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ORIGINAL PAPER

A critical analysis of Australia's ban on the sale of electronic nicotine delivery systems

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Abstract Australia does not allow adult smokers to buy or use electronic nicotine delivery systems (ENDS) that contain nicotine without a prescription. This paper critically evaluates the empirical and ethical justifications provided for the policy by Federal and State governments, public health advocates and health organisations. These are: (1) that ENDS should only be approved as products for smoking cessation when there is evidence from randomised controlled trials that they are effective; (2) that as a matter of precaution we should not allow the sale of ENDS to smokers as consumer products because we do not know what their long-term effects will be; and (3) that allowing ENDS to be sold as consumer goods will enable the tobacco industry to market ENDS to young people which will also lead to an increase in youth smoking. We show that the arguments and evidence offered in support of all these claims is very weak. We also argue that even if the evidence were stronger, it would not justify denying adult smokers the right to use ENDS either to quit smoking or as a long-term alternative to smoking cigarettes. We outline ENDS policies that would more ethically address the public health concerns that motivated the current policy by allowing adult smokers to access ENDS for smoking cessation or tobacco harm reduction under tight regulations that discourage commercial promotion and adolescent use.

Keywords Nicotine · E-cigarettes · Public policy · Smoking · Tobacco

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Introduction

Tobacco smoking is a behaviour that was responsible for 100 million premature deaths globally in the twentieth century [1]. If current trends continue, smoking will cause over 1 billion deaths worldwide by the end of the twenty-first century [2].

Smokers primarily smoke to obtain nicotine by inhaling tobacco smoke into the lungs. The principal causes of premature death and diseases from smoking, however, are the toxins and carcinogens delivered to the lungs and circulatory system in tobacco smoke [3, 4]. In principle, the harms of smoking would be very substantially reduced if smokers could obtain their nicotine without the harmful by-products of smoking tobacco [5].

Tobacco control policies have primarily aimed to encourage smokers to quit and non-smokers not to start. Policies that aim to reduce tobacco-related harm by encouraging smokers to obtain nicotine in less harmful forms

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(such as gums, smokeless tobacco) are not supported in Australia [5]. This is largely because previous attempts to reduce harm by promoting filtered and low tar cigarettes failed to reduce smoking or smoking-related harm [5]. This history arouses understandable scepticism about other types of tobacco harm reduction.

The advent of electronic nicotine delivery systems (ENDS), or e-cigarettes in the mid-2000s renewed calls in Australia and other countries for tobacco harm reduction policies. ENDS are battery-powered devices that heat a liquid, typically propylene glycol and/or glycerine with flavourings and nicotine to create an aerosol that is inhaled like tobacco smoke. ENDS do not burn tobacco so they deliver much lower levels of carcinogens and toxins than combustible cigarettes [3, 6]. Hence, ENDS deliver nicotine in ways that are substantially less risky than smoking tobacco and could potentially be used by smokers to quit, in much the same way as nicotine replacement therapies, or could be used as a safer long-term alternative to smoking cigarettes [3, 6]. Neither use is allowed in Australia because the sale of nicotine for non-therapeutic human use is prohibited and no ENDS have been approved for therapeutic use.

This paper critically reviews the justification for Australia's prohibitive policy on the sale of ENDS. We explain in more detail what ENDS are and then describe how Australia's regulatory policy was implemented. We critically examine the justifications governments have provided for the policy. We argue: that these justifications are based on strong interpretations of weak evidence; that a sales ban is a paternalistic policy towards adult smokers that is also unjust; and that a ban embodies an incoherent approach to managing health risks. We conclude by describing policies that would address reasonable concerns about the potential adverse public health impacts of ENDS while allowing ENDS to be sold to adult smokers under tight regulations.

Electronic Nicotine Delivery Systems

ENDS come in a variety of types. The first types were "cigalikes" that looked like cigarettes and were used in ways that mimicked smoking. These devices delivered much lower levels of nicotine than combustible cigarettes, so their uptake among smokers was low. Second and third generation ENDS use a rechargeable battery and a tank which is filled with a liquid of the users' choice. Some devices allow the user to adjust the power and airflow settings to customise the nicotine delivery. These advanced ENDS devices are more popular with smokers and now dominate the ENDS market in the UK where ENDS are sold as consumer goods. More than 80% of e-cigarettes users in the UK use liquids that contain nicotine [7]. Smaller 'pod-style' ENDS have also been developed [8].

Advocates of ENDS argue that they will substantially reduce tobacco-related harm by (1) increasing the number of successful quit attempts among smokers and (2) by providing a lower risk, long-term alternative to cigarette smoking for those smokers who are unable or unwilling to quit using nicotine. Some advocates of ENDS see these products playing a key role in a comprehensive policy to phase out the sale of combustible cigarettes [3, 5, 9–11].

Australian ENDS Policy

The sale of ENDS that contain nicotine was banned in Australia via poisons regulations. In 2008, the National Drugs and Poisons Scheduling Committee determined that any ENDS that contained nicotine would be classified as a dangerous poison, if it was not intended for therapeutic use, and included in Schedule 7 of the Poisons Standard. If ENDS were intended for therapeutic use, they would be included in Schedule 2, which would allow them to be sold over the counter in pharmacies if approved as a therapeutic good by the Therapeutic Goods Administration (TGA) [12]. The TGA can only approve ENDS as a therapeutic good if they have been shown to be safe and effective for cessation in controlled clinical trials and the manufacturer meets the requirements for manufacturing therapeutic goods (e.g. GMP licence). In the interim, smokers who wanted to use ENDS could import nicotine solutions by using a Personal Importation Scheme for accessing unapproved therapeutic goods or have the nicotine liquid extemporaneously compounded by a pharmacist, if the smoker could find one who was willing and able to do so.

In 2011, the Committee amended the Poisons Standard to ensure that ENDS for therapeutic use would be available only on medical prescription (Schedule 4). The TGA website advises smokers that they can import nicotine for their personal use if: (1) they obtain a prescription from an Australian registered medical practitioner and (2) if they are allowed to import nicotine under their State or Territory drugs and poisons law. However, it is difficult for smokers to find Australian doctors who will prescribe an unapproved therapeutic good.

These regulations effectively ban the sale of vaporiser devices and refill liquids that contain nicotine because none have been approved for therapeutic use. They also make it illegal to possess and use ENDS containing nicotine in most states and territories unless users have a prescription. The use of ENDS that contain nicotine without a prescription is an offence in all Australian states that can attract substantial fines and even the potential for imprisonment [13]. Australian ENDS users have had their homes searched by the police and been prosecuted for possessing nicotine (e.g. [14]).

The Justification for the Australian Ban on the Sale of ENDS

The Commonwealth Department of Health (CDH) is the key national policy maker on ENDS whose special agencies include the TGA. It claims that the current Australian regulatory approach to ENDS is an evidence-based policy that uses a "precautionary approach" to "prevent harm when there is scientific uncertainty and until a body of evidence establishes the requirement for alternative regulation" [15].

The policy is justified, according to the Department, by "the lack of conclusive evidence around the safety risks posed to users by the unknown inhalation toxicity of nicotine and other chemicals used with e-cigarettes, passive exposure to e-cigarette vapour, risks associated with child poisoning, and issues around quality control and efficacy" [15].

A precautionary approach, according to the Department, also "takes into account the broader risks that e-cigarettes may pose to population health, namely their potential to disrupt the decline in tobacco use in Australia" [15]. Specifically, the CDH's concern is that "an increase in e-cigarette marketing and use may undermine tobacco control success by establishing new cohorts with nicotine dependence, renormalising smoking, encouraging dual use of tobacco and e-cigarettes, and discouraging quitting" [15].

Ethical Issues Raised by an ENDS Sales Ban

Sales Bans and Adult Smokers' Autonomy

As the first quotation above indicates, one justification of the ban on the sale, possession and use of ENDS is to protect the health of adult smokers because of uncertainty about the long-term health risks of using ENDS. This policy is paternalistic in the sense that it denies adult smokers the choice of using ENDS rather than tobacco cigarettes in order to protect the smokers' own health. The claim depends on a lack of knowledge about the long-term health risks of using ENDS instead of cigarettes.

We respect the autonomy of adults when we do not interfere with their free and informed choices [16]. Most ethical theories assume that adults are able to decide freely upon a course of action that they judge to be in their own best interests. Most would also agree that we should not interfere in adults' exercise of autonomy by coercing them into behaving in a certain way, or encouraging them to act in ways that we think are in their best interests by providing false or misleading information. A ban on sales to adult smokers in the interests of protecting their health over-rides the autonomy of adult smokers in these ways.

It may be argued that a sales ban is not paternalistic because smokers' autonomy is impaired by their nicotine addiction. Whatever the merits of this claim, the putatively impaired autonomy of smokers cannot be used only to justify a sales ban only on ENDS while allowing smokers to exercise their impaired autonomy to purchase the most harmful form of nicotine product, namely, combustible cigarettes. Any attempt to justify a sales ban on ENDS by appeal to the impaired autonomy of smokers would entail support for a ban on the sale of cigarettes to adult smokers for the same reasons.

While the commonly cited estimate that ENDS are 95% less harmful than combustible cigarettes is often questioned or disputed, the scientific consensus is that vaping exposes users to far fewer harmful substances than smoking tobacco [17, 18]. While experts tend to agree on this point, survey data shows that increasing proportions of smokers see little or no difference in health risks between ENDS and cigarettes, a set of beliefs likely to encourage dual use and a move from ENDS to cigarettes [19, 20]. Despite an absence of evidence that vaping is as harmful as smoking, and substantial evidence it is likely to be far less harmful, some health authorities have promoted the message that using ENDS is not safer than smoking, [21]. Indeed, one prominent tobacco control academic in the US has encouraged vapers to switch to smoking, Tweeting "Using e-cigs increases exposure to toxic chemicals for most users; they would be better off just smoking". [22].

Preventing ENDS Serving as a Gateway to Smoking for Youth

A second justification for the ENDS sales ban is that it is the best way to prevent the tobacco industry using ENDS to increase cigarette smoking among adolescents and young adults [15, 23]. This argument relies on equivocal evidence for a gateway effect of ENDS that in any case provides a poor justification for preventing adult smokers from accessing ENDS.

The gateway hypothesis is supported by observational evidence from a small number of cohort studies. A meta-analysis of longitudinal studies reported an association between the use in the past 30 days of e-cigarettes and the use of combustible cigarettes in the same time period [24]. This finding has been interpreted as evidence that ENDS serve as a gateway to cigarette smoking. The review dismissed a plausible alternative explanation of the reported association, namely, that experimentation with ENDS and tobacco cigarettes reflect a shared liability among young people to use different drugs and different forms of nicotine.

There were major weaknesses in the cohort studies included in the meta-analysis. First, most studies defined adolescent e-cigarette users or cigarette smokers as those who had ever used either product in the last 30 days. This was because very few young people in any of these studies were regular users of either tobacco cigarettes or ENDS. As a result these studies do not show what they are claimed to show, namely, that adolescents who use ENDS were more likely to become regular persistent cigarette smokers because they have used ENDS [24].

Second, most of these studies measured and controlled for a limited number of measures of the propensity to use nicotine. The association was weakest after adjustment for confounders in the largest study [25] which controlled for the most extensive list of confounders. In this study, the increased risk of past 30 day smoking among ENDS users was reduced from 7.78 to 1.75 (95% CI: 1.10, 2.78) after adjustment for confounders.

Third, the gateway hypothesis is inconsistent with population trends in cigarette smoking among young people in the UK and USA, both of which have allowed ENDs to be sold as consumer goods. There was a steep decline in youth smoking in UK over the same period in which vaping increased. The adult smoking prevalence in the UK is now the same as that in Australia, despite the absence of plain packaging or steep increases in tobacco tax in the UK [26]. There was also no increase in cigarette smoking among youth in the USA during the period when adolescent experimentation with e-cigarettes reportedly increased [27].

Fourth, a ban on the sales of ENDS to *adults* is not justified even if ENDS serve as a gateway to smoking in adolescents. As we argue in more detail below, a gateway effect would justify tighter regulation of ENDS to reduce youth access [27] but it does not justify a ban on sales to adults. If a gateway effect did justify a sales ban, then we would also be morally obliged to prohibit the sale of cigarettes to adults because a ban on all sales of cigarettes would surely be an even more effective way to prevent adolescents smoking cigarettes [28].

The Inequitable Effects of a Sales Ban

An ENDS sales ban denies adult smokers the choice to use ENDS and justifies this in terms of preventing adolescents being recruited to cigarette smoking. It thereby gives absolute priority to protecting youth while ignoring the interests that smokers have in reducing risks to their health. This policy clearly disadvantages addicted smokers, and especially socioeconomically disadvantaged smokers who find it difficult to quit smoking and want to reduce their health risks. The ban also ignores the interests of other vulnerable social groups that have a high smoking prevalence, such as persons with serious mental illnesses, substance use disorders, HIV, Hepatitis C, former prisoners, LGBTQI and Indigenous people.

Incoherent Risk Regulation

A sales ban on ENDS is an incoherent form of health risk management because it prohibits the sale of a less harmful way of obtaining nicotine (ENDS) while allowing the sale of the most harmful nicotine delivery system, the combustible cigarette. While the long-term health risks of ENDS may not be clear for many years, the risks of tobacco smoking are well-known, with up to two-thirds of continuing smokers expected to die from tobacco-related diseases [29]. The well-documented health risks of cigarettes were not regarded as sufficient to justify including smoked tobacco in the same poison classification as ENDs, either to protect smokers' health and wellbeing or to prevent cigarette smoking in adolescents, rather nicotine in tobacco prepared and packed

for smoking is given a specific exemption from poisons regulations.

Some defenders of Australian policy claim that it does not in fact prohibit ENDS because they could be approved as medicinal products for smoking cessation if they were shown to be safe and effective for this purpose [30]. This ignores the major obstacles to obtaining approval for ENDS by the TGA and the commercial disincentive to do so. The small independent companies that manufacture ENDS products do not have the funds or experience in pharmaceutical regulation to conduct clinical trials or apply to have their products registered as therapeutic goods. Only tobacco or pharmaceutical companies have had the financial resources to fund clinical trials and navigate the pharmaceutical regulatory process, however with some non-tobacco company owned products rapidly gaining market share, this may change in the future. An ENDS produced by a tobacco company was approved by the UK medicines regulator but it was never commercialised.

There appears to be a lack of interest by pharmaceutical companies in developing and commercialising ENDS as approved therapeutic products. The usual commercial risk in developing a new product may be increased if consumers do not use ENDS that satisfy the stringent performance requirements of medicines regulators (e.g. nicotine delivery and flavouring). Vapers report that it is important that they can experiment with nicotine strength, flavour, and devices to find the "right" combination to help them quit [31, 32]. Hence, restricting ENDS products to those approved as therapeutic goods may reduce their effectiveness as long-term substitutes for cigarettes. Furthermore, the features of ENDS that make them an effective substitute for cigarettes (e.g. rapid nicotine delivery, palatable flavours) are features that may be seen as undesirable in a smoking cessation aid as long-term use is seen as "abuse". As some smokers switch to vaping with no intention of stopping vaping, the medicinal paradigm of relatively short-term use of a product with low "abuse liability" may not be appealing or effective for smokers looking for a long-term substitute.

A Critique of the Evidence Base for Australian ENDs Policy

A major challenge for evidence based policies on ENDS remove is the lack of evidence on the use, harms and public health impacts of ENDS [18]. For example, there is limited information from randomised controlled trials on the safety and effectiveness of ENDS for smoking cessation and most of these trials evaluated first generation cigalikes. A recent well-conducted trial of a more advanced ENDS device compared to combination nicotine replacement therapy reported superior outcomes for those randomised to the ENDS [33].

ENDS have not been used for long enough, however, to assess any adverse health effects of their long-term use. We only have limited data on the extent of ENDS uptake among non-smoking youth and the impact of ENDS use on the prevalence of cigarette smoking among young people. The paucity of good quality data on these issues makes it difficult to assess the overall public health impact of ENDS use [18].

By contrast, we do have good evidence on the effects of the long term use of another tobacco harm reduction product, namely, low nitrosamine smokeless tobacco or snus. We have good epidemiological evidence that the adverse effects of long-term snus use are substantially less than those of smoked tobacco [34]. There is no evidence that snus has served as a gateway to cigarette smoking and it is also clear that snus has substantially reduced the population prevalence of smoking and not been used by non-smokers in Sweden, where it is widely used [34, 35]. It has also substantially reduced tobacco related diseases such as lung cancer [36]. Despite all this evidence, an Australian ban on the sale of smokeless tobacco products, including snus, introduced in 1991 [37] remains in place and no consideration is being given to its repeal. This suggests that epidemiological studies of long-term duration that demonstrate a health benefit for smokers who switch to ENDS may not be sufficient to change current policy. Abstinence from all nicotine use is seen by some in public health as the only acceptable goal for smokers. For example, the US Food and Drug Administration was quoted as saying "Switching to e-cigarettes does not mean quitting. Quitting means truly ending the addiction to nicotine." [38].

The sales ban on ENDS has been arguably justified by the use of evidential double standards. As noted above, weak observational evidence that ENDS are a gateway to cigarette smoking among youth has been used to justify the sales ban. Similarly, smokers' self-report of their success in quitting "cold turkey" is treated as good evidence that this is the "best way" to quit smoking; evidence from randomised controlled trials showing the superiority of drug assisted quitting to cold turkey is ignored [39].

On the other hand, observational evidence that ENDS have helped smokers to quit is dismissed. For example, survey evidence that access to ENDS has increased smoking cessation rates in the UK and USA, and not so far increased youth smoking rates in either country, is rejected [40–43]. Only evidence from randomised controlled trials is deemed to be acceptable in this case.

Cochrane evidence reviews are selectively cited. A Cochrane review of ENDS for smoking cessation which concluded that the evidence quality was "low" in quality has been used to support a sales ban. Yet a "low" quality grading in a Cochrane review of tobacco plain packaging did not preclude Australia from implementing plain packaging in 2012 [44].

Misuse of the Precautionary Principle

As noted above, a very rudimentary and unspecified form of the precautionary principle has been used to justify Australia's sales ban on ENDS [15, 45]. Supporters of the sales ban argue that public health action is justified in the face of uncertainty if there is reasonable evidence that failing to act will cause harm [46, 47].

No explicit formulation has been given of the precautionary principle by any of the health groups that have invoked it e.g. The Australian Medical Association and The National Health and Medical Research Council. They simply appeal to the need for policy makers to take action to prevent harm in the face of incomplete evidence. There are at least two major problems with the way that this principle has been used to justify the sales ban on ENDS.

First, the precautionary principle (however formulated) has been based on an incomplete risk assessment. Supporters of a sales ban have presented a worst case evaluation of the risks in allowing ENDS to be sold to smokers (namely, long-term harm to their health and a gateway to smoking for non-smoking young people). This analysis did not consider any benefits of allowing ENDS to be sold or any potential adverse effects of imposing a sales ban, such as, the development of a black market that provides unregulated ENDS products, or the denial of adult smokers the right to use these products for smoking cessation or tobacco harm reduction. Dr. Tony Bartone from the Australian Medical Association argued that ENDS would need evidence of "zero harm" before he would recommend them, and that they would need to be 100% less harmful than cigarettes before he would consider them for smokers [48]. This standard is not applied to any consumer products or to medicines, where decision-making is based on weighing up the risks and benefits. Professor Thompson from the Thoracic Society of Australia and New Zealand, stated that it would take 15–20 years for sufficient evidence to become available on ENDS safety [48].

Secondly, the precautionary principle invoked does not justify a sales ban. It could be used to justify some policy responses that minimised the risk of the adverse public health outcomes highlighted by the CDH. It does not justify the most restrictive type of public health policy, namely, a ban on the sale, possession and use of ENDS by adult smokers, when much less restrictive policies could arguably achieve the same goals.

Less Restrictive Alternatives to a Sales Ban

The assumption that a sales ban is justified by the precautionary principle depends on a number of empirically questionable assumptions. These are: (1) that a sales ban on ENDS is the best way to prevent adolescent uptake of ENDS and tobacco smoking; and (2) that a sales ban will not produce more adverse effects than less restrictive regulatory policies that address these concerns.

There are good reasons to question both assumptions. Australian policy makers have not banned the sale of cigarettes to adults in order to prevent adolescent uptake. Adolescent smoking has been effectively reduced in Australia instead by increasing cigarette sales taxes, introducing smoke free policies, reducing the visibility of cigarettes at the point of sale, banning advertising and enforcing age restrictions on cigarette purchase [49]. The same policies towards ENDS would be more ethically acceptable and better respect the interests of smokers than a ban on their sale or use.

We could minimise adolescent access to ENDS by restricting what products can be sold and where they can be sold. This may involve only allowing the sale of ENDS products that meet minimum quality assurance standards for consumer goods (e.g. childproof containers for nicotine, safe storage and handling instructions, and safety standards for batteries). Their sale could be limited to licensed tobacconists or vape shops, and shops that sell adult products. No advertising would be allowed to make claims about health benefits of using these products. The same advertising bans could also be applied as for tobacco products.

The use of ENDS in public places could be banned as an interim measure (under existing smoke free laws) until we have better evidence on the risks that ENDS pose to non-smokers. We could reduce the risk that ENDS would deter quitting by educating smokers about the risks of dual use. This information would make it clear to smokers that ENDS are most likely to reduce harm if and only if (1) they are used to assist smoking cessation or (2) they are used as a complete substitute for cigarettes. The risks of long term dual use of ENDS and cigarettes would be highlighted. Smokers would also be informed of uncertainties about the long-term health risks of using ENDS as an alternative to cigarettes.

These policies could be modified as evidence on the public health impact of ENDS became clearer. If, for example, ENDS proved to be as useful in cessation as their advocates claim, then regulatory policies could be relaxed to maximise public health gains. On the other hand, if evidence emerged that the sale of ENDS produced adverse public health effects, such as increasing smoking prevalence, these policies could be made more restrictive.

If the developing evidence indicates that ENDS are of public health value, then policies could increase smokers' access to alternatives to combustible cigarettes. These alternative products could include re-engineered pharmaceutical nicotine and low nitrosamine smokeless tobacco (SLT). This would require a liberalisation of the regulation of pharmaceutical nicotine (PN) to allow nicotine doses to be achieved similar to those from using smokeless tobacco and ENDS. Smokers who fail to quit smoking using NRT could be encouraged to switch to a lower risk non-therapeutic nicotine product such as SLT or ENDS that provided higher doses of nicotine than current NRT products.

If evidence showed that ENDS substantially reduced smoking and tobacco-related harm, then policy makers could encourage smokers to switch to using lower risk nicotine products by imposing lower rates of tax on them. They could also allow ENDs to compete directly with combustible cigarettes by only allowing ENDS and combustible cigarettes to be sold in a limited range of outlets (e.g. tobacconists, adult only stores).

Conclusions

The Australian ban on the sale, possession and use of ENDS has been poorly justified and it is weakly based in evidence. It is a paternalistic policy because it denies adult smokers access to a less harmful way of obtaining nicotine to use in quit attempts or as a harm reduction product, supposedly to protect their health. A sales ban is an incoherent form of risk management that prevents the sale of a less harmful nicotine product while allowing the sale of cigarettes, the most harmful nicotine product. A sales ban is poorly justified as a policy to prevent Australian youth from initiating smoking when there are other less restrictive policies that could achieve the same goal.

There are legitimate public health concerns raised by the advent of ENDS that justify a precautionary policy response. But this does not require a ban on the sale of ENDS to adult smokers. It would justify regulating ENDS in ways to minimise youth access and restrictions on how ENDS are marketed. These policies would allow the sale of approved ENDS products to adult smokers under restricted conditions that minimise youth access and uptake in much the same ways that have succeeded in reducing youth smoking.

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Compliance with Ethical Standards

Conflicts of Interest The authors have no conflicts of interests.

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