant and irritant constituents in e-cigarette aerosols to suggest a proinflammatory effect and that further investigation is needed.

The authors identified important research gaps – specifically studies investigating long-term chronic effects, noting that research to date only assessed short-term exposures and acute changes in health effects or biomarkers of recent exposures. Studies of longer clinical trials and observational cohort studies with repeated measures were needed. They argued that while the risk for an individual smoker who switches to vaping may decrease, as overall use increases population risk may also increase, especially if never smokers and former smokers take up vaping. The role of nicotine is also a factor needing closer scrutiny, as it has both pro- and anti-inflammatory potential, making it unclear how it may mediate the effects of the other aerosol constituents (Shields et al., 2017).

Maternal smoking and vaping

Maternal tobacco smoking during pregnancy is known to increase the risk of lifelong health consequences on offspring lung function, respiratory problems and asthma, but little is known about the impact of maternal e-cigarette use. The 2018 NASAM report found insufficient evidence to determine whether or not maternal e-cigarette use affects foetal development.

Animal studies examining the effects of prenatal nicotine on lung development (performed on mice, rats, sheep and monkeys) have consistently shown a measurable impact on offspring respiratory health suggesting that EC use in pregnancy could have adverse effects.

Concerned about the widespread perception that e-cigarettes are harmless, and with industry marketing in the US geared toward vulnerable populations, (those most likely to smoke or vape during pregnancy) Spindel and McEvoy (2015) decided to investigate the role of nicotine in maternal smoking during pregnancy on lung development and childhood respiratory disease, and implications for the use of e-cigarettes. They noted that e-cigarettes were capable of delivering as high or higher amounts of nicotine as conventional cigarettes, and that as they became more experienced, e-cigarette users tended to inhale higher levels of nicotine than users of conventional cigarettes.

Based on a detailed analysis of animal studies, the authors noted “a striking similarity between the effects of maternal smoking during pregnancy and the effects of prenatal nicotine exposure on offspring pulmonary function and respiratory disease” and they expressed concern that beliefs about e-cigarettes being safe “may also drive smokers to supplement cigarettes with e-cigarettes during pregnancy, thereby increasing nicotine exposure to the foetus” (Spindel & McEvoy 2015, p. 491). The authors acknowledged limitations on conclusions of this kind being made on the basis of

animal studies, but in the absence of epidemiological and other human reproductive data they made a strong case for warnings about the dangers of e-cigarette use during pregnancy.

Is vaping effective in smoking cessation?

“Vapers who use ECIGs much like NRTs, primarily as a tool for the purpose of quitting smoking as opposed to an extension of smoking or a hobby, may be more likely to attempt and eventually succeed at smoking cessation.”

Brandon et al., 2019

Effectiveness of e-cigarettes in smoking cessation

As summarised in this section, review studies investigating the effectiveness of vaping and smokeless tobacco in smoking cessation have provided limited evidence that vaping is effective in smoking cessation.

International reviews

Review studies have found limited evidence to support the belief that e-cigarettes are effective in smoking cessation. This was summarised in the comprehensive US review of the public health consequences of e-cigarettes (which included a systematic review and meta-analysis). It concluded that “existing systematic reviews consistently agreed that the available evidence base was insufficient to definitively answer the question of whether e-cigarettes helped smokers to quit. They uniformly identified the urgent need for additional studies of high scientific quality, especially RCTs” (National Academies of Sciences, Engineering, and Medicine, 2018, p. 576). The following conclusions were made in relation to the effectiveness of e-cigarettes in smoking cessation.

Conclusion 17-1. Overall, there is *limited evidence* that e-cigarettes may be effective aids to promote smoking cessation.

Conclusion 17-2. There is *moderate evidence* from randomized controlled trials that e-cigarettes with nicotine are more effective than e-cigarettes without nicotine for smoking cessation.

Conclusion 17-3. There is *insufficient evidence* from randomized controlled trials about the effectiveness of e-cigarettes as cessation aids compared with no treatment or to Food and Drug Administration–approved smoking cessation treatments.

Conclusion 17-4. While the overall evidence from observational trials is mixed, there is *moderate evidence* from observational studies that more frequent use of e-cigarettes is associated with increased likelihood of cessation.

These conclusions are somewhat different from the those of Public Health England (PHE) in their 2018 report. They state that “it is plausible” that e-cigarettes have contributed to higher than usual quit success rates in England during 2017, and then go on to state that “the evidence suggests that e-cigarettes have contributed tens of thousands of additional quitters in England” (McNeill et al., 2018, p. 16).

The PHE report examined 14 systematic reviews of e-cigarettes (EC) in smoking cessation and/or reduction, all of which concluded that further RCTs are needed. Of those reviews that included a meta-analysis, “two found a positive effect, four found an inconclusive effect and one found a negative effect for EC use on cessation” (McNeill et al., 2018, p. 125).

In a 2019 update of evidence report, Public Health England note that the National Institute for Health and Care Excellence (NICE) published 2018 guidelines on stop smoking interventions and stop smoking services delivered in primary care and community settings (McNeill et al., 2019). Guidance

was provided for health and social care workers to allow an informed discussion on e-cigarette products and their use in smoking cessation. This advice included the following key messages:

- Many people have found e-cigarettes helpful to quit smoking cigarettes
- People using EC should stop smoking tobacco completely, because any smoking is harmful
- The evidence suggests that ECs are substantially less harmful to health than smoking but are not risk free
- The evidence in this area is still developing, including evidence on the long-term health impact.

A Cochrane Review (McRobbie, Bullen, Hartman-Boyce & Hajek, 2014) examined the efficacy of ECs in helping people who smoke to achieve long-term abstinence; the efficacy of ECs in helping people reduce cigarette consumption by at least 50% of baseline levels; and the occurrence of adverse events associated with EC use.

The authors included 13 completed studies in total. Two were randomised controlled trials in which current smokers were randomized to EC or a control condition, with a combined sample size of 662 participants, and which measured abstinence rates or changes in cigarette consumption at six months or longer. Eleven cohort follow-up studies with at least six months follow-up, randomized cross-over trials, and cohort follow-up studies that included at least one week of EC use for assessment of adverse events, also met the review criteria.

None of the RCTs or cohort studies reported any serious adverse events (SAEs) related to EC use.

The authors' concluded that "there is evidence from two trials that ECs help smokers to stop smoking long-term compared with placebo ECs. However, the small number of trials, low event rates and wide confidence intervals around the estimates mean that our confidence in the result is rated 'low' by GRADE standards. The lack of difference between the effect of ECs compared with nicotine patches found in one trial is uncertain for similar reasons. ECs appear to help smokers unable to stop smoking altogether to reduce their cigarette consumption when compared with placebo ECs and nicotine patches, but the above limitations also affect certainty in this finding. In addition, lack of biochemical assessment of the actual reduction in smoke intake further limits this evidence." (McRobbie et al., 2014, p.2).

The above Cochrane Review was later updated (Hartmann-Boyce et al., 2016). The authors included RCTs in which current smokers (motivated or unmotivated to quit) were randomized to EC or a control condition, and which measured abstinence rates at six months or longer. They also included cohort follow-up studies with at least six months follow-up, randomized cross-over trials, RCTs and cohort follow-up studies that included at least one week of EC use for assessment of adverse events (AEs). There were 24 completed studies (three RCTs, two of which were eligible for the cessation meta-analysis, and 21 cohort studies) included in the review.

None of the studies included reported serious adverse events related to EC use. Mouth and throat irritation were most commonly reported.

The authors concluded that there was evidence from two trials that ECs help smokers to stop smoking in the long term compared with placebo ECs. However, their confidence in the result was still rated 'low' by GRADE standards, and the long-term safety of ECs was unknown.

The findings above were confirmed in a systematic review and meta-analysis investigating e-cigarettes and smoking cessation in real world and clinical settings, Kalkhoran and Glantz (2016) found 38 studies (of 557 identified) that met the review criteria. Of these, 15 were cohort studies,

three were cross-sectional, and two were clinical trials. By including ‘real world’ studies the authors attempted to address the difficulties of drawing conclusions from studies that did not reflect the way people were actually using e-cigarettes.

The interpretation of findings – including that “as currently being used, e-cigarettes are associated with significantly less quitting among smokers” – was contentious, and the authors concluded that “e-cigarettes should not be recommended as effective smoking cessation aids until there is evidence that, as promoted and used, they assist smoking cessation” (Kalkhoran & Glantz, 2016, p. 3).

Problems with the analysis were discussed in Lancet correspondence (Hajek, McRobbie & Bullen, 2016, e23) which claimed the review was “not an objective assessment of the evidence”. Hajek and colleagues argued that the review relied on poorly designed and selectively-included studies, and selectively used data from studies, and that limitations were acknowledged by the authors in the text but ignored in their conclusions.

Yet a later systematic review and meta-analysis investigating the impact of electronic nicotine delivery systems (ENDS) and/or electronic non-nicotine delivery systems (ENNDS) versus no smoking cessation aid, or alternative smoking cessation aids, in cigarette smokers on long-term tobacco use El Dib and colleagues (2017) also found limited evidence for effectiveness. The few available randomised controlled trials (RCTs) and prospective cohort studies were included in the review. Results from cohort studies suggested a possible reduction in quit rates with use of ENDS compared with no use of ENDS but the authors concluded that there is very limited evidence of these products on tobacco smoking cessation, reduction or adverse effects.

A review of all studies of e-cigarettes and smoking cessation or reduction undertaken in Australia, Europe, Iran, Korea, New Zealand and the United States, was carried out by Villanti and colleagues (2018) for the purpose of proposing a hierarchy of methodological criteria to consider when determining whether a study provides sufficient information to answer the question of whether e-cigarettes can facilitate cigarette smoking cessation or reduction.

Studies were assessed and coded by six proposed methodological criteria: (1) examines outcome of interest (cigarette abstinence or reduction), (2) assesses e-cigarette use for cessation as exposure of interest, (3) employs appropriate control/comparison groups, (4) ensures that measurement of exposure precedes the outcome, (5) evaluates dose and duration of the exposure and (6) evaluates the type and quality of the e-cigarette used.

The authors found that only a small proportion of studies seeking to address the effect of e-cigarettes on smoking cessation or reduction met their proposed quality standards. Those that did were consistent with the small number of randomized controlled trial findings, in suggesting that vaping can help with smoking cessation or reduction (Villanti, Feirman, Niaura et al., 2018).

New Zealand data

The extent to which vaping is being used as a smoking cessation tool is unclear in New Zealand, due to limited data publicly available on this topic. No data was found on heat-not-burn (HNB) product use for smoking cessation in New Zealand. However, recent studies of e-cigarette use in New Zealand have added considerably to an understanding of prevalence, rationale for use, perceptions and exposure to vaping devices in this country.

Merry and Bullen (2018) published a systematic review and narrative synthesis of 14 New Zealand studies, of varying design and purpose. Many were qualitative – using focus group and interviews, and nine used surveys of different populations (participant numbers ranged from 16 to 3,142). Nine

studies reported on exposure to, and perceptions of, e-cigarettes. There was one randomised cross-over trial.

Survey data suggested that prevalence of ever-use of e-cigarettes among smokers had increased from seven per cent in 2011, to 50 per cent in 2014 (only 3.4% of never-smokers had tried vaping in 2014). Current daily user prevalence among smokers was 2-5 per cent in 2013. Smoking was found to be a predictor of e-cigarette use. Younger adults were more likely to have ever used a cigarette.

Data from the Youth Insights Survey (YIS: $n=3,127$) found that ever use of e-cigarettes among adolescents increased from seven per cent in 2012 to 20 per cent in 2014, and similar prevalence was found among 15-17-year-olds surveyed in the 2014 Health and Lifestyles Survey (HLS: $n=2,594$). In 2014, current or ex-smoking was the most important predictor of ever-use in adolescents. Higher income was significantly associated with vaping, but ethnicity and school decile status were not. Almost two-thirds of YIS respondents cited curiosity, and about one quarter reported peer endorsement as their motivation for first trying an e-cigarette. Among adolescent smokers, 17 per cent cited smoking cessation, and 18 per cent cited reducing the number of cigarettes smoked as their motivation for trying vaping.

E-cigarette use analysed from the 2014 HLS and 2014 NZ Smoking Monitor Survey (NZSMS) data indicated that curiosity was also commonly reported as a motivation for EC use among adult smokers. Smoking cessation was cited by one quarter of all ever-users, and smoking reduction was the third-most cited reason, with current users more likely to substitute vaping for smoking some of the time. Some wanted to 'smoke' in areas where tobacco smoking was banned.

Limitations on these findings are discussed by the authors: these are mainly related to the heterogeneity of the studies included in this analysis, the small sample sizes of many of the studies, and low prevalence of e-cigarette use up until 2014, when the most recent population survey data was available. Nevertheless, the available data showed a rapid increase in uptake among New Zealanders, comparable with other countries. A high proportion of respondents reported exposure to e-cigarette advertising. The authors recommended further research into adolescents' and non-smokers' exposure to advertising to support policy development on advertising restrictions. "Further, the evidence regarding use in priority populations including Māori, Pacific Peoples, pregnant women and those with mental illness is inadequate." (Merry & Bullen, 2018, p. 42.) The authors argue for adequately representing these priority groups in future monitoring of e-cigarette use in population surveys.

More recent data from the Healthy Lifestyle Survey is discussed by Oakly and Martin (2019) in their study of dual use of ECs and tobacco. This paper provides an overall prevalence of current EC use (defined as those who reported using ECs 'less often than once a month' or more often) of 2.7 per cent, and among smokers or dual users, of 10.6 per cent. Current smokers were found to be about nine times more likely to be current EC users than non-smokers. The data showed that of those respondents who currently used ECs, 63.9 per cent also currently smoked tobacco (dual use).

The Health Promotion Agency investigated EC use and perceptions among current and ex-smokers in New Zealand (Guiney, Oakly & Martin, 2019) using data from 1,099 respondents in the 2017/18 NZ Smoking Monitor (NZSM). Data was analysed by smoking status ('current smokers, non-attempters'; 'recent quit attempters'; 'serious quitters'), age, gender and ethnicity.

There were significant differences in patterns of use by smoking status. Rates of EC use were highest among recent quit attempters.

Respondents who had tried an e-cigarette also varied by age and ethnicity, with the highest rates of ever use among young adults and Māori, but no differences were shown on measures of current and long-term daily use by age or ethnicity. No differences were shown on any measures by gender.

Table 1. Subgroup differences in patterns of e-cigarette use (data source: 2017/18 NZ Smoking Monitor)

Base	Ever tried an e-cigarette		Expect to try an e-cigarette in next 12 months	Currently use an e-cigarette	Long-term daily use of e-cigarettes ¹			
	All respondents		Those who had never tried an e-cigarette	Those who had tried an e-cigarette	Those who had tried an e-cigarette			
Age (years)	18 to 24	92% ^R	No differences	No differences	No differences			
	25 to 44	72%*						
	45 to 64	62%*						
	65+	40%*						
Gender	No differences		No differences	No differences	No differences			
Ethnicity	Māori	73% ^R	No differences	No differences	No differences			
	Pacific	64%*						
	Asian	60%*						
	European/Other	64%						
Smoking status	Non-attempters	62%	Non-attempters	20%*	Non-attempters	32%	Non-attempters	21%*
	Recent quitters	72%*	Recent quitters	24%*	Recent quitters	53%*	Recent quitters	40%
	Serious quitters	63% ^R	Serious quitters	7% ^R	Serious quitters	32% ^R	Serious quitters	34% ^R

*Significantly different from the reference group (R), from a logistic regression model including age, gender, ethnicity, and smoking status. ¹Used daily for at least one month.

New Zealand Quitline services provided by Homecare Medical report that data is being collected on the numbers of smokers also using e-cigarettes, and their intention in using them, from people using their service.³⁰ This data is reported routinely to the Ministry of Health.

Randomised Controlled Trials

Randomised controlled trials (RCTs) are considered the most rigorous way to measure the effectiveness of a new intervention or treatment. Although no single RCT is likely on its own to prove causality, randomization reduces bias and enables the examination of cause-effect relationships between an intervention and outcome, which is not possible with any other study design. Limitations of RCTs include relatively high cost, problems with generalisability (participants might not be representative of the population being studied) and loss to follow up.

Until recently, only one well-designed RCT had tested the efficacy of ECs for smoking cessation compared with other nicotine replacement therapy (NRT), and this New Zealand study found no significant difference between the two options (Bullen et al., 2013).

A recent pragmatic trial ($n=6,131$) compared four smoking cessation interventions and usual care to investigate whether financial, pharmacologic therapies, and ECs promote smoking cessation among unselected smokers (Halpern, Harhay, Saulsgiver, et al., 2018).

The four interventions consisted of usual care plus one of the following: free cessation aids (nicotine-replacement therapy or pharmacotherapy, with ECs if standard therapies failed); free ECs, without a requirement that standard therapies had been tried; free cessation aids plus \$600 in rewards for sustained abstinence; or free cessation aids plus \$600 in redeemable funds, deposited in a separate account for each participant, with money removed from the account if cessation milestones were not met.

³⁰ Communication with Quitline manager Ann Marie Searchfield, 22 January 2019.

Sustained abstinence rates through six months were under three per cent in all groups. With respect to sustained abstinence rates, redeemable deposits and rewards were superior to free cessation aids. Redeemable deposits were superior to free ECs. Free ECs were not superior to usual care or to free cessation aids.

The authors concluded that financial incentives added to free cessation aids resulted in a higher rate of sustained smoking abstinence than free cessation aids alone. Among smokers who received usual care (information and motivational text messages), the addition of free cessation aids or ECs did not provide a benefit (Halpern et al., 2018).

A more recent RCT compared ECs with nicotine replacement therapy (NRT) in UK Stop Smoking Services (Hajek et al., 2019). The 886 participants were randomised to either NRT products of their choice, or an EC starter pack. Behavioural support was provided for at least four weeks for all participants. Sustained abstinence for one year was the primary outcome, validated biochemically at the final visit. The one-year abstinence rate for the EC group was 18.0 per cent, compared with 9.9 per cent in the NRT group (RR 1.83; 95% CI, 1.30 to 2.58; $p < 0.001$), an impressive finding that led the authors to conclude that ECs were more effective for smoking cessation than NRT, when both products were accompanied by behavioural support.

The study found that EC use continued for much longer than NRT in those who had quit (at one year 39.5% of EC users were still vaping, compared with 4.3% of the NRT group still using the NRT product). The authors acknowledged that this finding could be problematic if it signalled ongoing long-term use of ECs, with associated as-yet-unknown health risks. However, it was also suggested that long-term vaping might prevent relapse to smoking.

The research was “hailed as a landmark by experts in public health in the UK who believe e-cigarettes have already helped bring down the smoking rate”³¹ but also attracted critical feedback from US clinicians Drs Borelli and O’Connor who wrote an editorial in response to the study, pointing to other research that had shown slightly higher abstinence rates from cessation products Bupropion and Varenicline (‘Champix’) than those in the e-cigarette study. Moreover, they pointed out that these products had been proven to be safe. They were concerned that promoting vaping as a smoking cessation tool could encourage children to learn addictive behaviours by watching adults vaping, and argued against EC use in smoking cessation services ahead of licensed nicotine replacement therapy. “We recommend that e-cigarettes be used only when FDA-approved treatments (combined with behavioural counselling) fail, and that patients be advised to use the lowest dose needed to manage their cravings and that there be a clear timeline and ‘off ramp’; for use”³².

The transferability of the findings of Hajek and colleagues (2019) to unaided or poorly supported quitting in the community is not known. Further trials were recommended by the authors to determine whether these results could be generalised outside UK Stop Smoking Services, and to compare different levels of support. A new trial has investigated the efficacy of vaping as a cessation tool in unsupported settings in New Zealand, but the results were not available for this review.

³¹ From an article in The Guardian on 30 January, 2019, retrieved on 31 January 2019 from : <https://www.theguardian.com/society/2019/jan/30/vaping-twice-as-likely-as-gum-to-help-smokers-quit-research-finds>

³² Belinda Borelli and George T O’Connor, quoted in The Guardian article of 30 January 2019 cited above.

Dual use and smoking cessation

Dual use (of both ECs and tobacco smoking) is a key area of research as it is important to understand whether this common phenomenon is likely to be a transition to eventual quitting of smoking altogether, or rather a prolonged state that does not result in quitting, or perhaps eventually results in relapse back to tobacco smoking only.

The majority of smokers who started using ECs in the US, France and the UK are dual users (Glantz & Bareham, 2018).

Because it is now well-established that dual users begin vaping to quit smoking, yet only a subset succeeds, Brandon and colleagues (2019) decided to investigate qualities of the vaping experience associated with greater propensity to quit smoking. The authors undertook secondary analysis of cross-sectional baseline data from dual users in the US to identify a national sample of dual users of combustible and electronic cigarettes who smoke and vape at least once per week ($n=2896$) who were enrolled into a randomized controlled trial in which they would receive either smoking cessation materials or no smoking cessation materials.

Four factors were identified in quitting success: vaping propensity (vaping frequency, positive expectancies), vaping enthusiasm (e-cigarette modifications, using non-tobacco flavours, puffs per use), nicotine/tobacco flavour (nicotine strength, tobacco flavours) and smoking cessation propensity (negative expectancies about smoking, motivation to quit smoking, reduction in smoking).

The authors concluded that among EC users who also smoke combustible cigarettes, frequent vaping combined with positive EC expectancies appears to predict greater smoking cessation propensity. However, vaping enthusiasm (measured by EC modifications, using non-tobacco flavours and puffs per use), higher nicotine content and use of tobacco flavoured solution may reduce cessation propensity. In other words, using ECs in ways that mimic cigarettes were less effective in smoking cessation – “vapers who use ECIGs much like NRTs, primarily as a tool for the purpose of quitting smoking as opposed to an extension of smoking or a hobby, may be more likely to attempt and eventually succeed at smoking cessation” (Brandon et al., 2019, p. 9).

There is evidence for substantial dual use in New Zealand adults aged over 15 years from the 2016 Health and Lifestyles Survey (HSL) data (Oakley et al., 2019).

A New Zealand qualitative study investigated dual use of e-cigarettes and conventional cigarettes, and why it is that many smokers adopt vaping without quitting smoking (Robertson, Hoek, Blank, Richards, Ling, & Popova, 2019). In-depth, semi-structured interviews were conducted with 20 dual users who reported smoking tobacco at least once a month. They found that dual use practices among participants evolved in four ways. “First, as an attempt to manage the ‘inauthenticity’ of vaping relative to smoking and to retain meaningful rituals. Second, as complex rationalisations that framed decreased tobacco use, rather than smoking cessation, as ‘success’. Third, as a means of alleviating the financial burden smoking imposed and to circumvent smoke-free policies. Lastly, dual use reflected attempts to comply with social group norms and manage stigma.” (Robertson et al., 2018, p. 13.) The authors concluded that dual use enabled smokers to navigate smoking restrictions and manage social norms.

This finding and the desire to circumvent smokefree policies are a particular concern – as it suggests EC use will not lead to quitting in some users. Although it is not yet clear what proportion of dual users are motivated to use ECs in this way, the findings argue against allowing vaping in areas designated smoke-free, for three main reasons.

1. Allowing vaping in these areas contributes to the 'normalisation' of nicotine addiction at a societal level.
2. Allowing vaping to take place in smokefree areas reinforces the notion that nicotine addiction is both acceptable and 'safe' rather than less harmful than tobacco. Those individuals (children, young people and non-smokers) who are curious about vaping will have their interest reinforced by seeing people vaping far more frequently than at present.
3. Finally, smokers will be able to manage their nicotine addiction more easily, and this will undermine their motivation to quit smoking.

Smoking cessation effectiveness in young people

In their review of longitudinal studies of young people, Chatterjee and colleagues (2016) found no good evidence that e-cigarette (EC) use promotes smoking cessation among adolescents. Because of the lack of data, and taking adolescent psychology into account, the authors suggest it is very likely that most adolescents use ECs for experimentation with tobacco rather than as a smoking cessation tool. This hypothesis is supported by longitudinal data from the US that indicates that EC use is associated with higher rates of smoking initiation amongst adolescents, even among those who would otherwise have no inclination to smoke (Gmel et al., 2016), and by National Youth Tobacco Survey data showing that declining youth smoking rates have reversed in the US since 2018, alongside increased EC use in this population (Gentzke, Creamer & Cullen, 2018). This is concerning, but it is too early to say whether it is a trend.

Concerns have also been raised about the rapidly rising prevalence of EC use, particularly in 2018 coinciding with the widescale uptake of JUUL podvapes amongst young people in the US and Canada. The increase in uptake of ECs in young people has led to concerns about re-normalization of smoking behaviour as well as the possible effects of addiction and long-term use of nicotine-containing products (Chatterjee, Alzghoul, Innabi, & Meena, 2016).

Vaping as a smoking cessation tool for Māori and Pacific

2017/2018 NZ Health Survey data shows that the 'current smoking' rate has continued to drop among Māori adults (33%, compared with 42% in 2006/07) and Pacific adults (23% compared with 27% in 2006/07) but both groups remain significantly higher than the general adult population prevalence (15%, down from 20% in 2006/07). Māori and Pacific prevalence remains unacceptably high, and reflects a cohort of heavily addicted adult smokers.

Very little evidence was found to answer the question of whether vaping is more effective than other products in helping Māori or Pacific smokers to quit. Bullen and colleagues (2013) collected and analysed Māori participant data (n=213) in their RCT investigating the effectiveness of e-cigarettes compared to NRT products. However, the authors did not note any difference between Māori and non-Māori in their discussion of findings.

This review only found one systematic review investigating the effectiveness of e-cigarette use in smoking cessation for 'vulnerable populations' with high smoking rates, and the definition did not include indigenous peoples. It did include people with substance use and mental health problems, those who are homeless, and those involved with the criminal justice system (Gentry, Forouhi, & Notley, 2018). Nine studies were identified for inclusion, but the quality was low, and it was not possible to assess whether ECs were effective for smoking cessation in vulnerable populations. No serious adverse events were identified. The authors suggested that further research should consider appropriate EC devices for practicality and safety, concurrent support, and comparison with best practice smoking cessation support.

Vaping has been identified by one Māori privately owned cessation service provider as a preferred and highly effective smoking cessation option for Māori, and there is anecdotal evidence that it can be effective in comprehensive cessation programmes for Māori women. The provider of *Vape2Save* services claims that using vaporisers reduces the cost normally spent (by smokers) on tobacco by up to 80%, and that “a trained practitioner from Indigenous Health Solutions ... took participants through the 8-week programme in the use of e-cigarettes transitioning them from smoking tobacco. With a confirmed success rate of 80% who quit smoking from the first two groups, this has been a remarkable and positive step ...”.³³ A March 2019 NZ Listener article on this programme stated that of the “more than 300 mostly Māori women who have completed the seven-week Auckland-based programme ... about 80% of them stopped smoking cigarettes completely for four weeks, which is the Ministry of Health’s definition of a non-smoker”.

It was not possible to verify these claims as no evaluations or published data on this programme were found in this review. It is also important to clarify that the Ministry of Health website states “It is good practice to record patients as ex-smokers after they have been smokefree for 28 days. However, smoking status should be checked at later time points as relapse to smoking is common.”³⁴

An online survey conducted in New Zealand by Truman, Glover and Fraser (2018) recruited subjects ($n=218$) from vaper and smoking cessation networks and follow-up surveys were conducted one and two months following the initial survey. Participants were adult smokers (aged 20-65+ years), mostly from the Auckland region. The majority were strongly tobacco dependent, and 15 per cent were Māori ($n=32$), but no discussion of findings for Māori was provided. The overwhelmingly positive findings reflected the views and experience of a group of individuals who were highly motivated to quit smoking through vaping. The authors noted that bias in the non-representative sample was “weighted towards those vapers who were most committed to vaping” of whom over 72 per cent claimed to have switched completely from smoking to vaping at the time of the surveys. These self-reported claims were not verified. While acknowledging the limitations of such a survey, the authors concluded that “the results of this survey are supportive of a wider use of ECs for smoking cessation in New Zealand” (Truman et al., 2018, p. 11).

Tucker and colleagues (2017) investigated whether nicotine-containing electronic cigarettes (NECs) could help to reduce smoking prevalence for Māori and Pacific peoples. This econometric study of 357 smokers (30.1% Māori/Pacific ethnicity and 69.9% NZ European/Other/Māori/Pacific) confirmed that Māori and Pacific smokers were significantly more price sensitive than NZ European/Other smokers.

These findings supported the notion that the availability of NECs at a lower price than tobacco cigarettes may enhance the effects of tobacco taxation increases in reducing smoking prevalence in Māori and Pacific smokers, and are therefore relevant to policy on tobacco product supply. The study found that NECs were rated as more satisfying than other options by Māori/Pacific smokers, which further supported the argument. However, the authors noted that earlier research (Bullen et al., 2013) had suggested that smokers may have a ‘honeymoon’ period when they first use NECs and their satisfaction may reduce over time. This presents a risk that they will return to smoking or become dual smokers, using vaping to manage their addiction and avoid social stigma.

³³ Retrieved from <http://tiakimanatu.org/epanui/vape2save-te-waipuna-puawai/> on 10 April 2019.

³⁴ Retrieved from <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/tobacco-control-information-practitioners/definitions-smoking-status> on 10 April 2019.

In a qualitative study investigating information-seeking behaviour about ECs containing nicotine, of the 39 adult participants, nine identified as Māori, five as Pacific, and two as Māori and Pacific. No differences in information-seeking behaviour were identified by ethnicity (Robertson et al., 2018).

International evidence examined as part of an analysis of the impact of tobacco excise tax (Ernst & Young, 2018) suggests that lower-income populations in high-income countries respond more strongly to tobacco taxation than higher-income people. However, the authors note that very few studies examine effects across ethnic groups, and there is currently insufficient NZ data to provide a robust estimate of the price elasticity of demand by ethnicity, deprivation or age.

However in a simple linear regression analysis assuming observed changes in prevalence occur as a result of changes in price, the authors estimated that “for every dollar change in average price of a cigarette or RYO equivalent daily smoking prevalence decreases by 10.0%, 0.8%, 3.0% and 4.7% for Māori, Pacific, Asian and European/Other respectively” between 2006/07 and 2012/13. Within the Māori population, they estimated that “for every dollar change in average price of a cigarette or roll-your-own (RYO), equivalent daily smoking prevalence decreases by 9.6% and 10.5% for Māori men and women respectively” (Ernst & Young, 2018, p. 87).

This finding is supported by Tucker and colleagues (2017b), who compared changes to smoking habits and addiction following tobacco excise tax increases in Māori, Pacific and NZ European smokers and concluded that tobacco excise tax may be particularly effective for Māori/ Pacific smokers and may contribute to a comprehensive tobacco control strategy aiming to reduce inequalities in smoking and smoking-related health outcomes for Māori and Pacific communities.

In summary, it seems self-evident that attractively presented, cheaper products that are similar in many ways to conventional cigarette smoking will be more acceptable and effective to smokers wishing to quit than other products, and there is both anecdotal and emerging evidence from clinical trials that this may be the case. However, no research was found in this review that demonstrated vaping is any more effective in smoking cessation than other approaches for Māori, Pacific or other high-prevalence groups.

Some evidence was found that annual increases in tobacco excise tax is resulting in a higher reduction in smoking prevalence for Māori than for other ethnic groups, and contributing to reducing inequalities in health outcomes.

What is known about vaping among children and young people?

“The last thing we want to happen is for our young generation of New Zealanders to pick up e-cigarettes thinking they are not harmful and inadvertently becoming an entry to a smoking habit.”

Dr Stuart Jones, Medical Director, Asthma and Respiratory Foundation NZ³⁵

Youth tobacco smoking prevalence trends

New Zealand Health Survey (NZHS) 2015/16 data on smoking trends³⁶ shows that smoking prevalence has declined consistently among all subgroups of youth (aged 15-24 years) since 2006/07. Among male youth, daily smoking prevalence decreased over the nine-year period in absolute terms by 8.2 per cent among Māori and 3.6 per cent among non-Māori youth (see Table 6 below). This is a 22.0 per cent relative decline for Māori and 20.9 per cent for non-Māori.

Among female youth, daily smoking declined over the nine-year observation period by 13.0 per cent in absolute terms among Māori and 8.3 per cent for non-Māori (see Table 2 below). This is a 28.5 per cent relative decline for Māori and a 49.1 per cent decline for non-Māori. Smoking has therefore declined more in absolute terms but less relatively among Māori female youth than non-Māori female youth, taking their different starting positions into account.

Table 2: Change in daily smoking prevalence, linear regressions, 2006/07–2015/16

		2006/07	2015/16	Absolute % change	Relative % change
Male youth	Māori	37.3 (30.9–43.7)	29.1 (24.6–33.7)	8.2 (0–16.8)	22.0% (2.2–41.6)
	Non-Māori	17.2 (14.1–20.2)	13.5 (11.3–15.8)	3.6 (0–8.0)	20.9% (1.1–43.3)
Female youth	Māori	45.9 (39.8–51.9)	32.9 (28.0–37.7)	13.0 (3.5–22.5)	28.5% (11.1–45.6)
	Non-Māori	16.9 (14.2–19.6)	8.6 (7.0–10.2)	8.3 (4.8–11.8)	49.1% (35.0–63.1)

Sources: NZTUS 2008/09 and New Zealand Health Surveys 2006/07, 2011/12, 2012/13, 2013/14, 2014/15 and 2015/16³⁷

ASH Year 10 snapshot results for 2018 showed that Māori and Pacific rates continued to be higher than non-Māori, non-Pacific, but rates have declined steadily each year since 2002, overall and for all ethnic groups. The prevalence of daily smoking among Māori has dropped to 5.2 per cent, compared with 1.9 per cent of all Year 10 students.³⁸

³⁵ Retrieved from <https://www.asthmafoundation.org.nz/your-health/e-cigarettes-and-vaping> on 22 January 2019

³⁶ Ministry of Health data retrieved on 22 January 2019 from <https://minhealthnz.shinyapps.io/nz-health-survey-2015-16-annual-update/>

³⁷ Retrieved from Ministry of Health website in January 2019.

³⁸ Retrieved on 9 April from https://d3n8a8pro7vhmx.cloudfront.net/ashnz/pages/70/attachments/original/1554281096/2018_ASH_Y10_Snapshot_Topline_FINAL.pdf?1554281096

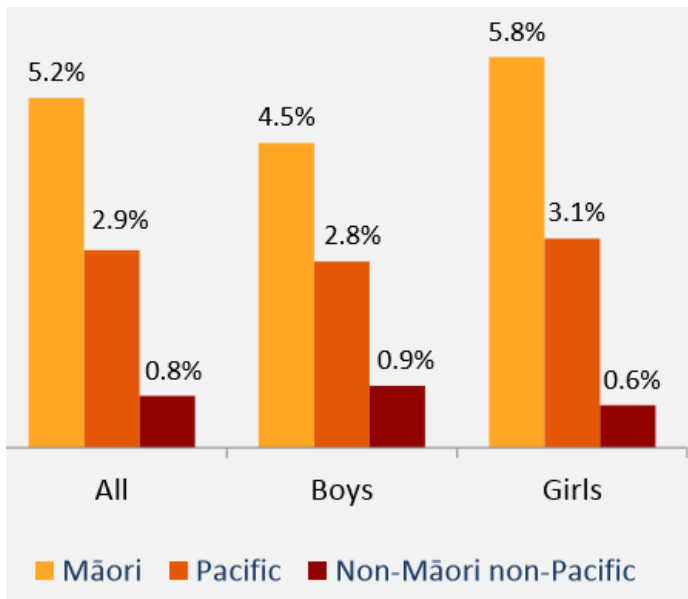


Figure 3. ASH Year 10 snapshot results by gender and ethnicity for 2018³⁹

However, ASH Year 10 survey data for 2018 shows that overall regular and daily smoking has levelled off since 2017 (see Figure 4 below).

Overall never, regular, and daily smoking rates relatively unchanged since 2017

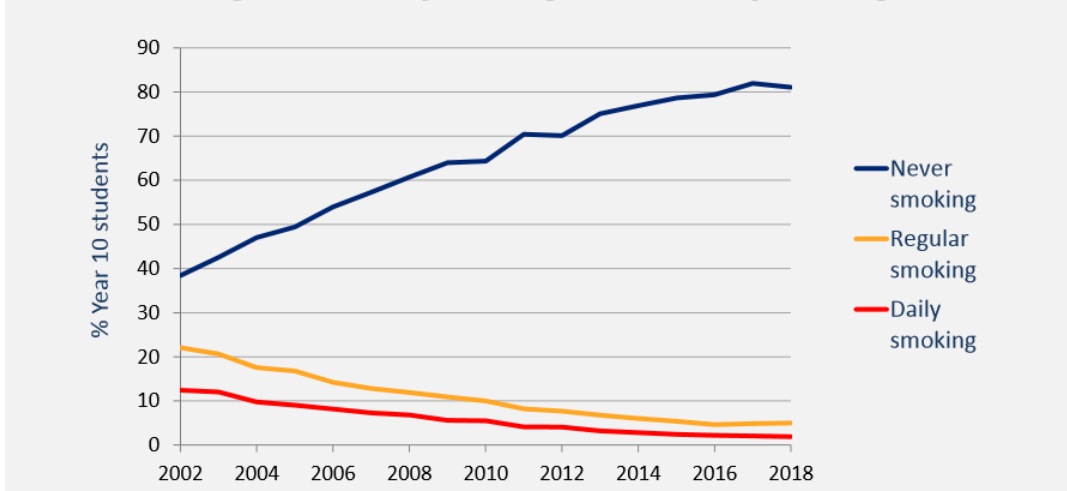


Figure 4: From ASH Year 10 Snapshot Topline Results for 2018⁴⁰

³⁹ Retrieved on 10 April 2019 from https://d3n8a8pro7vhm.cloudfront.net/ashnz/pages/70/attachments/original/1554281096/2018_ASH_Y10_Snapshot_Topline_FINAL.pdf?1554281096

⁴⁰ ASH 2018 fact sheet retrieved on 17 April 2019 from https://d3n8a8pro7vhm.cloudfront.net/ashnz/pages/70/attachments/original/1554281096/2018_ASH_Y10_Snapshot_Topline_FINAL.pdf?1554281096

Youth vaping prevalence and trends

International comparisons

A new study investigating the differences in vaping and smoking prevalence among adolescents in Canada, England and the US (Hammond et al., 2019), drew on national samples of 16-19-year-olds in 2017 and 2018 recruited in Canada ($n=7891$), England ($n=7897$) and the US ($n=8140$). Analyses were based on repeat cross-sectional samples from the ITC Youth Tobacco and Vaping Survey.

The authors noted widespread concerns that vaping could undermine reductions in smoking among young people, and as discussed elsewhere in this report, that a robust association had been found in prospective cohort studies between smoking and vaping, indicating that young people who vape had an increased risk of subsequent smoking, and vice versa. The causal relationship was unclear, but one explanation could be that exposure to one product might increase use of the other product.

Differences in regulatory regimes between the three countries were outlined and discussed. A more permissive regulatory approach was implemented in Canada in May 2018, which enabled ECs containing nicotine to be marketed and sold without premarket approval. These products were already widely available in vape shops and online, but after mid 2018 retail access increased in Canada, including for major brands such as JUUL and Vype, which use nicotine salt-based technology. The Canadian vaping market changed rapidly, more in line with the less restrictive regulatory settings in England and the US. All three countries prohibit the sale of ECs to minors.

As in many Western countries, smoking prevalence in young people has been trending down for several decades in Canada, although the rate of decline has slowed in recent years, with smoking prevalence at eight per cent among 15-19-year-olds in 2017.

Although there were no significant regulatory changes in the US or England during 2017 and 2018, the US market was impacted by the rapid growth in use of JUUL, which has a much higher nicotine content than other EC products (50mg/mL, compared with 3-24 mg/mL for other ECs). In England the nicotine level of all EC products including JUUL is capped at 20mg/mL, health warnings are required, and certain forms of marketing are restricted due to EU restrictions. In part because of these differences in the regulatory environments in the three countries, Hammond and colleagues hypothesised that the greatest increases in vaping would occur in Canada, followed by the US (as JUUL dominates the market there) with the least changes in England. The results confirmed the hypothesis – increases in vaping prevalence (vaping in the past 30 days) during 2017/2018 among adolescents were highest in Canada – by six percentage points, followed by the US – by five percentage points. England did not experience the same increases in vaping among adolescents, probably due to the EU cap on nicotine levels, but also likely due to the fact that at the time of the survey, JUUL was restricted to a limited number of outlets.

Hammond and colleagues (2019) identified an increase in smoking prevalence alongside the increase in JUUL use among Canadian adolescents (see Table 3 below) and noted that this increase raises important questions about the association between vaping and smoking behaviour. The possibility was discussed that the increase might be related to the legalisation of non-medical cannabis that took place in October 2018. This change was associated with an increase in cannabis use among adolescents, six months prior to date of legalisation. It was plausible that the increase in cannabis use could increase cigarette smoking. However, the authors found that the increase in smoking and vaping prevalence remained statistically significant even after adjusting for cannabis use, suggesting that the increase in vaping and smoking were not directly related to increased cannabis use.

Vaping and smoking measures	Canada				England				US			
	2017 (n=4038)	2018 (n=3853)	Adjusted odds ratio (99% CI) for change*	P value	2017 (n=3995)	2018 (n=3902)	Adjusted odds ratio (99% CI) for change*	P value	2017 (n=4095)	2018 (n=4045)	Adjusted odds ratio (99% CI) for change*	P value
Vaping												
Ever	29.3 (1182)	37.0 (1425)	1.50 (1.31 to 1.71)	<0.001	33.7 (1348)	32.7 (1276)	0.96 (0.84 to 1.09)	0.38	31.3 (1283)	33.6 (1360)	1.11 (0.97 to 1.28)	0.05
Past 30 days	8.4 (340)	14.6 (562)	1.95 (1.58 to 2.40)	<0.001	8.7 (347)	8.9 (346)	1.03 (0.82 to 1.29)	0.77	11.1 (454)	16.2 (655)	1.55 (1.28 to 1.88)	<0.001
Past week	5.2 (208)	9.3 (357)	1.99 (1.53 to 2.60)	<0.001	4.6 (184)	4.6 (178)	0.99 (0.73 to 1.36)	0.96	6.4 (262)	10.6 (429)	1.74 (1.37 to 2.22)	<0.001
≥15 days in past 30 days	2.1 (85)	3.6 (139)	1.86 (1.23 to 2.79)	<0.001	2.0 (80)	2.2 (87)	1.13 (0.71 to 1.79)	0.49	3.0 (124)	5.2 (210)	1.75 (1.23 to 2.49)	<0.001
Cigarette smoking												
Ever	31.9 (1288)	36.6 (1412)	1.31 (1.15 to 1.50)	<0.001	40.4 (1615)	39.8 (1555)	0.98 (0.86 to 1.12)	0.75	32.3 (1322)	33.1 (1337)	1.04 (0.90 to 1.19)	0.51
Past 30 days	10.7 (431)	15.5 (599)	1.60 (1.32 to 1.94)	<0.001	15.6 (622)	16.4 (641)	1.08 (0.91 to 1.29)	0.23	11.0 (451)	12.2 (494)	1.12 (0.91 to 1.38)	0.15
Past week	7.6 (308)	11.9 (460)	1.71 (1.37 to 2.14)	<0.001	9.8 (391)	11.3 (441)	1.19 (0.97 to 1.47)	0.03	8.5 (347)	8.8 (356)	1.04 (0.82 to 1.32)	0.67
≥15 days in past 30 days	4.8 (196)	7.4 (286)	1.64 (1.24 to 2.15)	<0.001	5.0 (200)	6.4 (248)	1.31 (0.99 to 1.72)	0.01	4.6 (189)	5.1 (205)	1.10 (0.81 to 1.50)	0.42

*Change from 2017 to 2018, in logistic regression models within country, adjusted for age, sex, and race/ethnicity.

Table 3 Changes in prevalence of smoking and vaping between 2017 and 2018 among adolescents aged 16-19 years, by country. Values are weighted per centages (numbers) unless stated otherwise. (From Hammond et al., 2019)

In a study of prevalence of electronic nicotine delivery systems (ENDS) among youth globally, (Yoong, Stockings, Chai et al., 2018), the authors reviewed prevalence studies from 13 countries that had been collecting population-level data prior to the end of 2015, including New Zealand. The data was found to be lacking in quality and consistency across countries (for example, the NZ data was for 15-17-year-olds only) but the authors were able to reach some conclusions. There appeared to be considerable heterogeneity in ENDS use across countries, and also between current smokers and non-smokers. Rates of current use among youth were highest in Poland (29.9%) and lowest in New Zealand (0.0%). Yet estimates of the prevalence of ever ENDS use among non-smoking youth was found to be highest in New Zealand (14.0%) and lowest in the US (4.2%) at that time.

Changes in ENDS use among youth over time were able to be compared across seven countries (US, UK, Poland, New Zealand, Korea, Canada and Italy) between 2008 and 2015. “Overall, it appeared that prevalence of ever use increased in four countries: Poland (20.9% in 2010 to 62.1% in 2013); Korea (0.5% in 2008 to 9.4% in 2011); New Zealand (7.0% in 2012 to 20.0% in 2014); and the US (2.7% in 2011 to 47.3% in 2013), decreased in Italy and Canada, and remained stable in the UK”. Yoong et al., 2018, p.305.)

These findings supported those in previous reviews – that current smokers were more likely to use ENDS, and that ENDS ever and current use was increasing in the majority of countries with multiple prevalence estimates. ENDS use appeared to be increasing in most countries among young people. Prevalence of current ENDS use was typically low among non-smokers but increasing use among this group is concerning in light of numerous longitudinal studies identifying a positive association between ENDS ever use and subsequent uptake of cigarette smoking at 12-months (Yoong et al., 2018).

These findings are concerning in light of recent evidence from the US that that the rapid increase in rates of youth vaping during 2018 have been accompanied by an increase in young people smoking all tobacco products. Data analysed from the 2011-2018 National Youth Tobacco Surveys by the CDC, FDA and National Cancer Institute found that in 2018, current use of any tobacco product was reported by 27.1 per cent of high school students and 7.2 per cent of middle school students. They found a 38.3 per cent increase between 2017 and 2018 in current use of any tobacco product. E-

cigarettes were the most commonly used product in both high school and middle school students. Gentzke and colleagues (2019) note that this increase in vaping “is consistent with observed increases in sales of the e-cigarette JUUL, a USB-shaped e-cigarette device with a high nicotine content that can be used discreetly and is available in flavours that can appeal to youths ... media reports and a survey indicate that JUUL devices are being used among youths in schools, including inside bathrooms and classrooms,” and concluded that this increase “has erased recent progress in reducing overall tobacco product use among youths.” (Gentzke et al., 2019, p. 161-162.)

New Zealand

The Ministry of Health (2019, p. 12) reports that

- The number of young people (14 to 15-year olds) who had ever tried vaping more than tripled between 2012 and 2016, with 27.7 per cent of young people having ever tried vaping in 2016, up from 20 per cent in 2014 and 7.1 per cent in 2012.
- 45.8 per cent of young Māori had ever tried vaping in 2016, compared with 22.2 per cent of non-Māori. In 2016, 33.4 per cent of young males, and 21.8 per cent of young females had ever tried vaping.⁴¹

These figures represent a large number of young people who are curious about vaping. ASH data shows that in 2018, the total number of 14-15-year-olds who had ever tried vaping was 8,274 (29.1%). Of these, 4,869 (59%) were never smokers, 1323 (16%) regular smokers, which includes 504 (6%) daily smokers (daily smokers are included in the regular smoker category).

Given that less than six per cent of Year 10 Māori students are currently smoking, the Ministry data above shows that young Māori non-smokers are even more interested in vaping than their non-Māori peers. However, as shown in Table 1, no ethnic differences were shown for current or long-term EC use, in 2017/18 NZ Smoking Monitor data.

ASH has conducted annual surveys of 20,000-30,000 Year 10 students on their smoking behaviour and attitudes since 1999. Questions on vaping have been included in recent years and ASH reported the following key findings on e-cigarettes from the 2018 survey⁴²

- Fewer than 1% of Year 10 students who never smoked reported using e-cigarettes daily
- Fewer than 2% of Year 10 students reported using e-cigarettes daily
- Students who smoke were over 4 times more likely to have tried an e-cigarette (even a single puff or vape) than students who never smoked
- A third of Year 10 students reported having tried an e-cigarette (even a single puff or vape)
- Students who smoke were over 4 times more likely to have tried an e-cigarette. ‘Tried’ includes students who had tried an e-cigarette only once
- Just over 1 in 5 Year 10 students who reported never smoking had tried an e-cigarette.
- However, very few – fewer than 1 in 100 – Year 10 students who reported never smoking used e-cigarettes daily.

It should be noted that while this ASH summary provides a fairly positive interpretation of these findings, it is very concerning that nearly 30 per cent of Year 10 students (14-15 years) had tried vaping, and over 20 per cent of these students who had never smoked had tried vaping. Most of

⁴¹ The Youth Insights Survey 2016, as cited in MoH Regulatory Impact Statement, 2019, p. 12.

⁴² Retrieved on 10 April 2019 from

https://d3n8a8pro7vhmx.cloudfront.net/ashnz/pages/70/attachments/original/1554281098/2018_ASH_Y10_Snapshot_E-cigs_FINAL.pdf?1554281098

these ‘tries’ will have been of nicotine-free products, as Year 10 data collection takes place between mid-May and early July, so 2018 data will not have picked up any changes in daily or weekly use that may have begun to occur towards the end of 2018 when it became legal in New Zealand to sell EC products containing nicotine. These products are now freely available in dairies, petrol stations and other places (including retail vans parked in close proximity to schools in some parts of New Zealand) and may contain quite high levels of nicotine.

It is also worth noting that cross-sectional data such as that from the ASH Year 10 surveys will not reflect the true proportion of adolescents who are never smokers when they first start using ECs. Some EC users who are now regular smokers may have started as exclusive EC users (or may have initially used ECs to try quitting). Concluding that the prevalence of regular EC use is much higher among smokers than non-smokers does not reflect the overall distribution of EC users according to smoking status because non-smoking is much more common than regular smoking. While it is correct to say that based on the Year 10 data, e-cigarette use prevalence is much higher among smokers than never smokers, it is also true that the overall number and proportion of e-cigarette users in smokers compared to never smokers is much more evenly split.

2018	n*	% Tried e-cigarettes	% Use e-cigarettes daily	% Use e-cigarettes daily or weekly
All	28,433	29.1	1.8	4.0
- Boys	13,446	33.5	2.3	4.8
- Girls	14,987	25.0	1.3	3.2
By smoking status				
- Never smoking	23,078	21.1	0.4	1.1
- Regular smoking	1,400	94.5	14.4	30.7
- Daily smoking	533	94.6	19.4	34.8

Figure 5. E-cigarette use in Year 10 students: ASH year 10 snapshot fact sheet 2018 (* n = number of participants)

ASH concluded that “these findings do not support the concern that e-cigarettes are a route into smoking among young people. Youth smoking rates continue to decline, daily use of e-cigarettes is rare and is largely confined to those who have smoked.”⁴³ This representation of the data is questionable. No data is provided in recent fact sheets to support the assertion that youth smoking rates continue to decline. In fact, the 2017 fact sheet indicates that daily smoking was levelling off, and the 2018 fact sheet confirms this trend, stating that “overall, never, regular and daily smoking rates (were) relatively unchanged since 2017”.

⁴³ ASH 2017 fact sheet retrieved on 17 April 2019 from https://d3n8a8pro7vhmx.cloudfront.net/ashnz/pages/70/attachments/original/1537220024/2017_ASH_Y10_Snapshot_E-cigs.pdf?1537220024

The change in levels of Year 10 smoking might be a key indicator of any ‘gateway effect’, but even if the trend was continuing to lower instead of levelling off, it could be argued that there might have been a greater downward trend if vaping had not introduced some students to smoking.

Data from other countries suggests that it may be premature to assume that New Zealand’s relatively low smoking prevalence among young people means that the ‘gateway effect’ is not a problem here. E-cigarette use among children and young people has increased very quickly in the last few years in North America. During 2017–2018 ‘current e-cigarette use’ increased in American school children from 11.7 per cent to 20.8 per cent (Cullen et al., 2018), and the US Surgeon General identified “a strong association between the use of e-cigarettes, cigarettes, and the use of other burned tobacco products by young people” (US Department of Health and Human Services, 2018). This increase appears to be associated with the availability and marketing of high-nicotine podvapes, of which JUUL is the market leader in the US. This product has only been available in New Zealand since late 2018, so the Year 10 data will not have picked up any increase due to this new development.

Youth data that is currently available was collected at a time when the Ministry had understood that vaping products manufactured from tobacco and smokeless oral tobacco could not be lawfully sold (in New Zealand) pursuant to section 29(2) of the SFEA. Anecdotal accounts suggest that the products were easily accessed online, but only nicotine free e-cigarettes were able to be sold legally. The Court judgement in 2018 that smokeless tobacco products can be legally sold in New Zealand has made them far more accessible and more likely to be addictive. The Ministry notes that “there is an absence of information to estimate the size and value of the New Zealand (vaping) market” (Ministry of Health 2019, p. 13).

Information about podvape sales in New Zealand was not able to be found at the time of writing this review, but according to the Premium Vape website which advertises sales of JUUL in New Zealand, it is “the world’s most popular pod vaping system. A pod system is the best e-cigarette for new vapers because it’s so easy to use. Each JUUL pod is a drop-in unit that contains both the e-cigarette’s flavoured nicotine e-liquid and the heating coil that turns the liquid to vapour. One JUUL pod contains about the same nicotine as a pack of full-flavoured cigarettes – and since each pod includes a new heating coil, you’ll never get anything but the freshest, boldest flavours when you vape with the JUUL.”⁴⁴

Current New Zealand youth prevalence data for either vaping or tobacco smoking will not yet be impacted by the popularity of this product among young people.

A study of vaping in Taranaki intermediate and secondary schools (Kidd, 2019) investigated the need for school vaping policies, using telephone interviews to survey principals and/or deputy principals from 17 schools. Site visits were also conducted at mobile and static retail vaping shops. Schools were asked about general vaping issues, numbers and types of vaping incidents on school grounds, and policies on vaping. The author found that overall, 59 per cent of schools reported at least one incident of vaping on school property, with the average number of incidents being five. Some schools reported ‘large numbers’ of students who either vaped or smoked on school grounds, and said that many of their students were nicotine-dependant. At least one school reported a mobile

⁴⁴ Material on how to obtain JUUL in New Zealand retrieved from <https://premiumvape.co.nz/blogs/news/buy-juul-in-new-zealand> on 10 April 2019.

retail van parked frequently within 400m of the school entrance. Only five of the 17 schools surveyed had a written policy prohibiting vaping on school grounds.

Vaping products were easily purchased in Taranaki dairies (where products were on display on shelves or at a front display) a vape shop and a mobile retail van.

New Zealand dairies have a poor record in restricting sales of tobacco products to minors – controlled purchase operations undertaken by public health services over many years indicate that they chronically break the law in this respect.

The Taranaki study provides an example of what is likely to be happening around New Zealand in the absence of a regulatory framework for vaping and smokeless tobacco products. Until this is in place, Kidd (2019) suggests that schools can protect the health of young people by developing policies on managing vaping issues at schools.

United Kingdom

In most parts of the UK, it is illegal to sell e-cigarettes to young people under the age of 18, there are restrictions on marketing of ECs, and the UK is subject to EU restrictions such as a limit on the level of nicotine in EC products of 20mg/mL. This may explain why vaping prevalence in children is much lower than in the US, although online sales enable limited access to this population.

	2015 (n=728)	2016 (n=814)	2017 (n=790)
All: Ever Use	22.2%	25.2%	28.0%
All: At least weekly	1.0%	1.3%	1.8%
Never smokers: Ever use	5.7%	8.8%	8.5%
Never smokers: Weekly use	0.3%	0.0%	0.0%
Regular Smokers: Ever use	81.8%	74.2%	75.8%
Regular Smoker: Weekly use	3.9%	9.6%	8.2%

Table 4: EC use among all 17 to 18-year-olds in Great Britain, and by smoking status (Source: ASH UK, from McNeill et al., 2018, p. 67)

Public Health England reports that “e-cigarettes are attracting very few young people who have never smoked into regular use” and that they “do not appear to be undermining the long-term decline in cigarette smoking in the UK among young people” (McNeill et al., 2018, p. 13).

The authors do discuss several studies that indicate young people who have never smoked in the UK and who try e-cigarettes are more likely to have tried smoking subsequently than those who have not tried them. However, they note that a causal link has not been established and neither has progression to regular smoking.

They recommend ongoing monitoring, especially of internet sales to minors, and reinforcement of age restrictions in the purchase of e-cigarettes, together with further research on trajectories of use between smoking and e-cigarette use.

The conclusions of Public Health England were partly drawn from a study by Bauld and colleagues (2017) who used data from five large-scale UK surveys of young people conducted between 2015 and 2017 (total n=60,000 young people aged 11-16 years) to assess e-cigarette use. They found that daily use of e-cigarettes was very low in this age group – less than one per cent, even though ever-e-cigarette use was higher, around 11 per cent among non-smokers and up to 92 per cent among

young people who smoked. Surveys across the UK showed a consistent pattern: most e-cigarette experimentation was not turning into regular use, and levels of regular use in young people who have never smoked remained very low.

Bauld and colleagues note that the UK has introduced rigorous regulations to reduce the potential risks of e-cigarettes but has sought to maximise the opportunity that e-cigarettes present for smoking cessation (Bauld, MacKintosh, Eastwood et al., 2017).

United States

The United States Centre for Disease Control and Prevention (CDC)⁴⁵ reported that current e-cigarette use had increased exponentially in the US over the seven years to 2018 from 1.5% (220,000 students) in 2011 to 20.8% (3.05 million students) in 2018 ($p < 0.001$). Furthermore, this increase in e-cigarette use occurred alongside an increase in use of any tobacco product among young people – reversing a decline observed in recent years and increasing overall tobacco product use (Cullen et al., 2018).

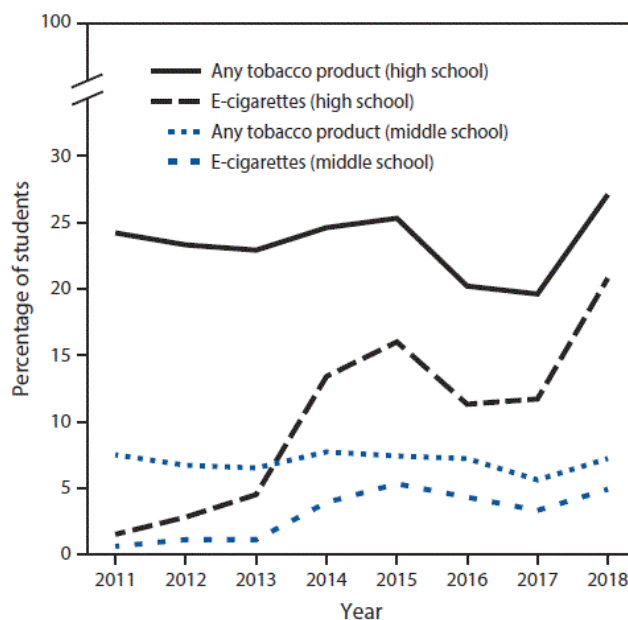


Figure 6. Percentage of middle and high school students who currently use e-cigarettes* and any tobacco product† — National Youth Tobacco Survey, United States, 2011–2018 (from Cullen et al., 2018)

* Current e-cigarette use was assessed by responses to these questions during the indicated survey years: “In the past 30 days, which of the following products have you used on at least one day?” and the response option, “Electronic cigarettes or e-cigarettes such as Ruyan or NJOY” (2011–2013); “During the past 30 days, on how many days did you use e-cigarettes such as Blu, 21st Century Smoke, or NJOY?” (2014); “During the past 30 days, on how many days did you use electronic cigarettes or e-cigarettes?” (2015); and “During the past 30 days, on how many days did you use e-cigarettes?” (2016–2018). During 2015–2018, e-cigarette questions were preceded by an introductory paragraph defining the product.

† Any tobacco product was defined as use of one or more of the following tobacco products on ≥ 1 day in the past 30 days: cigarettes, cigars (defined as cigars, cigarillos, or little cigars), smokeless tobacco (defined as chewing tobacco, snuff, or dip), e-cigarettes, hookahs, tobacco pipes, snus, dissolvable tobacco, and bidis.

⁴⁵ CDC. (2018) *Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students — United States, 2011–2018 Weekly* / November 16, 2018 / 67(45);1276–1277. Retrieved from https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w

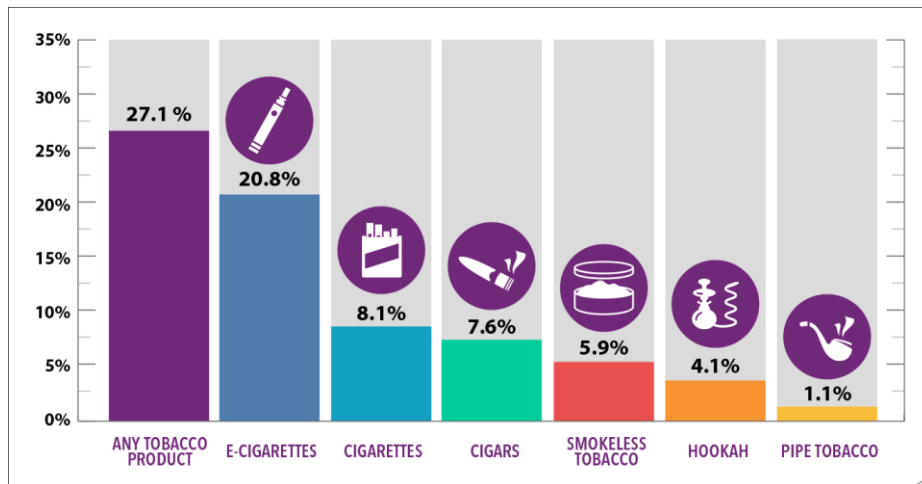


Figure 7. Tobacco product use among high school students—2018⁴⁶

Cullen and colleagues (2018) reported that

- During 2017–2018, current e-cigarette use among high school students (aged 14-18 years) increased by 78% (from 11.7% to 20.8%, $p < 0.001$). The proportion of current e-cigarette users who reported use on ≥ 20 of the past 30 days increased from 20.0% in 2017 to 27.7% in 2018 ($p = 0.008$).
- Among middle school students (aged 11-13 years), current e-cigarette use increased from 0.6% in 2011 (60,000 students) to 4.9% (570,000 students) in 2018 ($p < 0.001$) (Figure).
- Current use of any tobacco product⁴⁷ among high school students was 24.2% (3.69 million students) in 2011 and 27.1% (4.04 million students) in 2018 ($p > 0.05$). Current use of any tobacco product among middle school students was 7.5% (870,000 students) in 2011 and 7.2% (840,000 students) in 2018 ($p > 0.05$).
- During 2017–2018, overall tobacco product use increased by 38% among high school students (from 19.6% to 27.1%, $p < 0.001$) and by 29% among middle school students (from 5.6% to 7.2%, $p = 0.008$).
- The rise in e-cigarette use during 2017–2018 was likely because of the recent popularity of e-cigarettes shaped like a USB flash drive, such as JUUL; these products can be used discreetly, have a high nicotine content, and come in flavours that appeal to youths (4).
- In September 2018, the Food and Drug Administration (FDA) issued more than 1,300 warning letters and civil money penalty fines to retailers who illegally sold e-cigarette products to minors, the majority of which were blu, JUUL, Logic, MarkTen XL, and Vuse. (Cullen et al., 2018.)

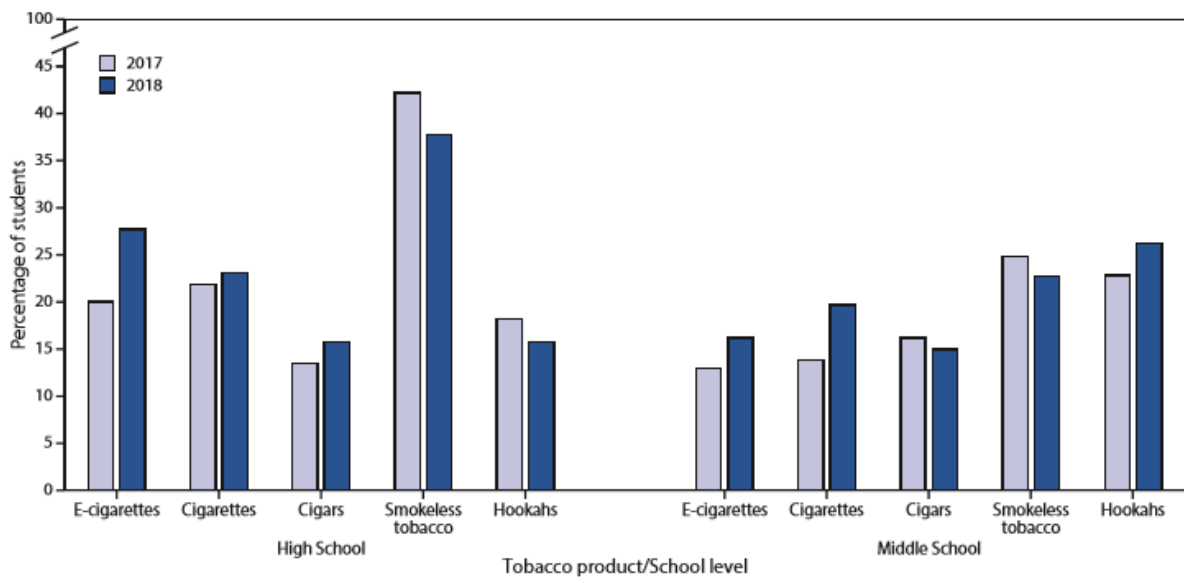
In a later report on tobacco use among middle and high schools students in the US (2011-2018) Genzke and colleagues (2019) also noted that the increase in e-cigarette consumption during 2017/18 among high school and middle school students was accompanied by an increase in the use of conventional cigarettes/any smoked tobacco.

“Furthermore, among current tobacco product users, approximately 40 per cent of high school students and one third of middle school students reported currently using more than one tobacco

⁴⁶ Retrieved from <https://www.cdc.gov/vitalsigns/youth-tobacco-use/> on 12 February 2019

⁴⁷ The CDC definition of ‘any tobacco product’ includes e-cigarettes.

product; the prevalence of using two or more tobacco products increased significantly by 22.8 per cent among high school students during 2017-2018.” (Gentzke et al., 2019, p. 163.)



Abbreviation: e-cigarettes = electronic cigarettes.

* Frequent tobacco product use defined as use of each respective tobacco product on ≥ 20 of the past 30 days.

† Frequency of use during the past 30 days was not available for pipe tobacco in the 2017 or 2018 surveys.

‡ Among youths who currently report using each respective tobacco product, defined as a response other than “0 days” to each of the following questions: “During the past 30 days, on how many days did you use e-cigarettes?”; Cigarettes: “During the past 30 days, on how many days did you smoke cigarettes?”; Cigars: “During the past 30 days, on how many days did you smoke cigars, cigarillos, or little cigars?”; Smokeless tobacco: “During the past 30 days, on how many days did you smoke tobacco, snuff, or dip?”; Hookahs: “During the past 30 days, on how many days did you smoke tobacco in a hookah or waterpipe?” For all questions, response categories included, “0 days, 1 or 2 days, 3 to 5 days, 6 to 9 days, 10 to 19 days, 20 to 29 days, and All 30 days.”

§ During 2017–2018, a significant increase in frequent use of e-cigarettes was observed only among high school students ($p < 0.05$). No significant changes were observed for any other tobacco product during 2017–2018 among middle or high school students.

Figure 8. Frequent use* of selected tobacco products† among US middle and high school students who currently used each tobacco product‡ – National Youth Tobacco Survey, 2017-2018¶

The authors concluded that “driven by an increase in e-cigarette use, current tobacco product use significantly increased among high school and middle school students during 2017-2018, erasing the decline in tobacco product use among youths that occurred in previous years.”

The authors called for “sustained implementation of proven population-based strategies, in coordination with FDA regulation of tobacco products” to reduce tobacco product use and initiation among children and young people in the US (Gentzke et al., 2019, p. 163).

Canada

A study investigating the prevalence of e-cigarette use among Canadians used participant data ($n=14,565$) from the 2013 Canadian Tobacco, Alcohol and Drugs Survey, and found that 8.5 per cent of all Canadians aged 15 years and over reported having ever tried an e-cigarette (Reid, Rynard, Czoli & Hammond, 2015). Current smokers and former smokers were more likely to have tried e-cigarettes than never-smokers. Past 30-day use was highest among youth (2.6%) and young adults (3.9%). The authors concluded that regular e-cigarette use among Canadians was much less prevalent than experimentation among both smokers and non-smokers, but that continued monitoring was a priority given the rapidly-evolving nature of e-cigarette design.

Azagba & Wolfson (2017) examined the association between current e-cigarette use and quantity of cigarette smoking. Cross-sectional data on current smokers were drawn from the 2014–2015 Canadian Student Tobacco, Alcohol and Drugs Survey among high school students ($n = 1411$). Current e-cigarette users reported smoking more conventional cigarettes in the past week compared to non-e-cigarette users. The authors concluded that the significant association found between e-

cigarette use and the number of cigarettes smoked may be driven by patterns of use among experimental or beginner smokers.

More recently (December 2018), Canadian teenage vaping rates were reported in the press⁴⁸ as having increased substantially, similar to the dramatic increase in the US. Furthermore, cigarette smoking in teenagers also appeared to be rising for the first time in 30 years, alongside the rapid increase in youth vaping attributed to the promotion and uptake of podvapes such as JUUL. The study related to this coverage has since been published (Hammond et al., 2019) and is discussed in the international comparisons section above.

Heat-not burn

Heat-not-burn (HNB) tobacco products are electronic devices that heat tobacco leaf and are like electronic cigarettes (e-cigarettes) in terms of producing aerosol. Philip Morris International (PMI) introduced the HNB tobacco product IQOS (I Quit Ordinary Smoking) in 2014 in Japan and Italy only. As of October 2017, IQOS is currently being test-marketed in 30 countries including New Zealand, Canada and the UK.² IQOS is intended to compete with available electronic nicotine delivery systems, or e-cigarettes,^{3 4} and other HNB tobacco products. Japan is the only country where a national roll-out of IQOS has occurred, and Japan's worldwide share of IQOS was 98% in October 2016 (Tabuchi et al., 2017). Philip Morris International has been reported as marketing this product aggressively to Māori for smoking cessation, by employing young Māori 'community activators' to sell the products for half price⁴⁹.

Heated tobacco products (HTPs), are a more recent product than e-cigarettes, and little has been published about perceptions of these products among youth. An investigation of youth perceptions was undertaken using data from wave 1 of the International Tobacco Control Youth Tobacco and E-cigarette Survey (2017), a web-based cohort survey of people aged 16–19 years from Canada, England and the USA. Respondents (n=12 064) were shown an image of IQOS and asked about their awareness, interest in trying and susceptibility to trying the product (Czoli, White, Reid, O'Connor, & Hammond, 2019).

Overall, 38.6 per cent expressed interest in trying the product. Interest and susceptibility to trying IQOS were found to be associated with male sex, current tobacco use and current e-cigarette use. The study demonstrated that awareness of HTPs, such as IQOS, is emerging among youth in Canada, England and the USA. Interest in trying these products is very high among smokers, but also present among non-smokers.

Use of other illicit drugs

The emerging trend for young people to transition from vaping to the use of cannabis and other substances is being monitored and investigated in the US, where e-cigarettes are now the most commonly used tobacco product among youth. In 2015, approximately one-third of US middle and high school students reported using e-cigarettes with non-nicotine substances (Trivers, Phillips, Gentzke, Tynan, & Neff, 2018).

⁴⁸ Press article titled Teen vaping in Canada has taken a 'worrisome' turn - New data suggests teen smoking rates in Canada are also rising, retrieved on 16 April 2019 from

<https://www.cbc.ca/news/health/health-canada-youth-teenage-vaping-smoking-hammond-1.4937593>

⁴⁹ Press coverage retrieved on 11 July 2019 from <https://www.newsroom.co.nz/2019/07/11/677880/big-tobacco-targeting-Māori-with-e-cigarettes>

Morean and colleagues (2015) surveyed 3847 Connecticut high school students to assess e-cigarette and cannabis use. They found that vaporizing cannabis using e-cigarettes was common among lifetime e-cigarette users, lifetime cannabis users, and lifetime dual users (e-cigarette 18.0%, cannabis 18.4%, dual users 26.5%). Students reported using e-cigarettes to vaporize hash oil and wax infused with THC and using portable electronic vaporizers to vaporize dried cannabis leaves. These findings raised concerns about the lack of e-cigarette regulations in the US, and the potential use of e-cigarettes for purposes other than vaping nicotine (Morean, Camenga, Cavallo & Krishnan-Sarin, 2015).

An Australian systematic review found evidence of current use of ECs to vape numerous illicit drug types, presenting both a potential population health risk and management issues for drug and alcohol clinicians (Breitbarth, Morgan & Jones, 2018). The authors also raise the issue of policing illicit drugs due to storage within EC fluids.

Breitbarth and colleagues (2018) found evidence that many cannabis users believe vaping cannabis was safer than smoking it and produced a 'stronger high'. EC technology was also being used for other drugs including synthetic cannabis, MDMA (ecstasy), cocaine, heroin, fentanyl and increasingly, methamphetamine. Online drug forums have identified the use of ECs, vape pens and/or table-top units to vaporise methamphetamine.

The demographics of EC use show a trend towards adolescents and young adults who believe that ECs are a safe product – which reflects marketing and reporting from health authorities. There is concern among researchers that children and young people are a group who tend to be risk takers and often do so collectively. "The use of illicit drugs via an easy to administer route and tool may result in higher usage levels ... potential increases in young adult use, addiction and toxicity, and paediatric accidental exposure." (Breitbarth et al., 2018, p. 107.)

These findings support anecdotal reports of the use of EC technology for cannabis and methamphetamine in Northland and other parts of New Zealand, whereby young people have been observed 'sharing a vape' with friends, with no idea of what they were consuming.

Gateway effect of vaping to smoking

"EC use is associated with higher rates of smoking initiation amongst adolescents, even among those who would otherwise have no inclination to smoke. There is a huge need to design policies that address the rising prevalence of EC use and re-normalization of smoking behaviour to protect our future generations. The absence of data on long-term safety should not be equated with safety; such was the case with cigarettes in the last century."

(Chatterjee et al., 2016)

The Ministry's 2018 Cabinet Paper on this topic notes concerns about vaping as a 'gateway' to tobacco smoking, but states that there is no robust evidence for this. The paper goes on to discuss the findings of two major reviews (National Academy of Sciences in the US and Public Health England), which both concluded that on the basis of current data "it is not possible to conclude that vaping causes smoking" (Ministry of Health 2018, p.4).

However, the Ministry of Health Regulatory Impact Statement (2019) acknowledges emerging evidence about the vulnerability of young people in terms of "the initiation, development and establishment of smoking behaviours" (Ministry of Health 2019, p. 12), and the need to restrict access to vaping and smokeless tobacco products by children and young people. The protection of

children and young people from potential risks associated with vaping is identified as a priority in Ministry of Health advice on amending the Smoke-free Environments Act 1990.

Concerns about the potential for vaping to be a gateway to tobacco smoking are widely held but the evidence remains disputed. This section discusses the evidence for and against the 'gateway effect'.

The US National Academies of Sciences, Engineering, and Medicine review (2018) concludes that

Conclusion 16-1. There is *substantial evidence* that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.

Conclusion 16-2. Among youth and young adult e-cigarette users who ever use combustible tobacco cigarettes, there is *moderate evidence* that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking.

Conclusion 16-3. Among youth and young adult e-cigarette users who ever use combustible tobacco cigarettes, there is *limited evidence* that e-cigarette use increases, in the near term, the duration of subsequent combustible tobacco cigarette smoking.

The Report of the US Surgeon General⁵⁰ states that "e-cigarette use is strongly associated with the use of other tobacco products including cigarettes..." and that "the use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe."

In the US, e-cigarette marketing is not subject to the same restrictions that apply to cigarettes, which allowed promotional expenditure to increase from \$3.6m in 2010 to \$125m in 2014. The tobacco industry's promotion of e-cigarettes used "well-established cigarette themes, including freedom, good taste, romance, sexuality, and sociability, as well as messages claiming the e-cigarettes are healthy, are useful for smoking cessation, and can be used in smoke-free environments. These messages are mirrored in the reasons that adults and youth cite for using e-cigarettes." (Glantz & Bareham, 2018, p. 217.)

Research indicates that children and young people (many of whom have never smoked) are also attracted by the novelty of vaping, the perception that it's relatively harmless and the flavourings. Patel and colleagues (2016) found that flavouring was more likely to be cited as a reason for e-cigarette use among younger age groups compared with those aged over 55 years, and that respondents aged 18-24 years were the most likely to be influenced by flavourings. The authors argued that public health efforts must ensure flavouring is not used to promote nicotine addiction, particularly amongst young people.

There is concerning US population data indicating that a majority of young people who vape also smoke, and that many young people who vape believe it is easy to quit smoking (Lee et al., 2018).

Public Health England (2018) appears confident that "e-cigarettes do not appear to be undermining the long-term decline in cigarette smoking in the UK among young people" but note that "never smokers in the UK who try e-cigarettes are more likely to have tried smoking subsequently than those who have not tried e-cigarettes. A causal link has not been established and neither has progress to regular smoking" (McNeill et al., 2018, p. 13).

A 'strong association' is not the same as a 'causal link', but causal links are hard to demonstrate and rely on long-term clinical data and costly research methodology.

⁵⁰ Retrieved from https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Fact_Sheet_508.pdf on 30 January 2019

Longitudinal studies can contribute to understanding of causal pathways. A systematic review and meta-analysis examining associations between e-cigarette use and subsequent smoking among adolescents and young adults (Soneji, Barrington-Trimis et al., 2017) investigated the findings of longitudinal studies that reported odds ratios for cigarette smoking initiation associated with ever use of ECs, or past 30-day cigarette smoking associated with past 30-day EC use. They found nine studies meeting their criteria (comprising 16,621 subjects), which demonstrated strong and consistent evidence of an association between initial e-cigarette use and subsequent cigarette smoking initiation, as well as between past 30-day e-cigarette use and subsequent past 30-day cigarette smoking.

“Adjusting for known demographic, psychosocial, and behavioral risk factors for cigarette smoking, the pooled odds ratio for subsequent cigarette smoking initiation was 3.50 (95% CI, 2.38-5.16) for ever vs never e-cigarette users, and the pooled odds ratio for past 30-day cigarette smoking at follow-up was 4.28 (95% CI, 2.52-7.27) for past 30-day e-cigarette vs non-past 30-day e-cigarette users at baseline. A moderate level of heterogeneity was observed among studies ($I^2 = 56\%$).” (Soneji et al., 2017, p. 788.)

Soneji and colleagues suggested strong EC regulation was needed to curb use among youth and prevent future population-level burden of cigarette smoking.

Chatterjee and colleagues (2016) reviewed four recent longitudinal studies from the that investigated the effects of e-cigarette use on onset of tobacco smoking among adolescents and young adults (total sample $n= 10,690$). They noted that all four studies were based on self-reported data including the never smoker status at initiation and the use of ECs; and that these are both subject to recall and reporting bias. They nevertheless concluded that e-cigarette use in young people does lead to a higher incidence of combustible cigarette smoking.

The first of the studies reviewed (Leventhal et al, 2015) studied a cohort of 2530 adolescents with diverse backgrounds, who had never smoked tobacco. A prospective longitudinal repeated measure design was used with a follow-up evaluation at 6 or 12 months. The prevalence of EC use in the initial sample of smokers and non-smokers ($n=3326$) was 18.6 per cent. Vapers were more likely to report smoking combustible tobacco products at both 6 months (30.7% vs 8.1%) and 12 months (25.2% vs. 9.3%). The authors adjusted for multiple covariates, including sociodemographic, environmental and intrapersonal factors and found a significant association between baseline EC use and subsequent use of any combustible tobacco product [adjusted OR 2.73 (95% CI, 2.00–3.73)]. They concluded that “Among high school students in Los Angeles, those who had ever used e-cigarettes at baseline compared with nonusers were more likely to report initiation of combustible tobacco use over the next year. Further research is needed to understand whether this association may be causal.” (Leventhal et al, 2015, p. 700.)

In the second longitudinal study reviewed by Chatterjee and colleagues (Primack et al., 2015), a cohort of adolescents aged 16-24 years who were never smokers and assessed as not susceptible to smoking ($n=694$) were surveyed by telephone at baseline and 12-month follow-up. The analyses were adjusted for covariates known to be associated with smoking. Six of the 16 (37.5%) participants using e-cigarettes progressed to combustible cigarettes, compared to 63 of the 678 (9.3%) non-users. Despite the limitations (low statistical power and other issues) Chatterjee and colleagues describe this US study as significant in adding to knowledge about the role of e-cigarettes as an independent risk factor for progression to tobacco smoking in young people otherwise at low risk of smoking.

The third longitudinal study investigated where 'ever' or 'rare' vaping behaviour could progress to smoking in a sample of 2338 high school students in Hawaii (mean age of 14.7 years at baseline). Wills and colleagues (2017) assessed e-cigarette use, tobacco cigarette use, and psychosocial covariates (demographics, parental support and monitoring, and sensation seeking and rebelliousness). Participants were surveyed in 2013 and again at 12-month follow-up. Of the students initially surveyed, 31 per cent admitted having ever used an EC, and nearly 68 per cent thought they were healthier than conventional cigarettes. Never smokers who had used an EC were found to be more likely to have used conventional cigarettes 12 months later (adjusted OR=2.87, 95% CI 2.03 to 4.05). EC use was not associated with reduced frequency of conventional smoking at the 12-month point. The findings may help validate "ever use of e-cigarettes" as a measure for smoking initiation (Chatterjee et al., 2016).

The final longitudinal study assessing the relationship between EC use and smoking in young people involved a cohort of 20-year-old Swiss males (n=5128), followed up at 15 months (Gmell, Baggio, Mohler-Kuo, Daeppen & Studer, 2016). EC users were found to have a higher consumption of cigarettes (62.5 vs 18.1 cigarettes per week, $p < 0.0001$) than non-EC users and higher nicotine dependence levels. Even after adjusting for nicotine dependence, Gmell and colleagues found that "EC users were more likely to have initiated smoking, become occasional smokers, and daily smokers. Although EC users had more quit attempts at follow-up, they were less likely to have achieved their goal" (Chatterjee et al., 2016, p.4).

In their review study, Glantz and Bareham (2018) discussed the findings of Soneji and colleagues (2017) which found the odds of subsequent cigarette smoking within 12 months had quadrupled among e-cigarette users, after adjusting for demographic, psychosocial, and behavioural risk factors for cigarette smoking. Glantz & Barham (2018, p. 219) concluded that "e-cigarettes are expanding the tobacco epidemic by bringing lower-risk youth into the market, many of whom then transition to smoking cigarettes."

Concerns about this prospect have also been expressed by Siddiqui and colleagues (2019) who refer to numerous longitudinal studies in North America and European settings and also suggest that the surge in popularity of e-cigarettes among youth could reverse the trend of reducing smoking prevalence in this age group (Siddiqui, Mishu, Marshall & Siddiqui, 2019). They suggest that the evidence is very strong for this effect, whether it is due to the 'gateway effect' – the theory of nicotine addiction developing through positive relationships with smoking peers, diluting the harm perceptions of cigarettes, and prompting smoking behaviours – or the so-called 'common liability' theory, whereby young people transition from ECs to tobacco smoking due to other factors that make them susceptible to both behaviours.

The possibility of a gateway effect to future cigarette smoking in young Canadians has been investigated in several longitudinal studies, which are able to explore the pathway between e-cigarette and cigarette use, particularly among different risk groups including susceptible and non-susceptible never-smokers. The objective of one such study was to examine whether baseline use of e-cigarettes among a sample of never-smoking youth predicted cigarette smoking initiation over a 2-year period (Aleyan, Cole, Qian, & Leatherdale, 2018).

Set in 89 high schools across Ontario and Alberta, Canada, the participants were a sample of grade 9–11 never-smoking students at baseline (n=9501) who participated in the COMPASS study over two years.

Overall, current e-cigarette users were more likely to try a cigarette 2 years later. This association was stronger among the sample of non-susceptible never-smokers (AOR=5.28, 95% CI 2.81 to 9.94; $p < 0.0001$) compared with susceptible never-smokers (AOR=2.78, 95% CI 1.84 to 4.20; $p < 0.0001$).

The authors concluded that their findings “support public health concerns that e-cigarette use may contribute to the development of a new population of cigarette smokers. They also support the notion that e-cigarettes are expanding the tobacco market by attracting low-risk youth who would otherwise be unlikely to initiate using cigarettes. Careful consideration will be needed in developing an appropriate regulatory framework that prevents e-cigarette use among youth.” (Aleyan et al., 2017, p. 1)

Hammond and colleagues (2017) were concerned that in the US, there was mounting evidence that the availability of e-cigarettes had expanded the nicotine market as a whole, rather than simply substituted e-cigarettes for tobacco smoking. In recent years, the total number of young Americans who are using any type of nicotine product has increased for the first time in decades (CDC, 2018). The Canadian market is very different from that in the US – there is almost no advertising or marketing through traditional media outlets, and although e-cigarettes with nicotine are widely available through vape shops and online, other outlets such as supermarkets cannot sell these products if they contain nicotine. However, the non-nicotine products were able to be sold to minors at the time of the study, and the authors questioned whether youth experimentation with non-nicotine vaping products might reduce the daily vaping prevalence among this group at one-year follow-up.

They investigated e-cigarette use and smoking initiation among Canadian youth in a longitudinal cohort study which analysed survey data from secondary school students aged 14-18 years ($n=19,130$) at baseline (2013/4) and one-year follow-up (2014/15). Youth who reported e-cigarette use in the previous 30 days at baseline were found to be more likely to initiate cigarette smoking and more likely to report having smoked daily at follow-up, even after adjustment for a range of other factors at baseline.

In discussing possible causality, Hammond and colleagues (2017) suggested that “at the individual level, e-cigarettes may be causally related to cigarette smoking because they provide early exposure to nicotine or greater exposure to environmental risk factors, including greater exposure to smokers or certain social settings. E-cigarette use may also help to ‘re-normalize’ smoking by promoting more positive normative beliefs about nicotine use and smoking, which are important predictors of uptake.” The authors concluded that the debate about whether e-cigarettes ‘cause’ smoking in young people will persist, and that “in the meantime, regulatory frameworks that succeed in shifting e-cigarette use away from youth and concentrating their use among cigarette smokers for the purposes of smoking cessation are likely to have the greatest public benefit.” (Hammond et al., 2017, p. 1335, p. 6.)

In summary, as Siddiqui and colleagues (2019) suggest, both ‘common liability’ and ‘gateway effect’ are possible explanations for the increase in tobacco smoking alongside EC use in young people. They ought to be considered as hypotheses, not facts. Future longitudinal research will need to control for common liability before confirming a causal inference between EC use and smoking. They also point out that the transition from EC use to smoking may take place during young adulthood rather than in school-age children, which would require cohort studies to include follow-up over longer periods than 12 or 24 months, and adopting of standardised measures that demonstrate the risk of transition from ECs to tobacco smoking.

What are the risks and benefits of promoting vaping as a harm reduction strategy?

Vaping as a harm reduction strategy for achieving Smokefree Aotearoa 2025

“Although proponents of e-cigarettes dismiss the idea, opponents fear that e-cigarette use could act as a gateway to the use of other more harmful drugs. ... They refuse to think that Big Tobacco is manufacturing e-cigarettes for altruistic purposes of reducing nicotine addiction and harm. Moving forward, they are looking back to years of lies, deception, and cover ups by the tobacco industry and their repeated attempts to deny that cigarettes are addictive and to develop safer products such as low-tar cigarettes that turned out to be no safer than previous products. They question the newly acquired harm reduction attitude of Big Tobacco when it continues to offer a cornucopia of child-friendly flavours familiar at pre-schoolers’ birthday parties.”

Bhatnagar, 2017

Introduction

A key argument for making e-cigarettes more widely available and promoting their uptake among smokers is the belief that vaping is significantly less harmful than cigarette smoking, and that large numbers of adult smokers will be able to either quit nicotine use entirely using ECs, or if not quit at least transfer their nicotine addiction to vaping and incur a lower risk of physical harm.

The harm reduction argument is compelling – it can be extremely difficult for heavily addicted adults to quit smoking. This cohort includes a high proportion of low-income, Māori, Pacific, mental health service users and other minority groups who tend to be unfairly impacted by structurally embedded social and economic disadvantage. Reducing smoking prevalence in this group is taking too long, and New Zealand is very unlikely to reach its goal of Smokefree Aotearoa 2025 on current projections (van der Deen, Wilson & Blakely, 2016).

The harm reduction approach is summarised in the problem definition section of the Ministry of Health regulatory impact statement *Supporting smokers to switch to significantly less harmful alternatives*: “There is an opportunity, through better regulation (and public information), to support smokers to switch to significantly less harmful alternatives, substantially reducing the risks to their health and those around them” (Ministry of Health 2019).

Public consultation was undertaken during 2016 using an online survey seeking responses to questions relating to proposed amendments to the SFEA 1990 (Ministry of Health, 2017). This approach would mean the sale and supply of nicotine e-cigarettes and e-liquid would be made lawful as consumer products, with appropriate regulatory controls, which would:

- prohibit their sale and supply in public places, to people under the age of 18 years
- restrict advertising
- prohibit their use in areas defined as smokefree in the SFEA.

Most of the respondents supported a fairly liberal approach to regulation. For example, the Ministry’s Regulatory Impact Statement (2019, p. 16) states that “under half of the submitters supported a ban on vaping in legislated smokefree areas” although it should be noted that of the 250 submissions, 39 (15.6%) respondents were from the tobacco and vaping industries, and 98

(39.2%) identified as vapers. Vapers tended to be more supportive than others of liberalising access, use in public places that are currently smokefree, and product promotion.

The tobacco industry has supported the Ministry's harm minimisation position, with industry leader Philip Morris International (PMI) declaring that they plan to "transform the tobacco industry in support of New Zealand's Smokefree 2025 initiative" in an interview published in design magazine *Ideologue*.⁵¹

The New Zealand vaping industry is also very supportive of the harm minimisation approach. The NZ Vaping Alliance (NZVA) was launched in 2015 and NZVPA President QJ Satchell stated in an accompanying media article⁵² that "a seismic shift is occurring in the New Zealand tobacco market as a significant number of smokers switch to e-cigarettes as a way to reduce health risks associated with cigarette smoking." The New Zealand Vaping Alliance was described in the same media article as "a group of New Zealand's leading e-cigarette retailers and keen vaping enthusiasts concerned at the absence of a collective voice on e-cigarette use and vaping community issues".

In stark contrast, the European Respiratory Society (ERS) Tobacco Control Committee recently released a position paper on tobacco harm reduction (ERS, May 2019), in which they argue why a harm reduction strategy should not be used as a population-based approach. They make the following arguments:

1. The tobacco harm reduction strategy is based on incorrect claims that smokers cannot or will not quit smoking
2. The tobacco harm reduction strategy is based on undocumented assumptions that alternative nicotine delivery products are highly effective as a smoking cessation aid
3. The tobacco harm reduction strategy is based on incorrect assumptions that smokers will replace conventional cigarettes with alternative nicotine delivery products
4. The tobacco harm reduction strategy is based on undocumented assumptions that alternative nicotine delivery products are generally harmless
5. Alternative nicotine delivery products can have a negative impact on public health even if 'stick by stick' they turn out to be less harmful than conventional cigarettes
6. Smokers see alternative nicotine delivery products as a viable alternative to the use of evidence-based smoking cessation services and smoking cessation pharmacotherapy
7. The tobacco harm reduction strategy is based on incorrect claims that we cannot curb the tobacco epidemic
8. Alternative nicotine delivery products are the tobacco industry's adaptation to declining tobacco consumption and acceptability of smoking, and increased regulation of cigarettes.

The ERS concludes that "the human lungs are created to breathe fresh air, not 'reduced levels of toxins and carcinogens' and the human body is not meant to be dependent on addictive drugs. ERS cannot recommend any product that is damaging to the lungs and human health. Therefore, ERS strongly supports implementation of WHO's Framework Convention on Tobacco Control and cannot recommend tobacco harm reduction as a population-based strategy." (ERS, 2019, p. 12.)

⁵¹ Retrieved from <https://idealog.co.nz/venture/2019/02/philip-morris-nz-its-stance-against-tobacco-industry> on 24 February 2019.

⁵² Retrieved from <http://www.scoop.co.nz/stories/PO1510/S00162/nz-vaping-alliance-launched.htm> on 16 April 2019.

Risks and benefits of promoting e-cigarettes – modelling studies

Risks and benefits can occur at both the individual and population level. Most people would agree that there are potential benefits from promoting ECs at an individual level. Smokers who are able to quit smoking altogether through using ECs, or substitute vaping for tobacco smoking, will undoubtedly benefit from access to EC and possibly other smokeless tobacco products. However, it is essential to understand whether the net effect of increasing access to ECs is likely to be positive or negative on smoking prevalence, reducing inequalities in health outcomes, and on population health.

The key problem with promoting ECs as a harm minimisation tool at a population level is that while they can potentially help cigarette smokers quit smoking, the approach may also facilitate cigarette smoking for young people and those who have never smoked, as well as recruiting ex-smokers back into nicotine dependence. The harm minimisation potential of e-cigarettes has recently been investigated using research methodologies designed to model various scenarios.

However, as more research findings are published and the EC technology changes, the assumptions underpinning current modelling scenarios, and conclusions reached, can quickly become outdated. For example, none of the modelling studies discussed in this section have taken into account the impact of user-friendly podvapes such as JUUL, which appear to have contributed to the rapid increase during 2017 and 2018 of children and young people regularly using ECs in the US and Canada. These and other product developments, new information about health impact, and various contextual changes need to be taken into account in reading the research.

Most of the current modelling studies have concluded a net harm from the introduction of ECs.

Soneji and colleagues (2017) set out to quantify the balance of health benefits and harms associated with e-cigarette use at the population level, using a Monte Carlo stochastic simulation model. The expected years of life gained or lost were calculated from the impact of e-cigarette use on smoking cessation among current smokers compared with the transition to long-term cigarette smoking among never smokers, for a 2014 US population cohort.

The model estimated that 2,070 additional current cigarette smoking adults aged 25–69 would quit smoking in 2015 and remain continually abstinent from smoking for ≥ 7 years through the use of e-cigarettes in 2014. The model also estimated 168,000 additional never-cigarette smoking adolescents aged 12–17 and young adults aged 18–29 would initiate cigarette smoking in 2015 and eventually become daily cigarette smokers at age 35–39 through the use of e-cigarettes in 2014. Overall, the model estimated that e-cigarette use in 2014 would lead to 1,510,000 years of life lost, assuming an optimistic 95% relative harm reduction of e-cigarette use compared to cigarette smoking. As the relative harm reduction decreased, the model estimated a greater number of years of life lost.

Based on scientific evidence known at the time of the study related to e-cigarettes the authors concluded that their use currently represents more population-level harm than benefit. Efforts at national and local levels would be needed to reduce e-cigarette use among youth and young adults if e-cigarettes were to confer a net population-level benefit in the future (Soneji, Primack, et al., 2017).

A similar conclusion was reached by Kalkhoran and Glantz (2015) in their study modelling the health effects of expanding e-cigarette sales in the US and UK using a Monte Carlo analysis. A harm reduction scenario in which e-cigarette use increased only among smokers interested in quitting with more quit attempts and no increased initiation of e-cigarette use among non-smokers; and another scenario in which ECs were taken up only by youth who would have smoked conventional

cigarettes, had population-level health benefits regardless of e-cigarette health costs in both the US and UK.

Conversely, scenarios in which e-cigarette promotion lead to renormalization of cigarette smoking or ECs were used primarily by youth who never would have smoked, showed net health harms across all EC health costs. In other scenarios, the net health effect varied on the basis of the health cost of ECs. Kalkhoran and Glantz (2015) concluded that widespread promotion of e-cigarettes may have a wide range of population-level health effects, depending on both EC health risks and patterns of use. The current uncertainty about the health risks of ECs, increasing EC use among youth, and the varying health effects at different EC health costs suggested a potential for harm.

The opposite conclusion was reached by Warner & Mendez (2019), who also compared potential health benefits and costs, using a dynamic model that tracks the US adult population's smoking status and smoking-related deaths over time. The authors simulated the effects of vaping-induced smoking initiation and cessation on life-years saved or lost to the year 2070. The base case assumed that vaping annually increases smoking initiation by 2 per cent and smoking cessation by 10 per cent. Using these assumptions, it was estimated that the population would gain almost 3.3 million life-years by 2070.

This analysis strongly suggested that the upside health benefit associated with e-cigarettes, in terms of their potential to increase adult smoking cessation, would exceed their downside risk to health as a result of their possibly increasing the number of youthful smoking initiators.

A recently published New Zealand study (Petrovic-van der Deen, et al., 2019) reached similar conclusions to Warner & Mendez, using a computer simulation model to estimate the likely net health impact of liberalising access to e-cigarettes in New Zealand. Note that this study began when it was illegal for nicotine containing ECs to be sold in New Zealand. The authors used the term 'liberalising access' to mean a scenario where ECs could be purchased only from pharmacies and specialist shops – that is, not in dairies, supermarkets and petrol stations alongside other tobacco products as is currently being planned. It also did not consider the impact of a public education campaign promoting the use of ECs for smoking cessation.

The study did take into account various known benefits of vaping as well as the known risks and concluded that the NZ population alive in 2011 was estimated to gain 236,000 extra years of healthy life over the remainder of the population's lifespan. The EC intervention was estimated to result in the same health gain as 10 per cent per annum tobacco tax increases per year for 15 years.

The authors acknowledged genuine scientific uncertainty with their results since there is limited knowledge about vaping and health – and vaping technology is also evolving rapidly. They also noted that other tobacco control interventions (for example, a sinking lid policy on tobacco sales) were significantly more likely to reduce smoking prevalence than improving access to ECs.

Key to all the modelling papers that find net benefit from ECs is the assumption that they have positive benefits on quitting and that substantial substitution from smoking to ECs occurs. As discussed elsewhere in this report, the evidence on ECs in supporting quitting at an individual level is far from established.

Impact of e-cigarettes on smoking cessation at an individual level

Vaping has quickly become popular around the world and appears to be a more appealing and therefore potentially a more effective way of helping adult smokers to quit than other nicotine replacement therapy options. A new randomised controlled trial has shown promising results when

vaping is offered to people enrolled in comprehensive smoking cessation programmes (Hajek et al., 2019), but other research findings are mixed. No independent, good quality research was found in this review on the effectiveness of heat-not-burn products such as IQOS in smoking cessation.

The US National Academies review study (NASEM 2018) found the following in relation to harm reduction at an individual level.

Conclusion 18-1. There is *conclusive evidence* that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.

Conclusion 18-2. There is *substantial evidence* that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems.

Conclusion 18-3. There is *no available evidence* whether or not long-term e-cigarette use among smokers (dual use) changes morbidity or mortality compared with those who only smoke combustible tobacco cigarettes.

Conclusion 18-4. There is *insufficient evidence* that e-cigarette use changes short-term adverse health outcomes in several organ systems in smokers who continue to smoke combustible tobacco cigarettes (dual users).

Conclusion 18-5. There is *moderate evidence* that second-hand exposure to nicotine and particulates is lower from e-cigarettes compared with combustible tobacco cigarettes.

There is good evidence that second-hand exposure to e-cigarette vapour can impact on health. A systematic review investigating the potential adverse health effects of passive exposure from inhaling EC vapour set out to summarise relevant articles published between 1996 and September 2015 and describe 1) the absolute impact of passive exposure from inhaling vapour when compared with background, and 2) the relative impact of passive exposure from inhaling vapour when compared with passive exposure from inhaling conventional cigarette smoke (Hess, Lachireddy & Capon, 2016).

The authors note that previous studies had demonstrated that the aerosol from ECs can contain toxic chemicals which are harmful to health. There were 16 studies of varying designs that met the review criteria, including direct exposure studies involving humans and animals, and indirect exposure studies using volunteer EC users or smoking machines. All papers had identified limitations, but the evidence was sufficiently strong for the review to conclude that the absolute impact from passive exposure to EC vapour has the potential to lead to adverse health effects, and that EC vapour contains elevated levels of nicotine, glycerine, propylene glycol, formaldehyde, acetaldehyde, metals, and other chemicals. However, the risk from being passively exposed to EC vapour is likely to be less than the risk from passive exposure to conventional cigarette smoke. The authors noted that studies undertaken by tobacco industry employees or funded by the Australian National Vapers Club had drawn different conclusions – that there was no risk to bystanders from being exposed to vaping.

The impact of e-cigarettes at a population level

Some researchers have investigated the impact of ECs at a population level, to clarify any contribution ECs may have made to reductions in smoking prevalence.

Public Health England used data from UK Stop Smoking Services which showed that for both 2015-16 and 2016-17, “the highest number of quit attempts involved combination NRT, though the highest quit rate was in people who used a licensed medicine and an EC consecutively” (McNeill et al, 2018, p. 115) to support their claim that e-cigarettes are effective in helping smokers to quit.

The claim of EC effectiveness in reducing smoking prevalence has been supported by at least one UK study that estimated how far changes in the prevalence of e-cigarette use in England had been associated with changes in quit success, quit attempts, and use of licensed medication and behavioural support in quit attempts, using a time series analysis of population trends (Beard, West, Michie & Brown, 2016). Participants came from the Smoking Toolkit Study, which involves repeated, cross sectional household surveys of individuals aged 16 years and older. Data are collected on about 1200 smokers each quarter. Prevalence of e-cigarette use in current smokers and during a quit attempt were used to predict quit success. Prevalence of e-cigarette use in current smokers was used to predict rate of quit attempts.

No clear evidence was found for an association between e-cigarette use and rate of quit attempts, use of NRT bought over the counter, use of prescription treatment, or use of behavioural support. The authors concluded that the increased prevalence of ECs in England did not seem to have been associated with a change in attempts to stop smoking, but it was associated with an increase in the success of quit attempts (Beard et al., 2016).

Zhu and colleagues (2017) examined whether the use of electronic cigarettes in the US, which increased dramatically by 2014, was associated with a change in the overall smoking cessation rate at the population level. Data on e-cigarette use were obtained from the total sample of the 2014-15 Current Population Survey-Tobacco Use Supplement ($n=161\ 054$). Smoking cessation rates were obtained from those who reported smoking cigarettes 12 months before the survey ($n=23\ 270$). Rates from the 2014-15 survey were then compared with those from 2010-11 and those from three other previous surveys, to establish rates of quit attempts and successfully quitting smoking (defined as having quit for at least three months).

E-cigarette users were found to be more likely than non-users to attempt to quit smoking, 65.1% v 40.1% and more likely to succeed in quitting, 8.2% v 4.8%. The overall population cessation rate for 2014-15 was significantly higher than that for 2010-11, 5.6% v 4.5%, and higher than those for all other survey years. The authors concluded that the substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level.

A new study investigating potential country-level health and cost impacts of legalising domestic sale of vaporised nicotine products (Petrovic-van der Deen, Wilson, Crothers et al., 2019) used Monte Carlo simulation modelling to assess the potential health and cost impacts of liberalising vaping in New Zealand. The method compared a ‘business as usual scenario’ that assumed no domestic vaping product sales, and current annual net cessation rates and smoking uptake rates by sex, ethnicity and age group, with an intervention base-case whereby the domestic sale of vaping products was legalised. The results suggested that widening access to vaporised nicotine products in NZ which at that time had restrictive access to these products could achieve substantive overall health gains and cost savings to the health system. However, the authors’ modelling could not rule out potential net health harm for the youngest age cohort (0-14-year-olds) or for the 65+ year-olds. For the young this was due to uncertainty about non-smoking youth becoming long-term and the impact on tobacco smoking uptake rates.

These findings support the approach of a fairly permissive regulatory environment to enable access for adult smokers, with regulations limiting youth uptake. It would mean in practice, “relatively light regulation of permitted retail settings and having no excise taxes on vapourised nicotine products (to ensure that vaping is less expensive than smoking). Product sales could be combined with targeted cessation advice (what type of device to use, nicotine strength etc). Second, standards for chemical constituents of the products to minimize health risk would be desirable. Third, regulations to reduce youth uptake might include age limits on sales, bans on any marketing aimed at youth, and possibly restrictions on flavours that might be particularly attractive to youth.” (Petrovic-van der Deen et al., 2019.)

A review study on harm minimisation and tobacco control (Abrams et al., 2018) does not include a methodology section, so it is not possible to establish why the authors have reached very different conclusions from other review studies cited in this report. In summary, the authors found that ECs are highly effective in smoking cessation, and that they pose very low risk of harm. They conclude that “a reframing of societal nicotine use through the lens of harm minimisation is an extraordinary opportunity to enhance the impact of tobacco control efforts” (Abrams et al., 2018, p.193).

The risks and benefits of increasing EC availability and marketing for smoking cessation

The above studies show some evidence that supports making ECs available for helping adults to quit. There is some evidence that this approach can be effective at both individual and population levels.

However, there are risks associated with taking an approach that effectively promotes nicotine-containing products (as a relatively harmless alternative to smoking) and made more widely available than other NRT medication, and more socially acceptable than tobacco smoking. The main risk is that the message of relative harm will reinforce marketing messages from the tobacco and vaping industries and be heard by young people and non-smokers as ‘harmless’.

People who had never thought about smoking are already curious about trying vaping and it is possible that many will become addicted to nicotine in a liberalised supply environment. New Zealand could follow the US trend of rapidly increasing numbers of children and young people becoming addicted to nicotine through vaping, and many going on to become smokers – the so-called ‘gateway’ effect that new US population data shows may have contributed to increased smoking prevalence in American school children (CDC, 2019).

The potential risks and benefits of promoting ECs for smoking cessation have been discussed within the New Zealand tobacco research community for some years, with a summary of potential benefits and harms posted in a blog (Edwards et al., 2017) titled ‘Achieving Smokefree Aotearoa by 2025: a response to critiques’ (see table 5 below).⁵³

⁵³ Public Health blog retrieved on 24 April 2019 from <https://blogs.otago.ac.nz/pubhealthexpert/2017/10/06/achieving-smokefree-aotearoa-by-2025-a-response-to-critiques/>

Table 5: Potential benefits and risks of increasing e-cigarette availability

Potential benefits	Potential harms
E-cigarettes used as cessation aids help smokers to quit. Results in increased successful quit rates.	Smokers who might otherwise have quit smoking altogether instead adopt long-term 'dual use' of e-cigarettes and smoked tobacco products. Results in reduced quit rates.
E-cigarettes act as an alternative for some smokers who cannot or do not wish to stop using nicotine resulting in transition to a reduced harm product compared to smoking tobacco.	Social, economic and cultural costs of maintaining addiction to nicotine among smokers who switch to e-cigarettes (which is still substance addiction, even though the health effects are less serious than for tobacco) instead of quitting smoking entirely.
E-cigarettes reduce smoking uptake by replacing tobacco products among young people likely to start smoking.	E-cigarettes increase smoking uptake by acting as a 'gateway' to starting smoking for children and young adults.
E-cigarettes reduce second-hand smoke exposure by reducing overall smoking prevalence.	E-cigarette uptake among children and young adults exposes them to adverse health effects (though likely much less severe effects than for smoked tobacco products) as well as social, economic and cultural costs of maintaining addiction.

Making ECs widely available with largely unrestricted access (allowing sales in most retail settings, including dairies, petrol stations and supermarkets) could potentially maximise use of e-cigarettes by smokers as an aid quitting or as complete substitutes for smoked tobacco products among those who want to continue to obtain nicotine. However, the authors argued that it would also maximise youth access to ECs, risking the prospect of a new cohort of children and young people becoming addicted to nicotine, and potentially starting to smoke.

An alternative approach would be to make e-cigarettes available, but with some restrictions. This would allow sales only in specialist vape shops and pharmacies, as both stores have (or could have) staff trained in using e-cigarettes and smoking cessation. This approach could enhance the successful use of e-cigarettes by ensuring that smokers buy them at locations where they will receive expert advice about their use (which device, which strength of e-liquid etc) and support for quitting smoking. Also, this option could minimise the risk of children and young people experimenting with, becoming regular users of e-cigarettes or going on to smoke conventional cigarettes.

In summary, the findings of modelling studies that assess benefits and harms of interventions depend on their underlying assumptions. By changing these assumptions, the harm/benefit ratio can change considerably. None of the studies included in this review assumed that EC and smokeless tobacco products would be displayed at front counters and available from every corner dairy, supermarket, and petrol station. Neither do they take into account new population survey information about the impact of podvapes on youth uptake of all tobacco products, or assume a national public education campaign that promotes the use of these products as 'relatively harmless'. Yet most of them conclude that the potential harms from ECs outweigh their potential benefits.

While the findings of this review support more restricted access to EC and smokeless tobacco products, it must be acknowledged that the New Zealand tobacco control sector is divided on these matters. There are many who believe that ECs and other smokeless tobacco products ought to be made as widely available as possible and marketed comprehensively. They argue that ECs save lives,

that youth uptake is not a problem here, and that EC use in young people does not lead to tobacco smoking. Arguments are made that ECs also have the potential to reduce health inequalities, based largely on anecdotal reports that Māori smokers prefer vaping to other smoking cessation approaches, and that it is more effective for them.

These claims and reports are deserving of urgent investment in well-designed research – to test their validity and to inform the design and improve the effectiveness of stop smoking services for Māori and other priority groups.

Meanwhile, serious consideration must be given to protecting children and young people from the risk of exposure to nicotine addiction, in any form.

Regulation

How can these findings inform responses to proposed amendments to the SFEA 1990?

“As we wait for the relevant evidence to emerge, we have to find ways to regulate marketing, youth access, and labelling; to prohibit free sampling; and to set standards for contamination. Importantly, companies should not be permitted to claim that their devices are cessation aids unless they present rigorous, convincing data supporting their claims. Such minimal regulations would ensure that the use of e-cigarettes does not result in unintended harm ...”

(Bhatnagar, 2017)

Supporting smokers to switch to significantly less harmful alternatives

The Ministry of Health website describes the regulatory impact statement titled “Supporting smokers to switch to significantly less harmful alternatives” (updated January 2019)⁵⁴ as follows

This Regulatory Impact Statement seeks to balance the objectives of supporting smokers to switch to significantly less harmful alternatives with protecting children and young people from any risks associated with vaping in particular.

The regulatory controls in the Smoke-free Environments Act 1990 were designed primarily for tobacco products that are smoked. They are inadequate for vaping and smokeless tobacco products, which are less harmful to users.

There is an opportunity, through better regulation (and public information), to support smokers to switch to significantly less harmful alternatives, substantially reducing the risks to their health and those around them.

While acknowledging the lack of solid evidence regarding the safety and effectiveness of promoting vaping as a way to help smokers reduce or quit smoking, the Ministry of Health and many in the tobacco control sector in New Zealand support a harm minimisation approach to regulating this new industry. The approach is based on current knowledge about the relative safety of vaping, compared with tobacco smoking.

By amending the Smoke-free Environments Act 1990 to allow for the regulation of vaping and smokeless tobacco alongside other tobacco products, the Ministry intends to provide protections against the potential harm of these products, particularly in relation to young people.

The following section discusses research on the regulation of e-cigarettes around the world, regulatory issues that have arisen from this review, and how the Ministry intends to proceed, based on the conclusions section of their Regulatory Impact Statement (2019).

⁵⁴ Retrieved on 9 January 2019 from <https://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements/supporting-smokers-switch-significantly-less-harmful-alternatives>

International studies discussing vaping regulation

In 2013, the WHO Tobacco Free Initiative published a comprehensive report to provide countries with guidance on regulating e-cigarettes (Grana, Benowitz & Glantz, 2013). Policy suggestions included:

- Banning the use of e-cigarettes anywhere that the use of conventional cigarettes is prohibited
- Banning the sale of e-cigarettes to anyone who cannot legally buy cigarettes or in any venues where sale of conventional cigarettes is prohibited
- Applying the same marketing restrictions to e-cigarettes as are applied to conventional cigarettes
- Banning the practice of co-branding e-cigarette products with cigarettes or marketing in a way that promotes dual use
- Banning the use of characterising flavours in e-cigarettes, particularly candy and alcohol flavours
- Banning companies from making claims regarding tobacco-use cessation (until such a time when e-cigarette manufacturers and companies provide sufficient evidence that ENDS products can be used effectively for cessation)
- Prohibiting e-cigarette companies from making health claims about their products unless approved by appropriate regulatory agencies
- Calls for the development of standards for regulating product ingredients and functioning.

Bhatnagar (2017) has argued that the advent of e-cigarettes has heightened the need for a more in-depth understanding about which components of tobacco products cause damage. Lack of understanding of which constituents, ingredients and additives are contributing to tobacco-related diseases means that we lack sufficient data on how to effectively regulate tobacco products. In the absence of evidence about the potential harm of individual tobacco product constituents, marketing, youth access and e-cigarette labelling need to be regulated, free sampling prohibited and contamination standards set. To prevent unintended harm from the use of e-cigarettes and “erode years of public health gains in de-normalising tobacco use”, devices should be regulated to minimise the risk of explosion; bottles containing nicotine have child-proof packaging; and companies prevented from claiming that their devices are cessation aids unless they provide convincing data in support of such claims (Bhatnagar, 2017, p. 1874).

Global approaches to the regulation of electronic cigarettes were recently investigated in a study that attempted to classify and describe policy approaches taken by all countries that had regulated these products (Kennedy, Awopegba, De Leon, & Cohen, 2017). A search of Ministry of Health websites plus broad web searches, identified 68 countries as having regulations for e-cigarettes. Existing regulations of tobacco products were used by 22 countries, 27 had enacted new policies to regulate e-cigarettes, seven had made amendments to existing regulation, and 14 used a combination of new/amended and existing regulation.

Kennedy and colleagues (2017) found that the most common forms of regulation included sale bans, use restrictions (eg vape-free public places), age-of-purchase requirements and advertising and promotion bans. Out of the 68 countries that regulate vaping, the sale of e-cigarettes is banned in 25 countries, and minimum age-of-purchase policies are common. E-cigarette use is banned in enclosed public spaces such as bars, restaurants and other workplaces in 25 countries. Advertising and promotion are banned in 35 countries. Fourteen countries required health warning labels, and 13

regulate e-cigarette constituents and flavours. Six countries, including the UK, apply a tax to e-cigarettes. Safety standards are required in 26 countries.

The European Union's Tobacco Products Directive addressed the regulation of e-cigarettes across its 28-member states in 2016. Nicotine-containing liquid can now only be sold if the nicotine concentration does not exceed 20mg/mL.

The table below provides information about the regulatory approach taken by some other OECD countries. The information shows that the UK and many European countries have quite comprehensive regulations compared with the US and New Zealand. It should be noted that the New Zealand information is not accurately represented, as it pre-dated the *Philip Morris (NZ) Ltd v Ministry of Health (2018)* Court decision regarding the sale of tobacco sticks which has had implications for the importation and sale of other forms of smokeless tobacco.

Table 6. E-cigarette policies: approaches, product classification and regulatory domains addressed in some OECD countries (current to October 2016) adapted from Kennedy et al., 2017.

Country	Regulatory approach	Product classification(s)	Regulatory domain(s)
Australia	Existing law; statement	Poison, consumer good	Advertising/promotion, importation, sale
Canada	Existing law; notice	Drug, consumer good	Advertising/promotion, importation, manufacture, sale
Denmark	Existing law; new law	E-cigarette, medicinal	Advertising/promotion/sponsorship, health warning labelling, ingredients/flavours, minimum age, nicotine volume/ concentration, reporting/notification, sale, vape-free
Finland	New law	Medicinal, tobacco (imitation/substitute), tobacco-related product, e-cigarette	Advertising/promotion/sponsorship, child safety, health warning labelling, importation, ingredients/flavours, minimum age, nicotine volume/ concentration, reporting /notification, safety/hygiene, sale, vape-free
France	Amended law; decree; existing law	Medicinal, e-cigarette, consumer good	Advertising/promotion, child safety, ingredients/flavours, nicotine volume/ concentration, reporting/notification, safety/hygiene, sale
Germany	New law	Tobacco-related product, e-cigarette, consumer good	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, minimum age, nicotine volume/concentration, reporting/notification, safety/hygiene, sale, vape-free
Ireland	Existing law; new law	E-cigarette, medicinal, consumer good	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, nicotine volume/ concentration, reporting/notification, safety/hygiene, sale
Italy	Amended law/ordinance; decree	Tobacco-related product, e-cigarette	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, minimum age, nicotine volume/concentration, reporting/notification, safety/hygiene, sale, vape-free
Netherlands	Existing law; decree; order	E-cigarette, medicine, tobacco-related product, consumer good	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, minimum age, nicotine volume/concentration, reporting/notification, safety and hygiene, sale

Country	Regulatory approach	Product classification(s)	Regulatory domain(s)
New Zealand (this information is not accurate)	Existing law	Medicinal, tobacco, consumer good	Advertising/promotion/sponsorship, distribution, importation, sale
Norway	Existing law	Medicinal, tobacco surrogate, e-cigarette	Advertising/promotion, importation, minimum age, sale
UK	Existing law; new law; statement	E-cigarette, medicinal, consumer good	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, minimum age, nicotine volume/concentration, reporting/notification, safety/hygiene, tax
USA	New law	Tobacco product	Advertising/promotion, child safety, health warning labelling, minimum age, reporting/notification

Regulation of smokeless tobacco products in many OECD countries is changing quite quickly as new research findings are published. Information about the regulation of products in the UK has been published in a Public Health England update (McNeill et al., 2019).

Current EU minimum standards on maximum capacities and e-cigarette nicotine strength allowed are:

- tank capacity: 2ml
- e-liquid refill container capacity: 10ml
- nicotine strength of e-liquid: 20mg/ml

Other safety and quality standards are:

- child-resistant and tamper evident packaging
- prohibition of certain additives such as colourings
- protection against breakage and leakage, and a mechanism for ensuring re-filling without leakage.

The PHE report (2019) summarises e-cigarette (EC) and smokeless tobacco regulation developments in the UK, and notes that the following recommendations have been agreed by the Government, signalling a post-Brexit move away from current EU regulation towards a more liberalised regulatory environment. The report states that “Government will:

- Review vaping related regulations (eg limits on nicotine strength, tank size, advertising ban on health claims) ... and publish a plan for addressing ‘anomalies’ in the next annual Tobacco Control Plan
- Review the level of taxation on nicotine-related products which should directly correspond to the health risks that products present, to encourage less harmful consumption. Applying that logic, EC should remain the least-taxed and cigarettes the most, with heat-not-burn products falling between the two
- Conduct a review of regulations on EC and novel tobacco products which are currently applied under EU.

“The Government will also explore the 20mg/ml maximum nicotine refill limit, the 2ml size restriction on tanks, a block on EC advertising relative harm reduction potential and the notification scheme for vaping ingredients. The Government clarified that under the current code on television

and radio advertising, it is permissible for public health campaigns to promote the generic use of EC for quitting smoking.

“The Government also acknowledged that regular use of EC by young people in the UK remains very low, but they will continue to track their use in this country and consider further regulatory action if the data suggest that vaping is causing an increase in youth nicotine consumption.

“A review will take place of regulations on EC and novel tobacco products which are currently applied under EU legislation, to identify scope for change post-Brexit, including an evidence-based review of the case for discontinuing the ban on ‘snus’ oral tobacco. This should be part of a wider shift to a more risk-proportionate regulatory environment.” (McNeill et al., 2019, p. 21.)

Regulation of the advertising and marketing of e-cigarettes

Wadsworth and colleagues (2018) investigated the differences in e-cigarette advertising regulations between Canada, the United States, Australia and the United Kingdom, and how these related to the perceptions of smokers and ex-smokers who had heard of e-cigarettes ($n=3460$), using prospective cohort survey data.

Among other things, they were interested in whether participants from less restrictive countries were more likely to hold a positive opinion about e-cigarette messaging than those from more restrictive countries. However only the UK and Australian surveys asked questions about what participants thought of the material they had seen. In both countries, nearly half of participants perceived what they had seen and read about vaping to be positive. This was surprising because of the sales restrictions on e-cigarettes in Australia.

They found that participants from countries with less restrictive e-cigarette advertising regulations (the US and UK) were more likely to have seen advertisements and received free samples and special offers than those from Canada and Australia. Not surprisingly, US participants were more likely than those from the other countries to have noticed e-cigarette advertising on television, radio and on the internet over the previous six months. Males, younger participants and those with a high education were significantly more likely to have noticed online e-cigarette advertising.

The internet was a prominent source of advertising across all countries, including those that prohibited advertising. This is an important finding for New Zealand, given that very few vapers (8%) responding to the Ministry’s 2016 consultation (Ministry of Health, 2017) bought EC products in NZ shops – the majority obtained their product online, including from other countries.

Another study related to e-cigarette promotion examined awareness, ever-use and current use of nicotine vaping products (NVPs) in 14 countries with different regulations covering sales and marketing of the products (Gravelly et al., 2019). This was a cross-sectional analysis of adult current smokers and ex-smokers with data collected between 2013 and 2017. Countries were categorized into four groups based on regulations governing NVP sales and marketing, and level of enforcement as follows:

1. Most restrictive policies (MRPs): e-cigarettes were not legal to be sold or marketed with strict enforcement: Australia, Brazil, Uruguay;
2. Restrictive policies (RPs): not approved for sale or marketing with weak enforcement: Canada, Malaysia, Mexico, New Zealand;
3. Less restrictive policies (LRPs): legal to be sold and marketed with regulations: England, Netherlands, Republic of Korea, United States (US);
4. No regulatory policies (NRPs): Bangladesh, China, Zambia.

Generally, ever- and current-use of NVPs were found to be lower in MRP countries [ever-use: 7.1% to 48.9%; current use: 0.3% to 3.5%] relative to LRP countries [ever-use: 38.9% to 66.6%; current-use: 5.5% to 17.2%] and RP countries [ever-use: 10.0% to 62.4%; current-use: 1.4% to 15.5%]. Nicotine vaping use was highest among high-income countries, followed by upper-middle income countries, and then by lower-middle income countries.

Gravelly and colleagues (2019) concluded that with a few exceptions, awareness and use of nicotine vaping products (NVPs) varies by the strength of national regulations governing NVP sales/marketing, and by country income. The higher awareness and use of NVPs in high-income countries with moderately (e.g., Canada, NZ) and less (e.g., England, US) restrictive policies, is likely due to the greater availability and affordability of NVPs.

New Zealand research and debate on e-cigarette regulation

Any benefits of ECs at the population level are likely to be affected by the broader regulatory context in which they occur. Following the court case *Philip Morris v Ministry of Health* which found all tobacco products – except chewing and dissolving types – could be lawfully sold under the Smoke-free Environments Act – the Ministry of Health indicated in May 2018 that it would adopt a ‘risk proportionate’ approach to EC regulation.⁵⁵

New Zealand researchers have written numerous reports, papers and blogs on the regulation of e-cigarettes. Ideas for risk-proportionate regulation were discussed in a blog posted on World Smokefree Day⁵⁶ (Edwards, Waa, Hoek, Thornley & Wilson, May 2018). The authors proposed key features of a risk-proportionate approach, arguing that the framework should aim to minimise harm and maximise benefits to population health by accelerating progress towards New Zealand’s Smokefree 2025 goal. “As well as clarifying the appropriate regulatory approaches to vaping products, we see an overwhelming need for much stronger regulation of smoked tobacco products, as these are vastly under-regulated in relation to the harm they cause.”

Edwards and colleagues (2018) proposed the following over-arching aim: To reduce smoking-related harm to minimal levels by facilitating achievement of New Zealand’s Smokefree 2025 goal – minimal smoking prevalence for all peoples in Aotearoa, including Māori and Pacific peoples.

“The framework should aim to create an environment that maximises prompts to quit and support for smokers trying to quit, or if they are unable or unwilling to quit, to switch to lower-harm alternative products. Equally, regulation should minimise the chance of adolescents, young people or adult non-smokers experimenting with or becoming addicted to any nicotine-delivery products, particularly the most hazardous smoked tobacco products.

“The framework should include these critical features:

Comprehensive policies such as (but not limited to): taxation and price, distribution and supply, marketing, packaging and health warnings, safety standards, and product design and composition (including nicotine content and flavours).

Regulation proportionate to risk for **all types of nicotine-delivery consumer products** to ensure the least harmful products are the most affordable, accessible and appealing to smokers, while

⁵⁵ Retrieved from <https://www.health.govt.nz/news-media/news-items/ministry-consider-risk-proportionate-regulation-vaping-and-heated-tobacco-products> on 27 April 2019.

⁵⁶ Retrieved from <https://blogs.otago.ac.nz/pubhealthexpert/2018/05/31/smoke-heat-or-vapour-ideas-for-risk-proportionate-regulation-to-make-world-smokefree-day-irrelevant-by-2025/> on 27 April 2019.

the most harmful smoked tobacco products are the least affordable, accessible and appealing to both smokers and young people at risk of starting to smoke.

A **robust and responsive system for monitoring progress** towards the Smokefree 2025 goal, evaluating the impacts of policies and regulations, and making appropriate changes in response to evaluation.

“The framework must strengthen regulation of the most harmful smoked tobacco products. This approach will end the current untenable position where the supply, distribution, product composition, and design of tobacco products is essentially unregulated.” (Edwards et al., 2018.)

Potential new regulatory options for vaping had been earlier discussed by Wilson and colleagues (2015) but the context for regulating smokeless tobacco products in New Zealand has since changed, following the 2018 District Court decision and the Ministry’s recent work on regulation. This article nevertheless makes an important contribution to the debate, arguing that “the best long-term option for New Zealand should ideally be informed by ongoing local research and careful monitoring of sales, use, product quality and health effects” while pointing out the weaknesses of the current regulatory framework – the lack of licensing for retail tobacco outlets, no controls on tobacco product ingredients, no ban on duty-free sale of tobacco, a reticence to implement standardised plain packaging, and lack of action on a number of smoke-free environment issues such as smoking outside hospitals (Wilson et al., 2015, p. 93). The authors conclude by discussing some of the risks involved in re-opening the regulatory toolkit, given genuine scientific uncertainties and the vested commercial interests with a stake in the outcome.

The upcoming amendment to the legislation provides an opportunity argued for by many New Zealand tobacco control researchers and advocates to further restrict tobacco availability and supply. It is important to place the proposed amendments to the SFEA in the wider context of the comprehensive mix of strategies that are most likely to reduce smoking prevalence and health inequalities in New Zealand, and particularly to reduce prevalence among Māori. This ought to be based on an understanding of the most effective types of policy interventions, one of which is tobacco excise tax, as recently confirmed by the 2018 report to the Ministry of Health by Ernst & Young.

Some New Zealand tobacco researchers have questioned the Government’s plans to liberalise the e-cigarette market as an effective context for increasing quitting, and have argued for access only through Quit services, specialist vape stores and pharmacies, where staff can be trained in helping smokers to use vaping as a quit tool. Hoek, Blank and colleagues (2017) refer to research suggesting that successfully moving from smoking to vaping involves changing complex and multi-faceted practices (Hoek, Thrul, & Ling, 2017). Barriers to successful ‘switching’ from smoking to e-cigarettes without specialist support include:

- Smokers may find the e-cigarette they purchased ineffective and relapse to smoking
- Dual use (smoking and vaping) is common, and smokers will only realise the full benefits of moving to vaping if they quit smoking altogether
- Smokers often develop important rituals around smoking that they will need to replace if they are to quit smoking through vaping (eg preparing the cigarette they go on to smoke)
- Developing new practices and rewarding experiences may be crucial in determining how easily smokers find they can replace smoking with vaping

- Many smokers need advice on identifying an appropriate nicotine level in their e-liquid; too little, and vaping will not satiate their nicotine cravings, but too much, and they may experience feelings of nausea, headaches and dizziness
- Smokers may need advice on how to manage cravings without developing practices that *increase* their nicotine intake and addiction, and practical advice about using their e-cigarette.

Based on these findings, the authors argue that retail staff with experience of vaping and/or knowledge of addiction are essential to help smokers determine which device and e-liquid best suits their circumstances. Limiting sales of nicotine delivering e-cigarettes to stop smoking services, specialist vape stores and pharmacies would help ensure that people with relevant expertise and time are available to advise smokers and maximise the likelihood of successful smoking cessation (Hoek et al., 2017).

Achieving Smokefree Aotearoa 2025

New Zealand research has focused on vaping in the context of the comprehensive package of evidence- and feasibility-based tobacco control initiatives that are most likely to reduce tobacco smoking prevalence in line with the aspirations outlined in *Achieving Smokefree Aotearoa by 2025* (ASPIRE, 2017). The ASPIRE report clearly articulates the central importance of making tobacco products less available through legislation. This would enable transitioning current tobacco retailers out of selling tobacco products, which would eventually (within a specified timeframe) be sold only by a small number of specialist tobacco retail outlets. Reducing the appeal and addictiveness of tobacco products is another objective requiring regulation.

The ASPIRE plan includes making e-cigarettes more accessible and affordable than smoked tobacco.

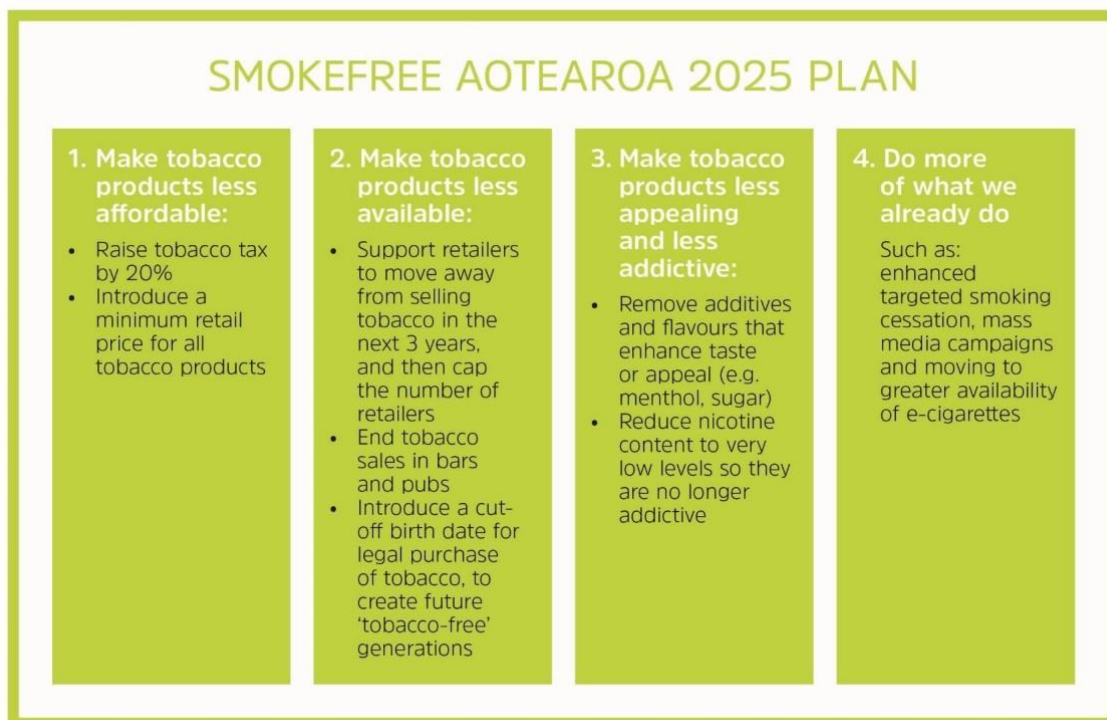


Figure 9. Smokefree Aotearoa 2025 Plan

Enhanced and comprehensive tobacco control in New Zealand

Edwards and colleagues (2016) argued that the impact of ECs 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 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:

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. (Edwards, Bullen, Walker et al., 2016, p. 6.)

The potential contribution of e-cigarettes to achieving Smokefree 2025

Edwards and colleagues (2016) investigated the potential of ECs in contributing to achieving the Smokefree 2025 goal and part of this report analysed different options for making nicotine-containing ECs available. However, this analysis is now outdated as it was undertaken at a time when nicotine-containing ECs were unable to be sold legally. The environment at the time of writing this current report is very different, as the products are not regulated and are now prominently displayed and available from many dairies, petrol stations and possibly in supermarkets.

The authors recommended the following:

- That the then status quo was maintained for **supply and availability** – i.e. the sale of nicotine-containing EC products be prohibited, but importation for personal use be allowed. The second preferred option was to allow restricted sale of nicotine-containing EC products through pharmacies and licensed specialist shops (with stipulations about proximity to schools, exclusion of minors from shops and training for staff in ABC cessation support).
- That cessation providers receive **resources and training in the use of ECs to support quitting**.
- In relation to **marketing, packaging and consumer information**, that marketing be limited to point of sale displays regulated to avoid exposure to children and young people, and consideration of targeted or mass media campaigns on potential benefits and harms of ECs (NB, this would be in the context of much more limited availability than is now the case).
- That existing consumer protection legislation be applied to EC **product design, minimum quality and safety standards be considered, and additives and flavours** for nicotine-containing ECs and e-liquids products sold within New Zealand be excluded.

- 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.
- **Tax and excise for cigarettes** – 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 non-smoking children and young people.
- Ministry of Health develops a framework for **monitoring and evaluating emerging evidence on ECs**, including their evolution and use (internationally and in New Zealand), and for evaluating the impact of ECs, especially on smoking prevalence in all population groups and progress towards the Smokefree 2025 goal.

A later ASPIRE blog *Will liberalising nicotine availability increase quitting?*⁵⁷ (Hoek, Blank, Wilson, Robertson & Marsh 2017) discusses the Government’s intention to legalise the sale and supply of nicotine e-cigarettes and e-liquid as consumer products, to reduce tobacco smoking harm. At this stage the proposal was that products would be able to be sold without restriction – including in dairies, service stations, and supermarkets.

In response to this idea, they suggest that “closer scrutiny highlights at least two potential flaws: first, that smoked tobacco should continue to be widely available and, second, that potentially addictive nicotine e-cigarettes are to be as widely available as ordinary consumer products and sold alongside these”.

Hoek and colleagues (2017) argued that “rather than make e-cigarettes as readily available as smoked tobacco, the Government has a crucial opportunity to reduce the supply of smoked tobacco, an approach that would enable it to proceed cautiously with liberalising nicotine e-cigarette sales. Limiting the sales of tobacco products to R18 (or R21) outlets could dramatically reduce tobacco availability. At the same time, allowing the sales of e-cigarettes from specialist vape stores and pharmacies would send a clear message that tobacco is no ordinary product. In addition, making e-cigarettes and nicotine e-liquid available from specialist vape stores and pharmacies would limit young people’s exposure to these products while providing smokers with access to expert advice on using a potential new smoking cessation product”.

In an analysis comparing the impact of five tobacco ‘endgame strategies’ on future smoking prevalence, population health and health system costs, van der Deen and colleagues (2018) modelled the impacts on smoking prevalence, health gains (quality-adjusted life-years) and cost savings of

1. 10% annual tobacco tax increases
2. a tobacco-free generation (TFG)
3. a substantial outlet reduction strategy
4. a sinking lid on tobacco supply and
5. a combination of 1, 2 and 3.

⁵⁷ Retrieved from <https://blogs.otago.ac.nz/pubhealthexpert/2017/04/24/will-liberalising-nicotine-availability-increase-quitting/#more-2539> on 31 January, 2019

The analysis suggested that business as usual smoking uptake and cessation trends were unlikely to achieve the Smokefree 2025 goal of below five per cent prevalence.

All selected tobacco endgame strategies were associated with reductions in smoking prevalence by 2025, down from 34.7%/14.1% for Māori/non-Māori in 2011 to 16.0%/6.8% for tax increases; 11.2%/5.6% for the TFG; 17.8%/7.3% for the outlet reduction; 0% for the sinking lid; and 9.3%/4.8% for the combined strategy (see Figure 7 below).

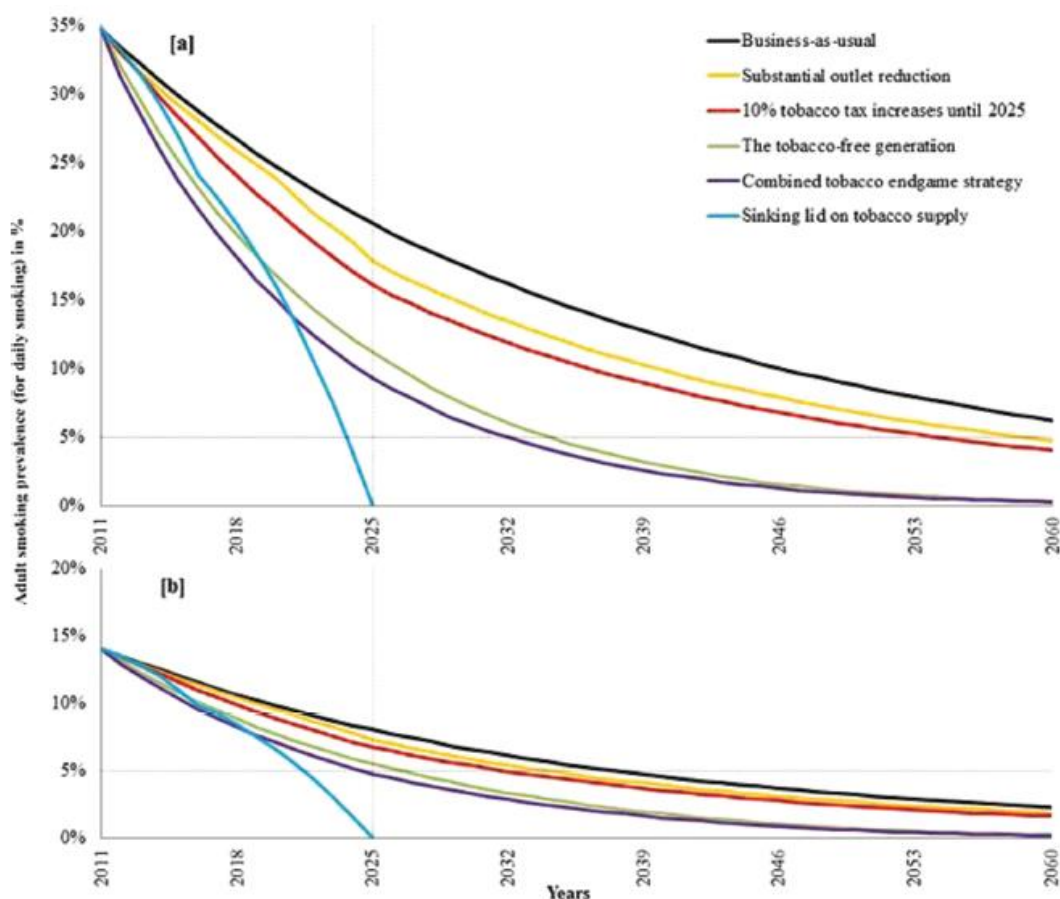


Figure 10 Projections of adult daily tobacco smoking prevalence for Māori in New Zealand (indigenous population) (a) and non-Māori (b) under BAU and five tobacco endgame strategies. (Note: As can be seen from the above figures, the effect of the combined tobacco endgame strategy on future smoking prevalence is smaller than the sum of the effects of the three individual endgame strategies (tax, outlet reduction and TFG strategy). Due to the TFG strategy, smoking uptake among young people is completely prevented from 2011 onwards, as such the effect of the outlet reduction and tax strategies will no longer affect the younger population of the 2011 cohort. TFG, tobacco-free generation. (van der Deen et al., 2018.)

Major health gains accrued over the remainder of the 2011 population’s lives, and the timing of health gain and cost savings greatly differed for the various strategies (with accumulated health gain peaking in 2040 for the sinking lid and 2070 for the TFG).

The authors concluded that implementing endgame strategies is needed to achieve tobacco endgame targets and reduce inequalities in smoking. The modelling studies provide provisional information on what approaches may be most effective in reducing prevalence.

Ministry of Health Regulatory Impact Statement

The Ministry of Health Regulatory Impact Statement (RIS) released in 2018 and updated in January 2019, clearly articulates the need to strike a balance between the need to reduce harm in adult

smokers by encouraging them to switch to vaping, and the need to protect children and young people from risks associated with increasing access to e-cigarette and other smokeless tobacco products. The RIS is an internal document which discusses the various options for developing a regulatory regime for vaping and smokeless tobacco products in New Zealand.

Having discussed the difficulties of regulating an industry where there is not a strong evidence base, outlining options for managing various risks, and summarising consultation with the sector, the Ministry set out a summary of their conclusions and preferred options (Ministry of Health, 2019, p. 35). This section provides a response to these preferred options, based on the findings of this review, and recent New Zealand tobacco researcher's online discussions and publications in this area.

Ministry of Health preferred options

- a. Extend coverage of the SFEA to include all vaping liquid (nicotine-free liquid and nicotine liquid that is not manufactured from tobacco), and vaping and smokeless tobacco product devices and components
- b. Retain the broad prohibition on promotion, advertising and sponsorship of vaping and smokeless tobacco products, with exemptions for:
 - i. display of products in specialist R18 stores
 - ii. the giving of free samples, discounts, rewards, and the co-packaging of products in specialist R18 stores
 - iii. identifying specialist R18 stores as retailers of vaping products
- c. Require specialist R18 vape stores to be notified to the Ministry to take advantage of the exceptions above and facilitate enforcement
- d. Set tailored annual sales reporting requirements for nicotine and nicotine-free vaping liquid
- e. Develop guidelines to support business owners, employers and local authorities to develop and implement vaping policies for their smoke-free areas
- f. Establish minimum product safety requirements for vaping and smokeless tobacco products, including as a group standard under HSNO for vaping liquids which trigger HSNO thresholds
- g. Provide a power in the SFEA which would enable flavours and/or colours to be prohibited in future should evidence come to light that they are being used to attract young people to vaping and the use of smokeless tobacco products
- h. Require vaping and smokeless tobacco products to be notified to the Ministry, via a web-based system, before they can be sold
- i. Recover the costs of regulatory scheme from the regulated industry consistent with The Treasury's guidelines.

Discussion of Ministry of Health preferred options

- a. **Extend coverage of the SFEA to include all vaping liquid (nicotine-free liquid and nicotine liquid that is not manufactured from tobacco), and vaping and smokeless tobacco product devices and components**

The extension of SFEA coverage to include all vaping and smokeless tobacco products is consistent with WHO (2013) advice to ban the use of e-cigarettes anywhere that conventional cigarette smoking is prohibited, and this approach is welcomed.

Of particular concern, the Ministry's preferred approach appears to enable vaping and other smokeless tobacco products to be sold in dairies, service stations, and supermarkets alongside other tobacco products. This is consistent with a harm reduction approach that is based on the assumption that vaping is effective in smoking cessation for spontaneous quitting (ie unsupported by stop smoking services), and that improved access for all will make it easier for smokers to switch to vaping.

However, this approach is not consistent with current evidence in this area, which suggests that vaping is most likely to be effective when used in the context of structured quit programmes, alongside behavioural counselling (Hajek et al., 2019). The majority of vapers also continue to smoke tobacco (Patel et al., 2016) and there is some evidence that dual smokers can have worse health outcomes than smokers (Wang et al., 2018). The liberalisation of access to smokeless tobacco products will make them more accessible to both non-smokers and young people – and will reinforce online marketing to these populations.

The evidence discussed in this report suggests that expert advice on device choice and use, vape strength may be required and could be best provided through training of staff in specialist vape shops, pharmacies and in stop smoking services.

The Ministry's regulatory review provides an opportunity to strengthen the SFEA along the lines argued by New Zealand research summarised in this report, and based on sound evidence. In particular, the sale of tobacco products ought to be restricted by transitioning current tobacco retailers out of selling tobacco products, so that eventually they can only be sold by a small number of specialist tobacco retail outlets. This would be consistent with the Ministry's stated intention (2018) to undertake a risk-proportionate approach, which could apply the principle that less harmful vaping products are more available than the most harmful smoked tobacco products.

Restricting the sale of all tobacco products would enable a more effective approach to helping smokers to switch to vaping. Qualitative research indicates that many smokers find vaping unsatisfying (Robertson et al., 2019, Hoek et al., 2017) and this might explain why so many continue to smoke and use vaping as a way to negotiate smoke-free restrictions in public spaces. By limiting access to smoking cessation services, specialist vape stores and pharmacies, smokers could be provided with advice on how to use vaping to quit or reduce smoking more effectively.

- b. Retain the broad prohibition on promotion, advertising and sponsorship of vaping and smokeless tobacco products, with exemptions for:**
 - I. display of products in specialist R18 stores**
 - II. the giving of free samples, discounts, rewards, and the co-packaging of products in specialist R18 stores**
 - III. identifying specialist R18 stores as retailers of vaping products**

The evidence found in this review supports the broad prohibition on promotion, advertising and sponsorship of vaping products. However, the exemption for the giving away of free samples, discounts and awards has been argued against by some researchers, who argue that free sampling should be prohibited (Bhatnagar, 2017).

Online marketing and sales of vaping and smokeless tobacco products is common. It would be complicated to monitor free samples, discounts and so on taking place outside the actual vape shops, and relatively easy for those under the age of 18 years to be recipients. A simple ban on these activities would be easier to administer and monitor. There are already examples of vaping products being given away as part of promotions on youth radio stations and at music concerts primarily attended by young people. If the purpose of liberalising access to vaping and smokeless tobacco is helping adult smokers to quit, free samples would be best used in the context of smoking cessation services, alongside good advice and personal support.

Options **c.**, **d.**, **h.** and **i.** above seem clear and sensible.

However, in recommendation **c.**, the meaning of the term ‘notified’ could be clarified.

A licensing scheme could be specified for both vaping and tobacco retailers that would enable standards for facilities, training and other functions, and make enforcement easier as possible withdrawal of the license would provide an incentive to comply. Such a scheme could be self-financed through a licence fee.

For recommendation **d.**, note that such a requirement should apply to tobacco product retailers also.

e. Develop guidelines to support business owners, employers and local authorities to develop and implement vaping policies for their smoke-free areas

The SFEA allows for smoking restrictions in some public places, but there are many outdoor public places that are not yet covered, and this can create difficulties at a local level where some councils are more lenient than others. The majority of New Zealanders are non-smokers and prefer not to be exposed to second-hand smoke, and where the restrictions are unclear, conflict can arise.

The Ministry prefers to rely on the development of guidelines for business owners, employers and local authorities to develop and implement their own policies in relation to vaping in those areas not yet covered by the Act. Placing the onus on these parties to be proactive about vaping is unlikely to be effective and may create public confusion. There is an opportunity to extend the coverage of the SFEA to additional public places, such as outdoor areas in hospitality venues, transport hubs, parks and playgrounds, which will further reduce the social acceptability of tobacco smoking, and also decrease the risk that addiction to vaping becomes normalised amongst children and young people.

f. Establish minimum product safety requirements for vaping and smokeless tobacco products, including as a group standard under HSNO for vaping liquids which trigger HSNO thresholds

Restrictions on some smokeless tobacco constituents known to be toxic may be covered by HSNO requirements. However, the Ministry is silent on restricting nicotine levels. This appears to be an oversight, in light of evidence about both the addictiveness of nicotine, data on the high levels of nicotine in some smokeless tobacco products, and evidence on its impact on cognitive development in children and young people (US Surgeon General, 2019). The European Union’s Tobacco Products Directive states that nicotine-containing vaping liquid can only be sold if the nicotine concentration does not exceed 20mg/mL. A review of nicotine levels in currently available vaping products was beyond the scope of this review, but it’s likely that many products sold here exceed this level.

The detail of how such standards are to be developed, monitored and enforced need to be clarified and communicated.

- g. Provide a power in the SFEA which would enable flavours and/or colours to be prohibited in future should evidence come to light that they are being used to attract young people to vaping and the use of smokeless tobacco products**

There is little doubt that some flavours appeal to young people, and this is probably not a coincidence. While it could be argued that flavours are important as a substitute to smoking to adult smokers as well, there is good evidence that children and young people are attracted by flavourings such as fruit, chocolate, and bubble gum (Glantz & Bareham, 2018, Patel et al., 2016). There is no reason to wait to place restrictions on colouring and flavourings, at least those that are known to be favoured by children.

A possible alternative could be to address this issue through packaging, so that vaping products either have to be sold in plain packaging or any child-friendly packaging (for example, cartoon characters) and naming of products to appeal to children would be banned. Such an approach would need to specify how this would be monitored and enforced.

Issues not covered in the proposed approach

Health warning labelling

Health warning labelling does not seem to be included in the proposed approach, but it is a feature of the e-cigarette regulation in many OECD countries including the UK, US, Germany, Denmark, Ireland, Italy and the Netherlands.

There is some evidence from animal studies that vaping during pregnancy may be harmful to the foetus, especially if the mother uses vaping as a way of reducing smoking during pregnancy and mistakenly increases her intake of nicotine (Spindel & McEvoy 2015). Consideration ought to be given to health warnings/advice about vaping in pregnancy.

- g. Establish minimum product safety requirements for vaping and smokeless tobacco products, including as a group standard under HSNO for vaping liquids which trigger HSNO thresholds**

Restrictions on some smokeless tobacco constituents known to be toxic may be covered by HSNO requirements. However, the Ministry is silent on restricting nicotine levels. This appears to be an oversight, in light of evidence about both the addictiveness of nicotine, data on the high levels of nicotine in some smokeless tobacco products, and evidence on its impact on cognitive development in children and young people (US Surgeon General, 2019). The European Union's Tobacco Products Directive states that nicotine-containing vaping liquid can only be sold if the nicotine concentration does not exceed 20mg/mL. A review of nicotine levels in currently available vaping products was beyond the scope of this review, but it's likely that many products sold here exceed this level.

Protections for young people

The Ministry's RIS states that improved regulation is necessary to "reduce the likelihood that vaping and smokefree tobacco products, which have associated health risks (including the potential for addiction), can be accessed by children and young people". However, there is very little in the RIS that addresses the issue of protecting children and young people from the risk of becoming addicted to nicotine through experimenting with vaping. Extending coverage of the SFEA to include all vaping and smokeless tobacco products will make it illegal to sell these products to young people under the age of 18 years, but the products can easily be accessed online or in other retail outlets such as dairies, which have a poor record of restricting tobacco product sales to minors and are difficult to monitor. Providing a power to prohibit flavours and/or colours in future "should evidence come to

light that they are being used to attract young people” seems weak in light of fairly strong evidence described in this review that children and young people are attracted to vaping because of the flavourings and colourings, and that fruit flavourings are most popular with this group.

A key issue relating to the promotion of ECs and smokeless tobacco products to children and young people is that of online marketing (by both international and New Zealand-based commercial interests), through social media. It is clear from research summarised in this report that many New Zealanders are both impacted by online advertising, and purchase products online. Monitoring and regulation in this area does not appear to have been considered or addressed in the Ministry’s approach.

The evidence summarised in Section Three of this report suggests an urgent need for the new regulations to prioritise the protection of children and young people from experimenting with and becoming addicted to ECs. ASH Year 10 surveys show relatively high experimentation with ECs among 14-15-year-olds, and the very recent introduction of podvapes such as JUUL into the New Zealand market has not yet been picked up in these surveys. However, both 2017 and 2018 ASH Year 10 Surveys showed that the trend of reducing smoking prevalence in this age group, had levelled off. The 2018 ASH Year 10 fact sheet states that “overall, never, regular and daily smoking rates (were) relatively unchanged since 2017”.

Many researchers are underlining the need for vigilance in light of substantial longitudinal research evidence of a strong association between EC use and smoking initiation in young people. Siddiqui and colleagues (2019), and many others argue strongly for a restriction in sales and marketing to non-smoking groups, especially young people.

This year the US Food and Drug Administration (FDA)⁵⁸ reported on national survey results that showed 97 per cent of youth aged 12-17 years who vaped, had used a flavoured product in the last month, and that 70.3 per cent of current youth vapers said they used the products because they liked the flavours. Fruit flavours were by far the most popular. The FDA has taken the following steps to protect children and young people from vaping.

- Measures were taken to foreclose the sale of products to minors online by working with online distributors such as eBay
- Warning letters were issued to manufacturers, distributors and retailers for selling kid-friendly vape products
- Nationwide undercover investigations were carried out on vaping shops and online stores resulting in over 1300 warning letters to retailers who illegally sold products to minors
- Required manufacturers and retailers to submit plans describing how they would address the issue of minors’ access to their products
- Provided guidance to the industry signalling a move to strengthen regulations and enforcement on the sale of flavoured vaping products to minors.

At a public forum in early April 2019, Associate Minister of Health Jenny Salesa stated that Government was taking a precautionary approach with regulation, and particularly wanted to ensure children and non- smokers did not start vaping – while supporting a switch to vaping for current

⁵⁸US Food and Drug Administration (2019). Modifications to Compliance Policy for Certain Deemed Tobacco Products. Retrieved on 28 March 2019 from <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM633281.pdf>

smokers. Key components announced regarding the proposed legislation and approved by Cabinet at this stage were:

- Regulate like tobacco
- No sales to under 18-year-olds
- No vaping in legislated smoke-free areas
- No promotion, advertising at point of sale
- Will require annual sales data reporting
- Product safety requirements
- Regulate flavours and colours.

Medicines Act 1981

The Ministry (2019) notes that the Medicines Act 1981 regulates products that make a therapeutic claim (eg to support smoking cessation) and also the importation of nicotine (MoH 2019, p. 13). It is unclear how/whether this Act is being used or considered as a vehicle for placing the onus on the vaping/tobacco industry to meet requirements for demonstrating cessation effectiveness.

Improving publicly available information on vaping and smokeless tobacco

While acknowledging the addictiveness of nicotine delivered to the lungs through e-cigarettes the authors of Public Health England reports on ECs expressed concern that “less than half of adults in Great Britain think e-cigarettes are less harmful than smoking” because this belief might prevent smokers from switching to less harmful e-cigarettes. In their 2015 report, the PHE called for accurate public information on relative harms to address “misperceptions of nicotine and different nicotine-containing products” (McNeill et al., 2018 pp. 20, 21).

A qualitative study investigated the information-seeking behaviour in 39 adult ENDS users in New Zealand found that participants had difficulty accessing useful information about the impact of EC use on health (Robertson et al., 2018). Commercial product information was much easier to find and likely to depict products in a positive light, than information based on independent scientific research.

Participants were positive about their interactions with staff in vaping shops, but this was not necessarily aimed at helping them to quit smoking. It was unclear whether retailers were equipped to provide advice in smoking cessation. Robertson and colleagues (2018) suggested that health authorities could play an important role in providing useful information for smokers wanting to switch to vaping. They also pointed to research on the prevalence of dual use and suggested that the transition from smoking to vaping might require more powerful stimuli and reinforcers than improved information.

Improving publicly available information is the second of the two key aims in the Ministry’s Cabinet paper on vaping and smokeless tobacco (2018), and progress has been in this area made during the time of writing this report.

The Ministry of Health is working with the Health Promotion Agency (HPA) “on preparing information for the public on vaping as a way to stop smoking. A campaign will be developed to encourage smokers to switch to vaping and will be supported by information for the wider public on the risks and benefits of vaping. Vaping as a way to stop smoking is one element of New Zealand’s

comprehensive approach to tobacco control, and has the potential to contribute to achieving the Government's goal of a Smokefree Aotearoa 2025.”⁵⁹

The fact sheet on vaping now available online on the New Zealand Quitline website⁶⁰ states that “nicotine is addictive and is the reason people find it hard to quit smoking” but that “for people who smoke, nicotine is a relatively harmless drug.”

As previously noted in this report, messages conveying that a product is ‘relatively harmless’ can easily be interpreted as ‘harmless’ by both young people and adults. Most products are relatively harmless compared to a product that is known to kill two-thirds of those who use it.

The Ministry is working with the Health Promotion Agency on a public campaign, and key messages have been agreed and posted on the Ministry’s website (see below).

Key messages on vaping

- The best thing smokers can do for their health is to quit smoking for good
- Vaping products are intended for smokers only
- The Ministry considers vaping products could disrupt inequities and contribute to Smokefree 2025
- The evidence on vaping products indicates they carry much less risk than smoking cigarettes but are not risk free
- Evidence is growing that vaping can help people to quit smoking
- Stop smoking services must support smokers who choose to use vaping products to quit
- There is no international evidence that vaping products are undermining the long-term decline in cigarette smoking among adults and youth, and may in fact be contributing to it
- Despite some experimentation with vaping products among never smokers, vaping products are attracting very few people who have never smoked into regular vaping, including young people
- When used as intended, vaping products pose no risk of nicotine poisoning to users, but vaping liquids should be in child resistant packaging
- The Ministry of Health is identifying safety standards for vaping products in New Zealand. In the meantime, vapers should buy their products from a reputable source, such as a specialist retailer⁶¹.

The evidence presented in this report does not support three of these key messages.

1. This review was unable to find evidence supporting the message that “vaping products could disrupt inequities”.
2. The statement that “There is no international evidence that vaping products are undermining the long-term decline in cigarette smoking among adults and youth, and may in fact be contributing to it” is not supported by the evidence found in this review. For example, in a systematic review and meta-analysis of 9 longitudinal studies, Soneji and colleagues (2017) found strong and consistent evidence of an association between initial e-

⁵⁹ Retrieved on 14 February from <https://newsletter.hpa.org.nz/campaigns/reports/viewCampaign.aspx?d=r&c=BAE1E0C2C9F2C8BA&ID=4378B816DB7EE6022540EF23F30FEDED&temp=False&tx=0>

⁶⁰ Retrieved on 19 February, 2019 from <https://quit.org.nz/help-to-quit/vaping>

⁶¹ Retrieved from Ministry of Health website on 26 April from <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-and-smokeless-tobacco>

cigarette use and subsequent cigarette smoking initiation. More recent evidence from large population studies in the US and Canada indicates that the long-term decline in reduction of tobacco product consumption among young people appears to have reversed alongside an increase in EC consumption (attributed to the advent and uptake of podvapes). In New Zealand, the long-term reduction in Year 10 smoking prevalence has stalled for two years in a row. 2018 Year 10 data does not take into account widespread online and point of sale marketing and availability of nicotine-containing ECs since mid-2018.

3. NZ and international data found in this review does not support the claim that “Despite some experimentation with vaping products among never smokers, vaping products are attracting very few people who have never smoked into regular vaping, including young people”.

For example, ASH Year 10 data showed that 30 per cent of Year 10 students (14-15 years) had tried vaping during 2017, and over 20 per cent of these students who had never smoked had tried vaping. 2018 data will not have picked up any changes in daily or weekly use that may have begun to occur towards the end of 2018 when it became legal in New Zealand to sell EC products containing nicotine, and JUUL came onto the NZ market. These products are now freely available in dairies, supermarkets and other places and may contain quite high levels of nicotine.

At least one international review study concluded that in many countries, ECs are bringing lower-risk youth into the market, many of whom then transition to smoking cigarettes (Siddiqui et al., 2019; Glantz & Barham, 2018). Siddiqui and colleagues (2019) found that the evidence is very strong for this effect, whether it is due to the ‘gateway effect’ – the theory of nicotine addiction developing through positive relationships with smoking peers, diluting the harm perceptions of cigarettes, and prompting smoking behaviours – or the so-called ‘common liability’ theory, whereby young people transition from ECs to tobacco smoking due to other factors that make them susceptible to both behaviours.

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