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PHILIP MORRIS INTERNATIONAL

SUSTAINABILITY REPORT 2018

PHILIP MORRIS

AUSTRALIA NEW ZEALAND PACIFIC ISLANDS

28 June 2019

The Hon Scott Morrison MP
Prime Minister
Parliament House
CANBERRA ACT 2600

Dear Prime Minister

Congratulations on your hard work and leadership which led to the re-election of the Morrison Government. I wish you every success in your role and look forward to working constructively with you in the future to address policy issues of mutual interest and concern.

The 46th Parliament will present you with a wide range of social and economic policy challenges to address. Few will be more important than the need to address the stagnation of smoking prevalence rates in Australia and the impact this has on the lives of Australia's almost 3 million smokers, their loved ones and public health more broadly.

Earlier this month, the Australian Institute of Health and Welfare released *Australia's health 2018*, its biennial report on the health of Australians. In relation to smoking, it highlights:

- that past declines in daily smoking have slowed;
- the significant health inequalities facing Australia's smokers; and
- the burden of disease caused by smoking.

This is even more concerning as Australia's approach to addressing smoking s now at odds with other developed nations that commonly experience declining smoking prevalence.

It is no coincidence that they embrace tobacco harm reduction policies by making less harmful products available to adult smokers in a controlled, regulated way. All OECD nations except for Australia and Turkey have now embraced this approach.

Much new evidence has emerged since the House Standing Committee on Health, Aged Care and Sport and both the Senate Economics References and Community Affairs committees each last considered this matter. While tobacco harm reduction remains controversial in Australia, it is the law overseas with bipartisan support, backed by government policy and the Department of Health in other comparable countries. In many cases, support for quitting and switching to less harmful products is proactively supported and promoted through national government advertising campaigns.

The United Kingdom, Europe and the United States have long endorsed tobacco harm reduction principles as a meaningful way to reduce smoking rates and placed vaping at the centre of their approach. Most recently, the Trudeau Government in Canada has legalised and regulated vaping, and the Ardern Government in New Zealand is in the process of doing so, and even though the law is not yet updated, they are still actively encouraging Kiwis to switch from cigarettes to less harmful, smoke-free alternatives.

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In reading this, you will likely have doubts, both about the message and the messenger. However, as Australia's progress in reducing smoking stalls, other countries are acting. With Australia due to update the National Tobacco Strategy this year, I ask you to develop your own independent understanding of the latest evidence on this important policy topic and how we can get the policy settings right.

A good starting place is the New Zealand Ministry of Health vaping website launched earlier this month (www.vapingfacts.health.nz) which sets out the facts on vaping and notably states:

> *Vaping has the potential to help people quit smoking and contribute to New Zealand's Smokefree 2025 goal.*

Philip Morris is also committed to securing a Smoke-Free Future, as the greatest real-world contribution we can make to society is to replace cigarettes with smoke-free products (SFP) which are a less harmful alternative to smoking, thereby minimising the negative impact of smoking on public health.

This will seem incredible to some, however, in only a few years we have made progress in achieving this transformation. In 2018, SFPs represented 13.8% of our total net revenues, up from nothing only a few years before. In three countries, such revenues exceeded those of our combustible products and 6.6 million people have stopped smoking and switched to *IQOS*, our most advanced SFP. However, while these products remain banned in Australia, nearly 3 million smokers are without new alternatives to smoking cigarettes.

On 30 April 2019, the world's toughest and most respected regulator, the US Food and Drug Administration (FDA), finalised its rigorous science-based review through the premarket tobacco product application pathway for *IQOS*. This legislated mechanism doesn't exist in Australia, but enabled the FDA to determine that "authorizing these products for the U.S. market is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes." The FDA also found that "few non-tobacco users would be likely to choose to start using *IQOS*, including youth."[1]

I trust you will agree that this is an important development and deserves consideration in the Australian context. Indeed, we are now presented with an enormous public health opportunity: to allow adult smokers who would otherwise continue smoking, the chance to switch to a scientifically-substantiated less harmful alternative.

To discuss this further, s 47F , Manager Public Policy and I would like to arrange to meet with you in the sitting weeks commencing 22nd and 29th July 2019 or otherwise at a convenient time at your electorate office. To arrange a meeting, please contact s 47F

Best wishes for all your endeavours throughout the 46th Parliament. I look forward to speaking with you soon.

Yours sincerely

s 47F

Director External Affairs AU NZ & PI

Ps this is a major economic policy issue, as well as a social / health topic.

[1] *FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway*, US FDA Media Release, 30 April 2019. Available here: https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway

FDA NEWS RELEASE

FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway

Agency places stringent marketing restrictions on heated tobacco products aimed at preventing youth access and exposure to the new products

For Immediate Release:

April 30, 2019

The U.S. Food and Drug Administration today announced it has authorized (/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders) the marketing of new tobacco products manufactured by Philip Morris Products S.A. for the IQOS "Tobacco Heating System" – an electronic device that heats tobacco-filled sticks wrapped in paper to generate a nicotine-containing aerosol. The FDA has placed stringent marketing restrictions on the products in an effort to prevent youth access and exposure.

Following a rigorous science-based review through the premarket tobacco product application (PMTA) pathway, the agency determined that authorizing these products for the U.S. market is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes. The products authorized for sale include the IQOS device, Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks and Marlboro Fresh Menthol Heatsticks. While today's action permits the tobacco products to be sold in the U.S., it does not mean these products are safe or "FDA approved." All tobacco products are potentially harmful and addictive and those who do not use tobacco products should continue not to. Additionally, today's action is not a decision on the separate modified risk tobacco product (MRTP) applications that the company also submitted for these products (/tobacco-products/advertising-and-promotion/philip-morris-products-sa-modified-risk-tobacco-product-mrtp-applications) to market them with claims of reduced exposure or reduced risk.

"Ensuring new tobacco products undergo a robust premarket evaluation by the FDA is a critical part of our mission to protect the public, particularly youth, and to reduce tobacco-related disease and death. While the authorization of new tobacco products doesn't mean they are safe, the review process makes certain that the marketing of the products is appropriate for the protection of the public health, taking into account the risks and benefits to the population as a whole. This includes how the products may impact youth use of nicotine and tobacco, and the potential for the products to completely move adult smokers away from use of combustible cigarettes," said Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products. "Importantly, the FDA is putting in place postmarket requirements aimed at, among other things, monitoring market dynamics such as potential youth uptake. We'll be keeping a close watch on the marketplace, including how the company is marketing these products, and will take action as necessary to ensure the continued sale of these products in the U.S. remains appropriate and make certain that the company complies with the agency's marketing restrictions to prevent youth access and exposure. As other manufacturers

seek to market new tobacco products, the FDA remains committed to upholding the vital public health standards under the law and using all the tools at our disposal to ensure the efficient and appropriate oversight of tobacco products."

Under the PMTA pathway (/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications), manufacturers must demonstrate to the agency, among other things, that marketing of the new tobacco product would be appropriate for the protection of the public health. That standard requires the FDA to consider the risks and benefits to the population as a whole, including users and non-users of tobacco products. Importantly this includes youth. The agency's evaluation includes reviewing a tobacco product's components, ingredients, additives and health risks, as well as how the product is manufactured, packaged and labeled. The review for the IQOS products took into account the increased or decreased likelihood that existing tobacco product users will stop using tobacco products, and the increased or decreased likelihood that those who do not use tobacco products will start using them.

In particular, through the FDA's scientific evaluation of the company's applications, peer-reviewed published literature and other sources, the agency found that the aerosol produced by the IQOS Tobacco Heating System contains fewer toxic chemicals than cigarette smoke, and many of the toxins identified are present at lower levels than in cigarette smoke. For example, the carbon monoxide exposure from IQOS aerosol is comparable to environmental exposure, and levels of acrolein and formaldehyde are 89% to 95% and 66% to 91% lower than from combustible cigarettes, respectively.

Additionally, IQOS delivers nicotine in levels close to combustible cigarettes suggesting a likelihood that IQOS users may be able to completely transition away from combustible cigarettes and use IQOS exclusively. Available data, while limited, also indicate that few non-tobacco users would be likely to choose to start using IQOS, including youth.

While these non-combusted cigarettes may be referred to as "heat-not-burn" or "heated" tobacco products, they meet the definition of a cigarette in the Federal Food, Drug and Cosmetic Act. Therefore, these products must adhere to existing restrictions for cigarettes under FDA regulations, as well as other federal laws that, among other things, prohibit television and radio advertising. In addition, to further limit youth access to the products and exposure to their advertising and promotion, the FDA is placing stringent restrictions on how the products are marketed – particularly via websites and through social media platforms – by including requirements that advertising be targeted to adults. The company must also give notification to the FDA of, among other things, its labeling, advertising, marketing plans, including information about specific adult target audiences, and how it plans to restrict youth access and limit youth exposure to the products' labeling, advertising, marketing and promotion. The agency has issued a document (https://www.fda.gov/media/124174/download) providing its rationale for these postmarket requirements, which highlight important considerations for reviewing the company's applications as well any potential future PMTAs for other products.

The FDA also is requiring all package labels and advertisements for these products to include a warning about the addictiveness of nicotine, in addition to other warnings required for cigarettes, to prevent consumer misperceptions about the relative addiction risk of using IQOS compared to combusted cigarettes.

With the authorization of these products, the FDA will evaluate new available data regarding the products through postmarketing records and reports required in the marketing order. The company is required to report regularly to the FDA with information regarding the products on the market, including, but not limited to, ongoing and completed consumer research studies, advertising, marketing plans, sales data, information on current and new users, manufacturing changes and adverse experiences. The FDA may withdraw a marketing order if it, among other reasons, determines that the continued marketing of a product is no longer appropriate for the protection of the public health, such as if there is an uptake of the product by youth.

The FDA is continuing its substantive scientific review of the company's MRTP applications. The company would need to receive an MRTP order from the FDA before they could market a tobacco product with any implicit or explicit claims that, among other things, a product reduces exposure to certain chemicals or that use of the product is less harmful than another tobacco product or would reduce the risk of disease. If a company markets a tobacco product as an MRTP without authorization, the company would be in violation of the law and may face FDA advisory or enforcement actions.

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Related Information

- Premarket Tobacco Product Marketing Orders (/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders)
- Premarket Tobacco Product Applications (/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications)
- Modified Risk Tobacco Products (Modified Risk Tobacco Products)
- Market and Distribute a Tobacco Product (/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product)
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Potential Country-level Health and Cost Impacts of Legalizing Domestic Sale of Vaporized Nicotine Products

Frederieke S. Petrović-van der Deen,[a] Nick Wilson,[a] Anna Crothers,[b] Christine L. Cleghorn,[a] Coral Gartner,[c] and Tony Blakely[a,d]

Background: The net impact on population health and health system costs of vaporized nicotine products is uncertain. We modeled, with uncertainty, the health and cost impacts of liberalizing the vaporized nicotine market for a high-income country, New Zealand (NZ).

Methods: We used a multistate life-table model of 16 tobacco-related diseases to simulate lifetime quality-adjusted life-years (QALYs) and health system costs at a 0% discount rate. We incorporated transitions from never, former, and current smoker states to, and from, regularly using vaporized nicotine and literature estimates for relative risk of disease incidence for vaping compared with smoking.

Results: Compared with continuation of baseline trends in smoking uptake and cessation rates and negligible vaporized nicotine use, we projected liberalizing the market for these products to gain 236,000 QALYs (95% uncertainty interval [UI] = 27,000 to 457,000) and save NZ$3.4 billion (2011 NZ$) (95% UI = NZ$370 million to NZ$7.1 billion) or US$2.5 billion (2017 NZ$). However, estimates of net health gains for 0- to 14-year olds and 65+ year olds had 95% UIs including the null. Uncertainty around QALYs gained was mainly driven by uncertainty around the impact of vaporized nicotine products on population-wide cessation rates and the relative health risk of vaping compared with smoking.

Conclusions: This modeling suggested that a fairly permissive regulatory environment around vaporized nicotine products achieves net health gain and cost savings, albeit with wide uncertainty. Our results suggest that optimal strategies will also be influenced by targeted smoking cessation advice, regulations around chemical constituents of these products, and marketing and age limits to prevent youth uptake of vaping.

Keywords: Health system costs; Quality-adjusted life-years; Vaping; Vaporized nicotine products

(*Epidemiology* 2019;30: 396–404)

The most appropriate regulatory approach for vaporized nicotine products, such as e-cigarettes and other vaping devices, is widely debated. Regulations on these products range from fairly liberal (e.g., the United Kingdom and the United States) to bans on sale, possession, and use (e.g., Australia, Thailand, and Singapore).[1] Vaping prevalence has increased rapidly among smokers in settings with liberal access to vaporized nicotine products,[2] while regular use among never smokers remains low. For example, in the United States, 12% of current smokers and 13% of recent former smokers vape regularly, whereas only 0.3% of never smokers vape.[3] Vaping prevalence has also increased,[4] but remains much lower in countries with more restrictive policies (e.g., only 4.4% of current smokers in Australia vape).[5]

The population health and health system cost impacts of vaporized nicotine products will depend on multiple factors, including their impact on smoking uptake and cessation. A recent extensive review suggests a positive impact on quit rates,[2] particularly in settings with less restrictive regulation.[4] However, concerns remain about potential adverse impacts on youth smoking[6] and the health impact of long-term vaping. Vaping is likely to be less harmful than smoking, but more health-damaging than complete abstinence.[2,7]

While experimental trials and cohort studies have researched these components individually, computer simulation models can bring all factors together[8] and incorporate uncertainty. Thus far, one tobacco industry study[9] and seven independent studies[2,10–15] have used simulation models. Future net health benefits from the introduction of vaporized nicotine products were found in most or all scenarios of six studies,[2,9,10,12,13,15] in only a few scenarios in one study,[11] and in none of the scenarios of the most recent study.[14] This latter

Submitted May 15, 2018; accepted January 23, 2019.

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The authors report no conflicts of interest.

SDC Supplemental digital content is available through direct URL citations in the HTML and PDF versions of this article (www.epidem.com).

Data availability: Supporting information regarding the multistate life-table model approach and data inputs can be found online in Blakely et al. and Pearson et al. Data sharing with other researchers or official agencies of the precise data used in the modeling is potentially possible subject to agreement with the government agencies making it available to the researchers (the Ministry of Health).

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ISSN: 1044-3983/19/3003-0396
DOI: 10.1097/EDE.0000000000000975

study failed to account for potential health benefits of youth taking up vaping instead of tobacco smoking and the potential small reductions in health harm among those who simultaneously vape and smoke tobacco (dual use).

In our study, we model the impacts of liberalization of the vaporized nicotine product market in New Zealand (NZ). As a result of a NZ court ruling, the products became legal to sell in 2018. The Ministry of Health has interpreted the laws covering smoked tobacco as also applying to vaporized nicotine products (e.g., age limits on sales) but specific new regulations are being drafted. Overall, NZ vaporized nicotine product regulation is moving toward that of the United Kingdom and the United States and away from the more restrictive setting in Australia.

Our study aimed to advance previous studies modeling vaporized nicotine products in two key ways. First, we performed probabilistic uncertainty analyses and scenario analyses around input parameters related to these products, to determine which parameters (and their attendant uncertainty) are most influential on the estimated health gains. This type of analysis can help prioritize areas for further research. Second, none of the previous models have reported changes in health system cost outcomes from vaping, despite costing issues being important to policy-makers.

METHODS

Overview of the Model

We adapted an established[16–18] tobacco multistate life-table model (see the online supplementary information in Pearson et al.[17] for a detailed description) to estimate the impacts of legalizing the domestic sale of vaporized nicotine products on population health outcomes and health system costs over the lifetime of the NZ population alive in 2011 (4.4 million). Briefly, the core multistate life-table model is populated with epidemiologic parameters for disease-specific incidence, prevalence, and case-fatality rates for each of the 16 tobacco-related diseases (see eTable 1; http://links.lww.com/EDE/B465), calculated from rich NZ data and then processed for epidemiologic coherence using DISMOD II.[19] Tobacco-related disease costs were those excess to nondiseased citizen costs, estimated for the first year of diagnosis, last year of life if dying of that disease, and otherwise prevalent disease. These costs were estimated using national linked hospitalization, pharmaceutical, laboratory, primary care, outpatient, and other data, linked to cost weight data. All costs were estimated by sex and age, and all epidemiologic estimates additionally by ethnicity (Māori and non-Māori). For the remainder of this Methods section, we focus on the modeling aspects specific to vaporized nicotine products.

The multistate life-table model was adapted by incorporating transitions from the existing never smoker, former smoker, and current smoker states to, and from, regularly vaping (either sole or dual use) with specification of disease incidence relative risks of vaping compared with tobacco smoking and patterns of use, drawing on expert judgments in recent major reports.[2,7] Table 1 details the six smoking and vaping states distinguished in the model.

TABLE 1. Six Smoking and Vaping States Used in the Multistate Life-table Model

Smoking and/or Vaping State	Definition
NS	A person who has never smoked at all or has never regularly smoked one or more manufactured or RYO tobacco cigarettes per day[20]
NSCV[a]	As above for NS and currently vapes daily or nondaily (i.e., "Do you now use an e-cigarette every day, some days, or not at all?")[3,20]
CS	A person who currently smokes one or more manufactured or RYO tobacco cigarettes per day[20]
DU	As above for CS and who currently vapes daily or nondaily (i.e., "Do you now use an e-cigarette every day, some days, or not at all?")[3,20]
FS	A person who does not smoke currently, but previously smoked one or more manufactured or RYO tobacco cigarettes per day[20]
FSCV	As above for FS and currently vapes daily or nondaily (i.e., "Do you now use an e-cigarette every day, some days, or not at all?")[3,20]

[a]The definition of current vaping included both daily and nondaily vaping as all VNP-related input parameters used in this modeling (parameters 4 to 11 in eTable 2; http://links.lww.com/EDE/B465) are based on this definition. While it is likely that VNP parameter effects and thus related health outcomes differ by frequency and duration of VNP use, at present there is insufficient evidence to parameterize this accurately. As such, prioritizing this type of VNP research was a key recommendation by the National Academies of Sciences Engineering and Medicine after their substantive investigation into the public health consequences of VNPs.[21]

CS indicates current smoker; DU, dual user; FS, former smoker; FSCV, former smoker and current vaper; NS, never smoker; NSCV, never smoker and current vaper; RYO, roll-your-own; VNP, vaporized nicotine product.

In the business as usual scenario (by 5-year age group and by sex and ethnicity) the NZ population alive in 2011 was simulated in a life-table until death or age 110 years, under projected all-cause mortality and morbidity rates.[18] The impact of the legalization of vaporized nicotine product sales on future quality-adjusted life-years (QALY) and costs was captured via changes in the distribution of population members in the six states compared with business as usual, mathematically combined with the relative risks of vaping and smoking for the 16 diseases to generate population impact fractions (PIFs). For example, assume a simple scenario of 30% smoking prevalence in business as usual, reducing to 25% after an intervention, with the incidence rate ratio (RR) of coronary heart disease (CHD) for smokers compared with nonsmokers being 1.66. (Actual current smoker vs. nonsmoker disease incidence RRs used in the model are in eTable 1; http://links.lww.com/EDE/B465.) Then after the intervention, the CHD incidence rate will reduce by 2.75%, through the population impact fraction (*PIF*):

$$PIF = \frac{\sum_i p_i \times RR_i - \sum_i p_i' \times RR_i}{\sum_i p_i \times RR_i}$$
$$= \frac{(0.3\times1.66 + 0.7\times1) - (0.25\times1.66 + 0.75\times1)}{(0.3\times1.66 + 0.7\times1)} = 2.75\%$$

where p_i is the prevalence of smoking and nonsmoking pre-intervention, and p_i' is the postintervention prevalence of smoking. The model is actually far more sophisticated than this, with time lags such that quitters are directed through a 20-year-long tunnel state with annual reductions in disease incidence rates according to formulae in Hoogenveen et al. (2008),[22] and multiple smoking–vaping combination states. The population impact fraction is used to set intervention disease incidence rates in the 16 parallel disease life-tables, which flow onto disease-specific changes in morbidity and mortality rates, and health system costs. The total QALYs (life-years lived, adjusted for morbidity) and health system cost are then tallied up for each annual cycle of the model, for all sex by age cohorts propagated through the model, and for both business as usual and intervention arms, with the difference between these arms being the "intervention effect."

Approach to Parametric Specification of Input Parameter Uncertainty

We used the following principles to specify uncertainty in the parameters. First, we used beta or logistic distributions for proportions, log-normal distributions for ratios, and normal distributions for other measures. Second, where robust confidence intervals from external studies were available, we used those. Third, where expert opinion was relied upon (as is inevitably the case for harms from vaporized nicotine products), we aimed to include all plausible estimates within the 95% uncertainty interval (UI) for a parametric distribution with a mean and median approximating the "expected" values. Fourth, for other variables with unknown but likely wide uncertainty (e.g., prevalence of vaping, and other examples in eTable 2; http://links.lww.com/EDE/B465), we used 20% of the mean as the standard deviation (SD). Fifth, most random draws from input parameter uncertainty distributions were 100% correlated across sex, age, and ethnic cohorts in each iteration (see eTable 2; http://links.lww.com/EDE/B465, for details).

The Business as Usual Scenario

The business as usual scenario assumed no domestic vaporized nicotine product sales. In line with our previous modeling work,[16–18] this scenario assumed a continuation of current annual net cessation rates (i.e., the annual permanent quit rate, or the net of cessation attempts and relapse) and smoking uptake rates specified by sex, ethnicity, and age group, resulting in ongoing reduction in smoking prevalence into the future.[23]

The Intervention Base Case: The Domestic Sale of Vaporized Nicotine Products Is Legalized

For consistency with our previous modeling work[16–18] and to allow for comparisons in a tobacco control intervention league table,[24] we modeled the intervention base case as if legalization occurred at the start of base year 2011. The intervention cost was that of a new law to legalize the domestic sale of vaporized nicotine products (see eTable 2; http://links.lww.com/EDE/B465).

The US data on vaporized nicotine products in a liberalized market setting are probably the highest quality data internationally, which we used to parameterize the intervention base case. Rapid growth in vaporized nicotine product sales was observed from 2011 to 2014 in the United States, but sales stayed relatively steady from mid-2014 till the end of 2016,[25] suggesting an achieved steady state. A recent US study estimated current use of vaporized nicotine products to be 2.4% using a definition of vaping every day or some days, with use highest in 18- to 24-year olds (3.4%) and lowest in 65+ year olds (0.9%).[3] In addition, current vaping is reported by 11.5% of current smokers (i.e., dual users), 13.2% of former smokers who quit between 1 and 2 years ago (i.e., former smoker current vaper), and 0.3% of never smokers (i.e., never smoker current vaper).[3] We applied an age gradient to prevalence of vaping for the latter three categories of vapers (see eTable 2; http://links.lww.com/EDE/B465).

Given uncertainty around the applicability of US vaping patterns to other high-income countries, we applied wide uncertainty intervals to prevalence estimates (eTable 2; http://links.lww.com/EDE/B465).

State Transitions in the Model in the Intervention Base Case

At the end of each annual model cycle, population members could either remain in the same state or transition to other states. eFigure 1 (http://links.lww.com/EDE/B465) shows the possible transitions between the six smoking and vaping states. Transitions between the states in the intervention base case were calculated by combining NZ data on the prevalence of never smokers, former smokers, and current smokers and annual baseline smoking uptake and cessation rates specified by age group[23] with the above US data on vaping prevalence[3] (see eTable 2; http://links.lww.com/EDE/B465).

Transitions from Nonsmoking to Other States

As per our previous modeling work, we assumed that future never smoker transitions to never smoker current vaper, current smoker, or dual-user states only occurred at the age of 20 years reflecting the transition from youth experimentation to adult smoker status (90% of NZ adult smokers start smoking by this age;[26] transitions from current smoker to dual user at all ages are described below). We used probabilities for these transitions at the age of 20 years from the United States[13] (Figure 1). The framework distinguished such transition rates

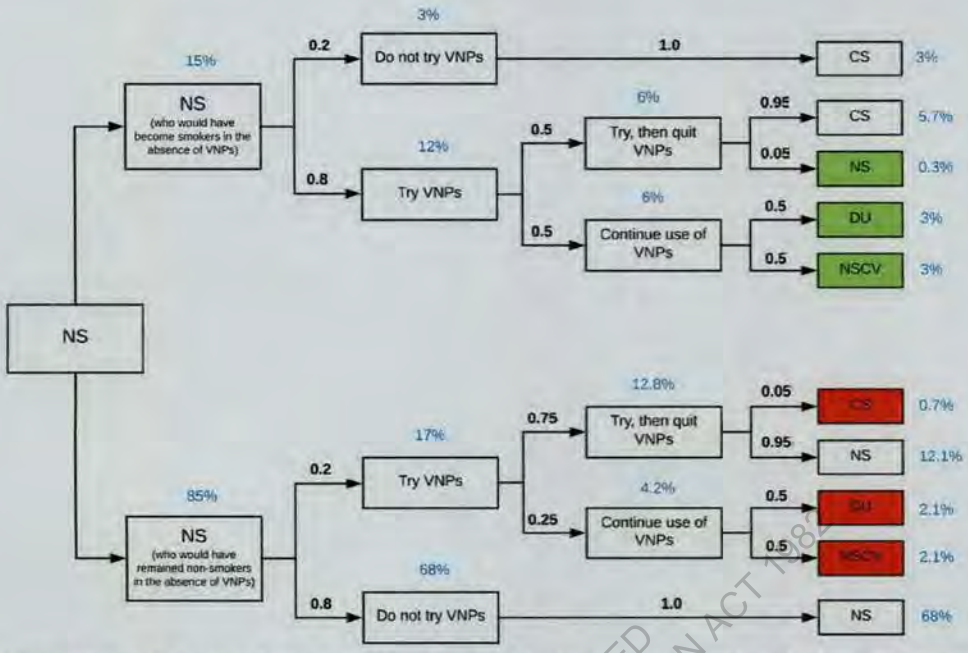

FIGURE 1. Transitions among 20-year-old never smokers to never smoker, current smoker, dual user, or never smoker current vaper. Bold black rates represent evidence-based estimates of transitions sourced from Levy et al.[13] The blue percentages represent an example cohort of 20-year olds in the multistate life-table model (as per explained in more detail in the Methods section). Red shaded boxes indicate net health harm relative to business as usual and the green shaded boxes indicate net health benefits compared with business as usual. CS indicates current smoker; DU, dual user; NS indicates never smoker; NSCV, never smoker current vaper; VNPs, vaporized nicotine products.

for never smokers who would have become smokers in the absence of vaporized nicotine products (i.e., baseline annual smoking uptake rate in the multistate life-table model), and those who would have remained nonsmokers (i.e., 1—baseline annual smoking uptake rate). This distinction is necessary as vaping uptake among the first group could result in harm reduction, whereas in the latter group uptake could result in increased harm. Given that evidence on these transition probabilities is incomplete[13] and future uptake patterns are uncertain, we applied wide uncertainty.

To illustrate how these transitions work, Figure 1 enumerates a fictitious 20-year-old cohort where the baseline smoking uptake was 15%. As such 15% of never smokers would have become current smokers under business as usual, while 85% would have remained never smoker in the absence of vaporized nicotine products. When applying evidence-based transition rates around the use of vaporized nicotine products, it is estimated that approximately 14.5% of the cohort becomes a current smoker when including dual use (3% + 5.7% + 3% + 0.7% + 2.1%), 5.1% never smoker current vaper (3% + 2.1%), and 80.4% remains never smoker (0.3% + 12.1% + 68%). Depending on the proportion that would have taken up smoking by the age of 20 years in the absence of vaporized nicotine products, this framework mostly resulted in a slightly lower youth smoking uptake rate compared with business as usual. Yet, the specified uncertainty around these transition rates (see eTable 2; http://links.lww.com/EDE/B465) also captured worsening of these trends, for example, for the 14.5% value above (current smokers + dual users) had uncertainty ranging from 12.3% to 15.7% (compared with 15% under business as usual).

Transitions from Smoking and Dual-user States

Studies suggest smokers frequently transition back and forth between current smoker and dual-user states, at all ages.[27,28] At each point in time, we forced 11.5% of all smokers to "reside" in the dual-user state and the remainder (88.5%) in the current smoker state, consistent with United States data. Population members in the current smoker and dual-user states could transition to former smoker or former smoker current vaper states under annual net cessation rates specified by sex, age, and ethnicity.[23]

There is evidence that liberalization of vaporized nicotine products increases tobacco smoking cessation rates in the total population. Using estimates from the largest and most recent cohort study,[3] we specified an increase in annual net (tobacco smoking) cessation rates of 14% (95% UI = 1.4% to 28%) in the intervention base case. As our model was a closed cohort, the vaping prevalence diminished over cycles by 1.3%. Accordingly, we decayed the initial 14% increase in net cessation by 1.3% per annum (95% UI = 0.6% to 1.9%) (eTable 2; http://links.lww.com/EDE/B465).

Of all the current smokers and dual users who quit smoking at the end of each annual cycle, 13.2% transitioned to the former smoker current vaper state (i.e., the prevalence of vaping among former smokers[3]), and the remaining 86.8% transitioned to the former smoker state. However, studies suggest that dual users are more likely than current smokers to transition to being a former smoker current vaper, with an odds ratio of 2.53 (95% confidence interval = 1.29, 4.97)[27,28] that we specified within the model to ensure dual users were more likely to transition to former smoker current vaper than current smokers.

Transitions from Current Vaper to Other States

Never smokers current vapers could quit vaping at any age after 20 (i.e., transition back to never smoker) and former smokers current vapers could quit vaping at any age after 21. Owing to scarce data on vaping cessation patterns, vaping quit rates were assumed to be the same as baseline annual net smoking cessation rates consistent with other models (with scenario analysis described in eTable 2; http://links.lww.com/EDE/B465).[9,10,13]

Relative Harm of Vaping Compared with Tobacco Smoking

The multistate life-table model used relative risks of tobacco smoking for current smokers compared with never smokers for the incidence of 16 tobacco-related diseases as detailed in Blakely et al.[16] and eTable 1 (http://links.lww.com/EDE/B465). The model was extended for this study by including different relative risks of vaping compared with smoking, thereby differentiating disease incidence risks for those who were vaping only (former smokers current vapers and never smokers current vapers) and those who were both vaping and smoking (dual users). We followed the National Academies of Sciences Engineering and Medicine[2] and Public Health England[7] Report estimates that vaping confers approximately 5% of the risk of increased disease incidence owing to tobacco smoking, and in parallel that dual use decreases the risk by 5% (see eTable 2; http://links.lww.com/EDE/B465). Accordingly, we specified the relative harm for those who were vaping only (former smokers current vapers and never smokers current vapers) compared with current smokers as a logistic distribution with a median of 5% (95% UI = 0.5% to 38%; a logistic distribution better approximated the uncertainty range given in the National Academies of Sciences Engineering and Medicine Report than a beta distribution; see eTable 2; http://links.lww.com/EDE/B465). Similarly, for dual users, the relative health harm was specified as a logistic distribution with a median of 95% (95% UI = 62% to 99.5%).

Simulation

The intervention base case was simulated 2000 times in Monte Carlo simulations, drawing from the probability density function about all input parameters. The default was 0% discounting with 3% and 6% discount rates used in scenario analyses. We also ran other scenario analyses as detailed in eTable 2 (http://links.lww.com/EDE/B465). While the underlying model structure, demography, and epidemiology were stratified by ethnicity, limited or no data on vaporized nicotine product parameters by ethnicity meant it was inappropriate to present results by ethnic group.

RESULTS

Liberalization of the vaporized nicotine product market, compared with the business as usual scenario, was estimated to gain 236,000 QALYs (95% UI = 27,000 to 457,000) for the NZ population alive in 2011 over the remainder of their lives and save NZ$3.4 billion (95% UI = 370 million to 7.1 billion or US$2.5 billion in 2017 US$). This translates to 0.054 QALYs gained per capita (i.e., 19 additional days lived in full health for each person alive in 2011), and NZ$780 health system costs saved per capita or avoidance of 0.43% of all future healthcare expenditure in this cohort (bottom row of Table 2). By time horizon, 5.9% of all QALY gains were estimated to occur within the first 20 years (1.3% in the first 10 years and 4.6% in the second 10 years).

About 85% of health gains and cost savings accrued among those who were 44 years of age or younger in 2011. However, the 95% UI for lifetime QALYs gained and cost savings for 0- to 14-year olds included the null (Table 2), suggesting possible net health harm. QALY gains (35,000; 95% UI = −1,200 to 61,200) for 45- to 64-year olds were still substantive, although the 95% UI just included the null.

The tornado plot in Figure 2 shows the impact of vaporized nicotine product-related input parameters on overall uncertainty in QALYs when running the model separately for the 2.5th and 97.5th percentile for each of the input parameters. Uncertainty in QALY gains was mainly driven by the uncertainty about the impact of vaporized nicotine products on population-wide smoking cessation rates, the health harm from vaping among former smokers current vapers and never smokers current vapers relative to harm among smokers, and the annual transitions among never smokers to current smoker, dual user, or never smoker current vaper (i.e., the impact on youth smoking uptake rates).

Table 3 reports scenario results. Discounting by 3% or 6% per annum dramatically reduced the estimates. The second panel of Table 3 shows the cumulative impact of the three most uncertain variables revealed in Figure 2. A negligible 1.4% increase in population-wide cessation rates (the 2.5th percentile of this variable) lowered lifetime QALY gains to 116,000 (consistent with left-hand end of its bar in Figure 2). Under the most pessimistic scenario where vaping has near zero impact on cessation rates, 38% the risk of smoking, and results in an increase in smoking uptake among young people, vaporized nicotine product liberalization results in a *loss* of 52,200 QALYs. However, the probability of these three assumptions all being true is low (i.e., roughly $2.5\%^3 = 0.002\%$) and well outside the 95% uncertainty intervals presented above.

TABLE 2. Lifetime Health Gains (in QALYs) and Health System Cost Savings for the NZ Population Alive in 2011 Under the Intervention Base Case Compared with Business as Usual (0% Discounting[a])

	Remaining Lifetime (with 95% UIs)		First 10 years: 2011 to 2022 (% of Lifetime for Age Group)[b]		Second 10 years: 2021 to 2030 (% of Lifetime for Age Group)[b]	
Age Group (at Baseline)	**QALYs Gained**	**Net Cost Savings (NZ$ million for Year 2011)**	**QALYs Gained**	**Cost savings (NZ$ million)**	**QALYs Gained**	**Cost savings (NZ$ million)**
0–14 years	68,100 (−23,900 to 188,000)	$1,010 (−$530 to $2,930)	5 (0.01)	$0 (0.00)	57 (0.08)	$2 (0.16)
15–24 years	59,100 (13,000 to 117,000)	$930 ($218 to $1,910)	52 (0.09)	$1 (0.08)	662 (1.12)	$23 (2.49)
25–44 years	72,000 (13,200 to 126,000)	$1,070 ($257 to $1,910)	924 (1.3)	$25 (2.3)	3,400 (4.7)	$161 (14.8)
45–64 years	35,000 (−1,200 to 61,200)	$400 ($11 to $712)	1,820 (5.2)	$53 (13.1)	5,960 (17.0)	$164 (40.6)
65+ years	1,690 (−4,020 to 3,950)	$11 (−$24 to $26)	240 (14.3)	$4 (35.1)	689 (41.2)	$6 (55.3)
All age groups combined	236,000 (27,000 to 457,000)	$3,420 ($370 to $7,050)[d]	3,040 (1.3)	$83 (2.4)	10,775 (4.6)	$356 (10.3)
Per capita[c]	0.054	$780				
% Change[d]	0.14	0.43				

All results >1,000 rounded to three meaningful digits. QALY, quality-adjusted life-years; UI, uncertainty interval.

[a]3% discounted results are shown in Table 3. Of note, for all age groups combined (at 3% discounting), the net cost savings were NZ$1,260 ($280 to $2,170), or in 2017 US$ (allowing for Consumers price index inflation from 2011 to 2017 in NZ, then The Organisation for Economic Co-operation and Development purchasing power parity from NZ$ to US$) US$908 ($201 to $1,564).

[b]Expected value (i.e., without probabilistic uncertainty).

[c]Per capita results used the total NZ population in 2011 as the denominator.

[d]Percentage QALYs gained of all QALYs lived (173,000,000 for the 2011 population under no intervention) and percentage costs saved of all future healthcare expenditures (NZ$ 796 billion) over the remaining lifetime of the NZ population alive in 2011.

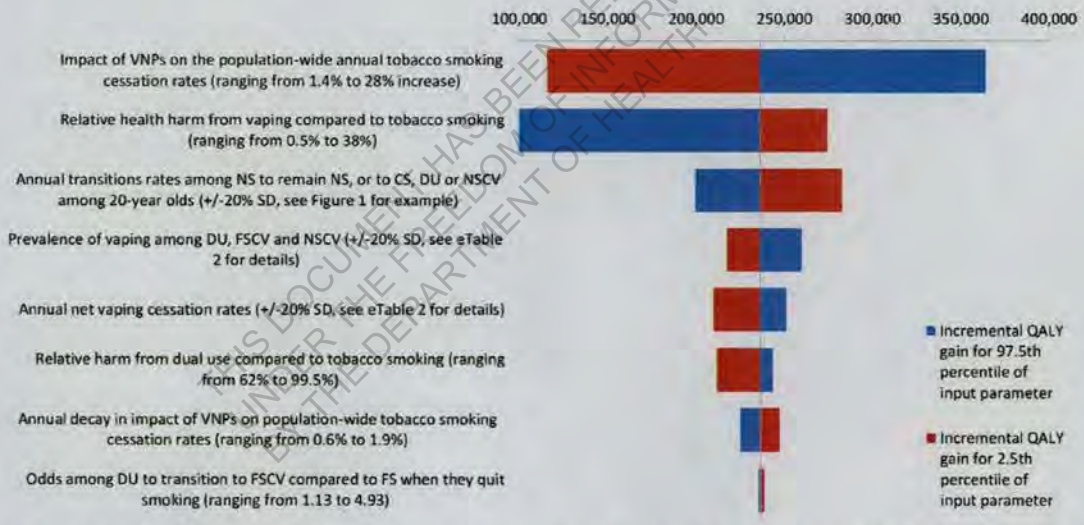

FIGURE 2. Tornado plot for QALYs gained for the base-case vaporized nicotine product scenario for the total NZ population alive in 2011, for the 2.5th and 97.5th percentiles (in parentheses) of the eight most influential input parameters. Analyses used in the tornado plot were run for the expected value from the base case only (i.e., uncertainty switched off). The expected value for the intervention base case was 236,000 QALYs. As such the tornado plot presents incremental QALY loss or gain compared with the central estimate of 236,000 QALYs. For more information on how the 2.5th and 97.5th percentiles of these input parameters were specified, see Methods section and eTable 2 (http://links.lww.com/EDE/B465). CS indicates current smoker; DU, dual user; FS, former smoker; FSCV, former smoker current vaper; NS, never smoker; NSCV, never smoker current vaper; SD, standard deviation; VNPs, vaporized nicotine products.

Assuming the positive impact of vaporized nicotine products on population-wide smoking cessation rates would decay faster than assumed in the base case (10% and 50% per year instead of 1.3%; see eTable 2, http://links.lww.com/EDE/B465, and explanatory footnotes to Table 3), QALYs, and cost savings reduced by 30%–50%. Using 1-year vaping quit rates from a recent small prospective cohort study,[29] instead of assuming they were equal to tobacco cessation rates, increased health gains and

TABLE 3. Scenario Analyses Around Lifetime Health Gains (in QALYs) and Health System Cost Savings for the NZ Population Alive in 2011 under the Intervention Base Case Compared with Business as Usual (0% Discounting Unless Stated Otherwise)[a]

Alternate Scenarios (Only Differences in Parameters from Base Case Listed)	QALYs Gained	Net Cost Savings (NZ$ Million)	% Change from Base Case QALYs Gained	% Change from Base Case Cost Savings
Base case (expected value)	236,000	3,450		
Discounting				
3%	60,900	1,240	−74	−64
6%	21,800	566	−91	−84
Pessimistic scenarios of parameters that drive uncertainty most in tornado plot in Figure 2				
Top parameter: close to zero cessation impact[b]	116,000	1,900	−51	−45
Top two parameters: close to zero cessation impact and 38% of smoking health risk for vaping[b]	−27,400	−196	−112	−106
Top three parameters: close to zero cessation impact, 38% of smoking health risk of vaping, and an increase in youth smoking uptake rates[b]	−52,200	−497	−122	−114
Annual decay in impact of liberalization of vaporized nicotine products on population-wide tobacco smoking cessation rates[c]				
10%	152,000	2,375	−36	−31
50%	110,000	1,828	−53	−47
Vaping quit rates				
52% of current vapers quit 1 year later	276,000	4,020	+17	+17
Using a different definition of current vaping[d]				
Current vaping only includes daily vaping	185,000	2,470	−22	−28

[a]Changes in base-case assumptions for vaporized nicotine product-related parameters are described in detail in the last column of eTable 2 (http://links.lww.com/EDE/B465).

[b]For the cessation impact, the 2.5th percentile value was selected (1.4% increase in net cessation rates), the 97.5th percentile value of the smoking health risk for vaping was selected (38%), and the 97.5th percentile values for the transition rates from 20-year-old never smoker to current smoker, dual user, or never smoker current vaper were selected (i.e., resulting in an increase in youth smoking uptake rates).

[c]As described in the Methods section, we increased net cessation rates (for tobacco) by 14% (95% UI = 1.4% to 28%) in the intervention base case, owing to evidence from Zhu et al.[3] and as described in eTable 2 (http://links.lww.com/EDE/B465). Because our cohort was a closed cohort, vaping prevalence fell over time meaning we decayed net cessation rates by 1.3% per annum. As the novelty of vaporized nicotine products may be responsible for initial spillover effect onto increasing population-wide net cessation rates, we undertook scenario analyses here about a 10% and 5% annual decay (rather than 1.3% per annum) in the 14% elevated net cessation rates back to business as usual net cessation rates.

[d]For this scenario, we reduced the prevalences of never smokers current vapers, former smokers current vapers, and dual users to only include daily vaping (this scenario analysis is described in eTable 2; http://links.lww.com/EDE/B465).

cost savings by 17%. Finally, using a different definition for current vaping by only including daily vapers (final row of Table 3; estimates from Zhu et al.[3]), reduced QALYs by 22% and cost savings by 28%.

DISCUSSION

We used Monte Carlo simulation modeling, drawing from probability distributions about each input parameter, to estimate net health gains and health system cost impact of liberalizing access to vaporized nicotine products. Our results suggest that widening access to vaporized nicotine products in NZ and other countries with (to date) restrictive policies around these products could achieve substantive overall health gains and cost savings to the health system. Even given generous specification of uncertainty about the input parameters to this modeling, our 95% UI about the total health gains did not include zero. However, our modeling could not confidently rule out potential net health harm for the youngest age cohort (0- to 14-year olds) or for the 65+ year olds, under base-case assumptions. For the young this is due to uncertainty about the percentage of nonsmoking youth becoming long-term vapers (i.e., beyond short-term experimentation) and the impact on tobacco smoking uptake rates. Policies to prevent youth uptake of either smoking or vaping should be an important adjunct to vaporized nicotine product liberalization. For 65+ year olds (and to some extent 45- to 64-year olds), there is potential net health harm as a proportion of smokers who quit smoking will move into long-term vaping. In sum, while overall health gain appears likely, this gain will be decades into the future given health gains and cost savings were predominantly for the younger age groups who are decades away from their peak noncommunicable disease rates.[16,18]

The uncertainty and scenario analyses identify vaporized nicotine product parameters that drive uncertainty around QALYs and costs the most, and in turn what type of future research should be prioritized, most notably: the impact of vaping liberalization on population-level smoking cessation rates; the relative health harm of vaping; and the impact of vaporized nicotine products on tobacco smoking uptake rates among youth (Figure 2).

A strength of our study is the use of probabilistic uncertainty analyses to generate a total 95% UI about health gains and cost savings (as opposed to deterministic uncertainty analyses in previous modeling studies[2,9,10,12,13]). We used tornado plots (Figure 2) to identify which parameter's uncertainty contributes the most uncertainty. We also used recent evidence on

the impact of the availability of vaporized nicotine products on the population-level smoking cessation rate, and estimates for the relative health harm from vaping compared with smoking based on two substantive reports recently published (National Academies of Sciences Engineering and Medicine[2] and Public Health England[7]). By using an evidence-based transition framework for the impact of vaporized nicotine products on youth smoking uptake,[13] we were able to account for both potential beneficial and negative health impacts of these products for youth. This is a strength compared with a recent modeling study[14] that did not take into account the potential benefits of youth taking up vaping instead of smoking. Our study is also the first study to report results for both younger and older age groups.

While previous modeling studies have hinted at potential healthcare expenditure savings from the availability of vaporized nicotine products,[12] ours is the first study to quantify it. We estimated that health system cost savings in NZ$ 2011, over the remainder of the population's lifespan, were NZ$3,420 million (95% UI = NZ$379 to NZ$7,050), or NZ$780 per capita. Only 12.7% of these undiscounted cost savings accrued in the first 20 years post-intervention. Financial projections are often considered with discounting; 3% per annum discounting reduced cost savings by two-thirds to 2011 NZ$1,260 million, or to US$908 million in 2017 real dollars (Table 3).

Limitations include prevalence estimates of current vaping corresponding to vaping every day and only some days.[3] The latter group could in theory also include vapers who vape once a week or once a month or less, with likely lower health risk than daily vaping. There is insufficient information to accurately parameterize a model for vaping frequency; improving such data is a research priority (as also recommended previously[21]). Nevertheless, we ran a scenario analysis with lower vaping prevalence (bottom row Table 3), resulting in a 22% reduction in health gains owing to the lower prevalence of daily vaping.

Many parameters were assumed to have a constant mean and uncertainty range into the future—an implicit stationarity assumption. Prevalence of vaporized nicotine product use may change in the future owing to changes in price, promotion, and regulation. Acceptability of these products to users and health risks of vaping may also change owing to quality control of ingredients and improvements in product design. These are inherent future uncertainties beyond what we could confidently include in the modeling. We used estimates from the United States where the vaping market has developed with little regulation. Future regulation of vaporized nicotine products may affect these estimates. For example, restrictions on flavors and settings where vaping is permitted may further reduce health risk and use by nonsmoking youth, but may also lower their uptake by current smokers.

Third, we assumed that the reduced harm from vaping (and dual use) applied to all tobacco-related diseases with the same percentage reduction in excess risks from smoking (an assumption also used in current peak body reports[2,7]).

Fourth, we assumed dual users had the same cessation rate as that from current smokers based on a longitudinal study[27,28]; if dual users are less likely to quit smoking than if they remained current smokers, then we will have overestimated the health gain and cost-savings. Conversely, if dual users quit at a higher rate than current smokers, we will have underestimated these outcomes. Further quality longitudinal data are needed for this parameter.

Finally, we did not model the potential impact of combining vaporized nicotine product availability with other tobacco control policies which could further encourage smokers to switch to vaping. For example, the US Food and Drug Administration announced it is considering implementing mandated nicotine reduction for smoked tobacco products while allowing innovation in vaporized nicotine products and other lower risk nicotine products.[30] Similarly, the ASPIRE2025 network has recommended legalization for these products in NZ in combination with other policies, including an annual 20% tax increase on smoked tobacco, reducing the number of tobacco retailers, and mandated nicotine-reduction in smoked tobacco.[31] Evidence from experimental studies suggests that vaporized nicotine products are economic substitutes for smoked tobacco and that the availability of the products is likely to increase the impact of tobacco tax increases on smoking.[32,33]

While our study and those of others have inherent uncertainty, there are findings that point to where precautionary regulation should focus. First, our findings support a fairly permissive regulatory environment where vaporized nicotine products are readily available to adult smokers along with regulations that limit the risks of youth uptake. The former may be facilitated by relatively light regulation of permitted retail settings and having no excise taxes on vaporized 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 flavors that might be particularly attractive to youth.[3]

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4.5 Tobacco smoking

The decline in daily smoking has slowed

Successful public health strategies over several decades have seen daily smoking rates in Australia decline. The National Drug Strategy Household Survey showed that the daily smoking rates halved between 1991 and 2016 (from 24% to 12%). However, there was no decline between 2013 and 2016 (AIHW 2017).

The majority of daily smokers are aged 40 and over

People aged 40–49 continued to be the age group most likely to smoke daily (16.9%) and no improvement in the smoking rate was seen for this group in 2016 (16.2% in 2013 and 16.9% in 2016).

The population of smokers is ageing and the majority (57%) of daily smokers in 2016 were aged 40 and over—different from the trend 15 years ago when the majority were aged 14–39. Long-term reductions in smoking have been largely driven by fewer people ever taking up smoking. Between 2001 and 2016, the proportion of people who reported never smoking rose from 51% to 62% (AIHW 2017).

Some groups are making positive changes

Considerable progress towards reducing smoking continued to be made among teenagers—the proportion of teenagers who were current smokers (people who reported smoking daily, weekly or less than weekly) declined from 5.0% in 2013 to 2.1% in 2016. Young people also continued to delay the uptake of smoking, with the average age at which people aged 14–24 smoked their first full cigarette increasing from 14.3 years in 2001 to 16.3 years in 2016 (a significant increase from 15.9 years in 2013).

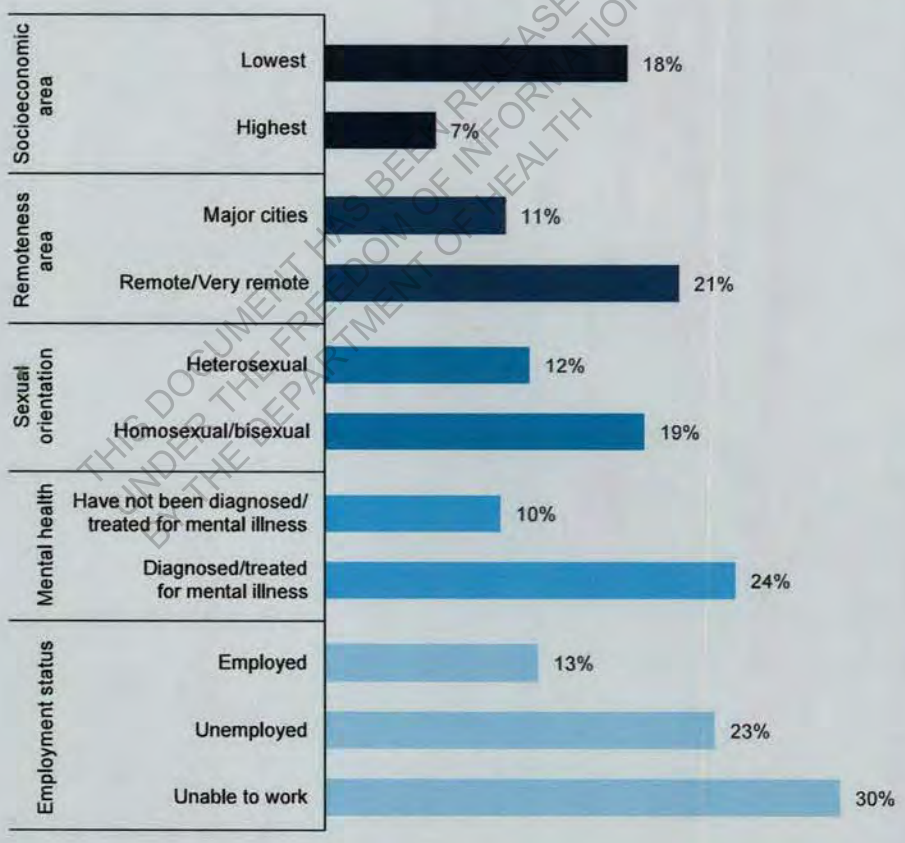
There were also fewer people being exposed to tobacco smoke: the proportion of dependent children exposed to tobacco smoke inside the home continued to decline, from 3.7% in 2013 to 2.8% in 2016 (a dramatic fall from 31% in 1995), and the proportion of pregnant women smoking during their pregnancy declined from 15% in 2009 to 10% in 2015.

People living in the lowest socioeconomic area were one of the few groups to report a decline in daily smoking between 2013 and 2016—from 20% to 18%—but they still have a much higher smoking rate than people living in the highest socioeconomic area (6.5%) (AIHW 2017).

Some groups are more likely to smoke daily than others

Good health is not shared equally among people in Australia and smoking is one example of a key risk factor for disease that contributes to these inequalities. Although some improvements are being made among these groups, daily smoking continues to be more commonly reported among Aboriginal and Torres Strait Islander people (see Chapter 6.5 'Health behaviours of Indigenous Australians'), people living in the lowest socioeconomic area, people identifying as homosexual/bisexual, and people who were unable to work or were unemployed (Figure 4.5.1).

Figure 4.5.1: Proportion of people who are daily smokers, by selected demographic characteristics, 2016



Source: AIHW 2017; Table S4.5.1.

Most smokers want to quit

According to the National Drug Strategy Housing Survey 2016, 7 in 10 (69%) current smokers planned to quit smoking and 3 in 10 (29%) tried to quit in the previous 12 months but did not succeed. The main reason smokers tried to quit or change their smoking behaviour was because it was costing too much money (52%).

Smoking is the leading risk factor for disease

Tobacco smoking is the leading preventable cause of death and disease in Australia and a leading risk factor for many chronic conditions.

The Australian Burden of Disease Study estimated that tobacco use contributed to almost 18,800 deaths in 2011—more than 1 in every 8 (13%) deaths. Taking into account illness as well as deaths, tobacco use caused more disease and injury burden in Australia than any other single risk factor and was responsible for 9.0% of the total burden of disease. The largest impact from tobacco use is on cancer, respiratory diseases and cardiovascular disease.

The total burden attributable to tobacco use was only slightly lower (0.2%) in 2011 than in 2003 (equivalent to an 18% decline in the age-standardised rate), despite reductions in tobacco use and exposure over this period. This may be because health improvements from reductions in tobacco use take longer to become evident in cancer and chronic respiratory diseases (for which burden rates are still increasing) than in cardiovascular disease (for which there has been a large decrease in burden) (AIHW 2016).

Smokers have poorer health than non-smokers

In 2016, smokers were less likely to rate their health as 'excellent' than people who had never smoked (8.3% compared with 22%) and were more likely than people who had never smoked to self-report being diagnosed with, or treated for, a mental illness in the previous 12 months (28% compared with 12% for people who had never smoked). The proportion of smokers self-reporting a mental illness also increased—both in recent years (from 21% in 2013), and over the last decade (17% in 2007).

The mechanisms linking tobacco smoking with mental health problems are complex; however, it is understood that people may perceive that smoking helps to relieve or manage psychiatric symptoms of their disorder (Minichino et al. 2013). It has also been shown that people with mental health conditions may find it difficult to stop smoking; however, on quitting, they are likely to experience improvements in their mood, general wellbeing, mental health and quality of life (Greenhalgh et al. 2016).

A high proportion of smokers also drink alcohol in risky quantities (49% exceeded the lifetime or single-occasion risk guidelines in 2016) and use illicit drugs (36% had used at least one illicit drug in the previous 12 months). Risky alcohol consumption and illicit drug use are both risk factors that increase the likelihood of a person's developing a disease or health disorder.

What is missing from the picture?

There are limited national data available on how and why people quit smoking, and how they successfully maintained quitting. Most survey questions related to changes in behaviour or stopping smoking are targeted at smokers not ex-smokers.

There are currently no regular data collections on smoking prevalence among homeless people or on the relationship status of household smokers (for example, parent or sibling).

Where do I go for more information?

More information on tobacco smoking is available at <www.aihw.gov.au/reports-statistics/behaviours-risk-factors/smoking/overview>. The reports *National Drug Strategy Household Survey 2016: detailed findings* and *Tobacco indicators: measuring midpoint progress—reporting under the National Tobacco Strategy 2012–2018* and other recent releases are available for free download.

More information on the Australian Burden of Disease Study is available at <www.aihw.gov.au/reports-statistics/health-conditions-disability-deaths/burden-of-disease/overview>. The report *Australian Burden of Disease Study: impact and causes of illness and death in Australia 2011* and other recent releases are available for free download.

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