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Commentary

Does the gateway theory justify a ban on nicotine vaping in Australia?

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ABSTRACT

Australia bans the sale, possession and use of liquid nicotine for vaping. One of the major arguments used to justify Australia's policy is that the availability of nicotine vaping products will lead a substantial number of young people who would otherwise not have smoked cigarettes to take up regular smoking (the gateway theory). In this article, we provide a critical analysis of the use of the gateway theory to justify Australian policy. We argue first that the evidence that vaping serves as a gateway to smoking is unconvincing. Smoking more often precedes vaping than vice versa, regular vaping by never-smokers is rare and the association is more plausibly explained by a common liability model. Second, we argue that even if the evidence were stronger it would not justify a ban on the sale of nicotine to adult smokers because there are other ways of preventing adolescent vaping that do not require a ban. We describe an alternative regulatory model for Australia that would address legitimate concerns about preventing adolescent uptake while allowing adult smokers to access these products for cessation or as an alternative to smoking cigarettes.

Smoking remains the leading preventable cause of premature death and illness in Australia, killing 21,000 Australians each year (Australian Institute of Health & Welfare, 2019). Although smoking rates have fallen steadily for several decades, the decline has slowed considerably since 2013 despite the introduction of plain packaging in 2012 and continued steep annual increases in cigarette taxes (Australian Bureau of Statistics, 2018; Australian Institute of Health & Welfare, 2017).

Australia is the only western democracy that still bans the sale, possession and use of liquid nicotine for vaping (Institute for Global Tobacco Control, 2018). In Australia, it is illegal under federal law to possess or use nicotine liquid for vaping without a prescription from a medical practitioner (Department of Health, 2015). This policy imposes a de facto ban on nicotine vaping because most Australian doctors are reluctant to issue prescriptions for nicotine when this practice is not endorsed by Australian health authorities. Substantial fines and prison sentences apply for illegal possession of nicotine liquid intended for vaping (Australian Tobacco Harm Reduction Association, 2020).

The Australian ban has reduced the uptake of vaping. Only 1.2% of Australian adults were current vapers in 2016 (Australian Institute of Health & Welfare, 2017). This is low compared to Canada (3%) (Health Canada, 2018), the US (3.8%) (Dai & Leventhal, 2019), New Zealand (4.7%) (Ministry of Health New Zealand, 2019) and Great

Britain (6.3%) (Office for National Statistics, 2019).

Vaping nicotine has been shown to be an effective quitting aid for some adult smokers who are otherwise unable to quit (Hajek et al., 2019). In many countries where it is legally available, vaping has been associated with increased quit rates and an accelerated decline in smoking prevalence (Beard, West, Michie & Brown, 2019; Zhu, Zhuang, Wong, Cummins & Tedeschi, 2017). (see Fig. 1)

One of the major arguments used to justify Australia's policy is that the availability of nicotine vaping products will lead young people who would otherwise not have smoked cigarettes to take up regular smoking (an application of the gateway theory). The claim is made that this gateway effect would impact sufficient numbers of people to undermine any benefits that adult smokers may obtain from using them to quit (Chapman, Bareham & Maziak, 2019).

In this paper we provide a critical analysis of the use of the gateway theory to justify Australian policy. We argue first that the evidence that vaping serves as a gateway to smoking is unconvincing. Second, we argue that even if the evidence were stronger, it would not justify a ban on the sale of nicotine liquid to adult smokers because there are other ways of preventing adolescent vaping that do not require a sales ban. We describe an alternative regulatory model for Australia that would address legitimate concerns about preventing adolescent uptake while allowing adult smokers to access these products for cessation or as an

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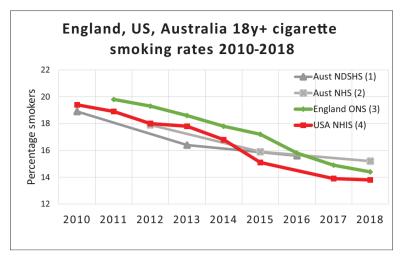


Fig. 1. Adult smoking rates in England, US, Australia 2010-2018 References

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- + view?ReadForm&prodno = 4364.0.55.001&viewtitle = National $\begin{tabular}{ll} $$\% 20 Health \% 20 Survey: \% 20 First \% 20 Results $$\sim 2017-18 \sim Latest \sim 12/$ \end{tabular}$ 12/2018&&tabname = Past%20Future

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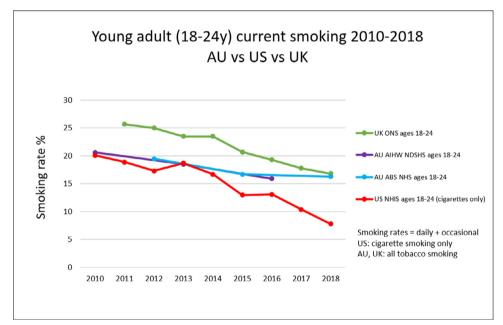


Fig. 2. Young adult current smoking trends, Australia, US and UK. 2010-2018 References

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U.S. Department of Health and Human Services Centers for Disease Control and Prevention. National Health Interview Survey 2010-18. Available at https:// public.tableau.com/profile/tina.norris#!/vizhome/FIGURE8 1/Dashboard8 1.

alternative to smoking cigarettes

What is the gateway theory?

The gateway theory postulates that certain types of drug use lead to other types of drug use. In the case of vaping, it proposes that young people who would never have become smokers will try vaping and that as a result a substantial proportion will become regular cigarette smokers. The gateway hypothesis requires vaping to precede smoking and other evidence of causality (Etter, 2018). The simple fact that vaping precedes smoking however does not necessarily indicate causation if the person had been highly likely to smoke anyway.

The gateway theory can be explained biologically or behaviourally.

The biological pathway is that vaping produces nicotine addicted adolescents who subsequently progress to smoking as the best way to satisfy their nicotine crayings. This version of the hypothesis requires a period of frequent or regular vaping to establish nicotine addiction. Under the behavioural model, it is also possible that vaping may increase the likelihood of initiating cigarette smoking by increasing adolescents' familiarity with the behaviour and sensations of smoking (Kozlowski & Warner, 2017).

Causation or common liability

In cross-sectional surveys of young people, there is an association between vaping and cigarette smoking, i.e. young people who vape are much more likely to smoke cigarettes (Soneji et al., 2017). The key question is whether the vaping has caused the young person to smoke or whether the association between vaping and smoking reflects a shared liability for risk taking.

Young people who vape may have other characteristics that put them at higher risk of smoking, making this group different from youth who do not vape. Potential confounders include other substance use, risk-taking behaviour, household smoking models, peer smoking, sensation seeking, mental health problems and low education. The association between vaping and smoking may be produced by these factors (all potential confounders) rather than the vaping itself.

Many studies have attempted to adjust for these confounders by the conventional approach of controlling for them in a regression analysis. However, full deconfounding is impossible in practice and most studies still carry some residual bias. (Etter, 2018) Lee and Fry reviewed 15 gateway studies of youth vaping and found that none adequately adjusted for confounding factors (Lee & Fry, 2019). Further extensive adjustment by the authors for additional confounders explained as much as 87% of the observed association between e-cigarettes and cigarette smoking.

In the presence of heavy confounding, one way to minimise bias and adjust for shared risk factors is propensity score analysis. Kim and Selya used this method to analyse data from the US Monitoring the Future study from 2015–16 in examining the relationship between youth ecigarette use and smoking while controlling for 14 associated risk factors. (Kim & Selya, 2019) They concluded that "the apparent relationship between e-cigarette use and current cigarette smoking is entirely attributable to shared risk factors for tobacco use".

On the other hand, a review by the National Academies of Sciences, Engineering and Medicine concluded that the studies that it assessed had considered a comprehensive range of confounding factors and that a causal link was established (National Academies of Sciences Engineering & Medicine, 2018). However, this conclusion is unconvincing because the analysis is not able to exclude residual, unadjusted confounding, as described earlier. The report also does not provide evidence to support the claim that the association between youth vaping and smoking is causal.

An established method to assess whether an association is causal is with the Bradford Hill framework which tests an association against a series of nine considerations, such as the strength of the association, specificity, temporal precedence and plausibility (Bradford Hill, 1965). Etter applied this analysis to youth vaping and concluded that "The gateway hypothesis cannot currently be either accepted or confidently refuted because the evidence for it is scarce and inconclusive" (Etter, 2018).

Residual confounding and the Bradford Hill analysis weaken the gateway argument leaving "common liability" as the most plausible explanation for the association between youth vaping and smoking (Vanyukov et al., 2012). This posits that there is a shared underlying predisposition to experiment with risky behaviours such as vaping and cigarette smoking, and others such as illicit drug use.

Smoking usually precedes vaping

The plausibility of the gateway theory is weakened by the finding that smoking more often precedes vaping than vice versa, i.e. most youth who tried vaping are already cigarette smokers or have previously experimented with cigarette smoking.

In the 2017 Australian Secondary Students' Alcohol and Drug Survey, two in three 12–17 year-olds who had ever vaped had first smoked (Guerin & White, 2018). In the US National Youth Tobacco Survey in 2015, 87.7% of current e-cigarette smokers who had smoked more than 100 cigarettes said cigarettes were the first product they had tried. Only 7.6% identified e-cigarettes as the first nicotine product they used. (West, Brown & Jarvis, 2019).

In the US Population Assessment of Tobacco and Health Study

(PATH) from 2013–2016, Berry et al. found that 85% of current smokers aged 12–15 years had not vaped before they began to smoke cigarettes (Berry et al., 2018). In a study of over 32,000 11–16 year-olds in Wales, de Lacy et al. reported that 85% of weekly smokers who had also vaped, had smoked prior to vaping (de Lacy, Fletcher, Hewitt, Murphy & Moore, 2017).

Regular vaping is rare amongst never-smokers

Further weakening the gateway hypothesis is the finding that most vaping by adolescents is experimental and infrequent. Regular vaping by never-smokers is rare, generally 1% or less in international surveys.

In Australia in 2017, 0.3% of 12–17 year old never-smokers had vaped on 3 or more days in the last month (Guerin & White, 2018). In New Zealand, 0.4% of year 10 students who had never smoked reported vaping daily in 2018 (ASH New Zealand, 2018). Bauld et al. analysed data from five large national surveys in the UK of 60,000 11–16 year olds (Bauld, MacKintosh, Ford & McNeill, 2016). Rates of at least weekly vaping by never-smokers were very low in all surveys ranging from 0.1–0.5%. In the 2018 US National Youth Tobacco Survey, 13.8% of all students (9–19 years) reported past 30-day vaping. However, only 0.4% of never-smokers vaped regularly (≥20 days in the last 30 days) (Glasser, Johnson, Niaura, Abrams & Pearson, 2020).

Use of nicotine and dependence

Not all adolescent vapers use nicotine, as required for the biological explanation of the gateway theory. Seventy eight per cent of past 30-day high school vapers (16–18 year olds) reported using nicotine in the 2018 US Monitoring the Future survey (Miech, Patrick, O'Malley & Johnston, 2017). The remainder vaped non-nicotine substances such as flavourings alone or cannabis.

In the UK in 2019, 31.7% of 11–18 year-old vapers said that they always used nicotine, 34.2% said they sometimes vaped nicotine, 19.6% never used nicotine and 14.4% didn't know (Action on Smoking & Health UK, 2019).

Nicotine dependence is rare in young people who vape but have never previously smoked. In the 2018 US National Youth Tobacco Survey only 3.8% of never-smokers who vaped in the last 30 days reported cravings and 3.1% wanted to vape within 30 min of waking (West et al., 2019).

Experimental or regular smoking

The gateway theory requires that adolescent vaping often leads to regular cigarette smoking. The evidence for this claim is weak because most cross-sectional and longitudinal studies of the association between vaping and cigarette smoking only report past 30-day smoking rates. This measure exaggerates the prevalence of regular smoking by including occasional or experimental smokers, including even those who have smoked a single cigarette. Approximately three in four youths who try smoking will not progress to daily use (O'Loughlin, Karp, Koulis, Paradis & Difranza, 2009; Saddleson et al., 2016).

A French study of 40,000 17-year-olds found no evidence of an increased risk of transitioning to daily smoking amongst ever-smokers who also experimented with e-cigarettes. (Chyderiotis, Benmarhnia, Beck, Spilka & Legleye, 2020)

Vaping as a diversion or quitting method

Contrary to the gateway hypothesis, vaping appears to divert a subset of youth at high risk of cigarette smoking away from smoking (O'Leary, MacDonald, Stockwell & Reist, 2017; Walker et al., 2020). Some adolescents may try vaping as a less harmful alternative to smoking and not progress to smoking (Kozlowski & Warner, 2017).

A number of studies have reported that some young smokers use

vaping to quit or as a safer alternative to smoking. In a survey of 10,000 US adolescent and young adult smokers, Camenga et al. found that 42% had used vaping to quit smoking (Camenga, Kong, Cavallo & Krishnan-Sarin, 2017). In a Canadian study of 14–15 year-olds, 33% used vaping to quit or reduce smoking (Khoury et al., 2016).

Decline in smoking rates

The rapid decline in adolescent smoking rates in the UK and US after the introduction of vaping is not consistent with the hypothesis that vaping is significantly increasing youth smoking rates.

Levy et al. analysed smoking rates in US youth and young adults (age 15–25 years) over the period of 2004–2018 to see if the trend changed after vaping became popular in 2014 (Levy et al., 2019). The study aggregated data from five different nationally representative surveys. Time trend analyses showed that the decline in past 30-day smoking accelerated two to four fold after 2014 in both youth and young adults. US youth smoking rates (12th grade) also fell by 25% in 12 months from 2018 to 2019 (7.6% to 5.7%) (Miech, Johnston, O'Malley, Bachman & Patrick, 2019).

In England, smoking rates in young people have also continued to decline rapidly. Cigarette smoking prevalence in 16–17 year-olds fell by 60% from 2015 to 2019, from 13.8% to 5.2% (West & Brown, 2019).

An international comparison of smoking rates in young adults (18–24 year-olds) does not suggest that youth vaping is increasing smoking uptake. Smoking rates in the US and UK where vaping is widely available, are declining much faster than in Australia where nicotine vaping is banned.

The rapid declines in smoking rates suggest, contrary to the gateway hypothesis, that vaping may be acting as a gateway out of smoking by replacing, rather than promoting, the smoking of tobacco cigarettes.

This hypothesis is supported by evidence from several studies in the US of the effects of bans on the sales of vaporisers to adolescents. These studies suggest that vaping is a substitute for smoking for some adolescents when it is more accessible than cigarettes. Two studies found that bans on the sale of vaporisers to minors in US states were associated with a significantly greater increase in adolescent smoking compared to states without such bans (Friedman, 2015; Pesko, Hughes & Faisal, 2016). A third study of 12th graders in the US that used a different methodology found that sales bans increased both vaping and smoking (Abouk & Adams, 2017).

A study of the effect of age restrictions on vaping rates found that smoking increased when vaping products became harder for adolescents to legally purchase (Pesko & Currie, 2019). A review of studies by Dave et al. found that minimum legal age of purchase laws significantly increased youth smoking of conventional cigarettes by approximately 8–12% of the mean smoking rate (Dave, Feng & Pesko, 2019).

Does the evidence justify a ban?

Australia's ban on nicotine vaping is intended to protect young people from smoking. However, as we have argued, there is no good evidence that vaping nicotine is leading significant numbers of young people to become regular smokers. The ban is likely to have a net harmful effect on public health by denying addicted adult smokers legal access to these less harmful products for cessation or as a long term substitute for smoking.

There is strong and growing evidence from randomised controlled trials that vaping is an effective quitting aid (Hajek et al., 2019; Walker et al., 2019). Vaping is increasing quit rates and lowering smoking prevalence in countries that allow its use (Beard et al., 2019; Zhu et al., 2017). The population impact of vaping is amplified because of its popularity amongst smokers. Vaping has become the most popular quitting aid in most countries where it is available (Caraballo, Shafer, Patel, Davis & McAfee, 2017; European Commission., 2017; West & Brown, 2019).

The small risk that vaping may lead some young people who would not otherwise have smoked to take up smoking must be weighed against the substantial and immediate benefits from helping adult and young smokers to quit. It also must be weighed against the benefit of diverting some young people away from smoking.

Increasing adult smoking cessation with vaping also reduces smoking-related harm amongst young people. Youth smoking is heavily influenced by adult behaviour, and young people are less likely to become smokers if their parents and older siblings have quit (Leonardi-Bee, Jere & Britton, 2011). Parents who switch to vaping live longer and have improved health and finances which benefits the whole family. Furthermore, young people are no longer exposed to second-hand smoke when smoking parents quit.

The ban on vaping in Australia is having other harmful unintended consequences. It has produced a thriving black market for nicotine vaping products in the absence of any regulation or quality control. The ban is forcing smokers who wish to quit with vaping to commit a criminal offence. It is also infringing the rights of smokers to choose a safer alternative to improve their health. It is also hard to justify a policy which allows the sale of the most lethal consumer product in history while banning a far safer alternative.

A ban on the sale and use of nicotine is also an unnecessarily restrictive policy. A less restrictive and more nuanced approach could achieve a better public health outcome (Hall, Morphett & Gartner, 2019).

Balanced risk-proportionate regulation

An appropriate regulatory policy should reflect the substantial risk difference between vaping and smoking while balancing the needs of adult smokers and young people.

Such an approach would allow access to regulated nicotine vaping products as consumer products for adult smokers who are unable to quit with conventional treatment. It would also restrict the access of young people to nicotine vaping by limiting how and where these products could be obtained.

A suggested framework for regulation is outlined in Fig. 3 and is similar to the current regulatory model in the UK under the Tobacco and Related Products Regulations (legislation.gov.uk, 2016).

Conclusion

The association between nicotine vaping and cigarette smoking provides weak support for a gateway hypothesis. Smoking more often precedes vaping than vice versa, regular vaping by never-smokers is rare and the association is more plausibly explained by a common liability model. If there is a gateway effect, it is small at the population level because smoking prevalence has continued to decline despite an increased uptake of vaping in countries that allow it.

Even if the evidence for a gateway hypothesis were stronger, it would not justify a ban on the sale of nicotine vaping products to adults. More proportionate regulatory policies could minimise youth uptake while allowing adult smokers to access these products for cessation or as a lower risk substitute for cigarette smoking.

Conflict of Interest Statement

Colin Mendelsohn: I have received funding from Pfizer Australia, Johnson & Johnson Pacific and Perrigo Australia for teaching, consulting and conference expenses. I have never received payments from electronic cigarette or tobacco companies. I am a Board member of the Australian Tobacco Harm Reduction Association (ATHRA), a health promotion charity. ATHRA has received unconditional funding for establishment costs from small Australian vape businesses. Vape industry funding has not been accepted since March 2019.

Wayne Hall: None.

Availability for adult smokers

- Legalise the sale, possession and use of nicotine e-liquid for vaping as a
 consumer product up to a maximum nicotine concentration (to be decided). This
 would require exempting low concentrations of nicotine for vaping from the
 Poisons Standard (Federal Department of Health, 2019)
- Public messaging that frames vaping as a smoking cessation tool and educates adult smokers about the benefits of vaping as a quitting aid or as a safer alternative to smoking
- Restricting advertising to adult smokers such as at the point-of-sale. A good model is the UK Code of Advertising Practice (UK Advertising Code, 2016)
- Labelling to include risk-proportionate health messages regarding toxicity and addictiveness; full list of e-liquid ingredients; advice to keep out of the reach of children; and advice on overdose management
- Quality and safety standards for hardware, electrical safety and e-liquids
- Public vaping restrictions to be guided by the low risk of second-hand vapour
- Post marketing reporting and recall procedures under the supervision of the Australian Competition and Consumer Commission
- Light taxation of vaping products to maintain a favourable price differential with smoking (Chaloupka, Sweanor, & Warner, 2015)

Fig. 3. A suggested framework for regulation in Australia

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Reducing risks to young people

- Restrict sales of vaping products to specialist vape shops, tobacconists, pharmacies, adult stores and other suitable outlets and require strict proof of age at purchase points and via internet sales
- Maintain the current minimum age of sale for vaping products and e-liquids at 18 years and improve enforcement
- Consider access for selected young smokers with written permission of a parent or doctor
- Responsible advertising to adult smokers, avoiding any appeal to under 25s
- Packaging to restrict appeal to young people (images, colours, text)
- · Restriction of e-liquid brand and flavour names which appeal to youth
- Child-resistant containers for e-liquid
- Further restrict access to smoked tobacco products, such as by reducing tobacco licences; enforcement of minimum age of sales; raise the age for tobacco sale to 21 years (Friedman, 2019)

CRediT authorship contribution statement

Colin P. Mendelsohn: Conceptualization, Writing - original draft, Project administration. **Wayne Hall:** Conceptualization, Writing - review & editing.

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