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18.0 Introduction

Harm reduction is an approach within public health that aims to reduce the harmful consequences of drug use, without necessarily eliminating or even reducing consumption. This approach has been successfully and widely adopted within the areas of alcohol and illicit drug use. For example, needle exchange programs are now considered best practice, and have led to reduced rates of infection transmission among injecting drug users. Other examples include opioid substitution therapy with methadone or buprenorphine for heroin dependence, and blood alcohol limits and random breath testing for drivers to reduce harms of alcohol use.

Robust evidence demonstrates that quitting smoking leads to significant health benefits. Large-scale cessation would likely lead to benefits greater than any other public health effort. However, many smokers fail to quit, despite knowledge of the substantial health risks from tobacco use. For these smokers, harm reduction has been proposed as an alternative to what has been termed a ‘quit or die’ strategy, which promotes cessation as the only viable alternative to smoking in order to reduce health risks.

Harm reduction within the framework of tobacco control was first considered in the 1950s, when evidence of the harmfulness of smoking first came to light. For decades, attempts were made to develop cigarettes that were less harmful, such as “light”, “low-tar”, and “low-nicotine” products, which ultimately failed to reduce health risks due to compensatory smoking, and were used deceptively by the tobacco industry to keep smokers smoking. The concept of harm reduction then became salient again in the 1990s, when public health experts proposed a range of regulatory approaches to minimise the enormous harms caused by tobacco. A seminal article by Warner, Slade, and Sweanor suggested that, rather than banning the use of all nicotine delivery products, a more realistic approach might be to discourage use of the most dangerous products (cigarettes), while making less hazardous products readily available to adults. Reducing the addictiveness, rather than harmfulness, of cigarettes was a contrasting approach that was proposed about the same time. A report presented by the American Medical Association (AMA) Council on Scientific Affairs in 1998 recommended that cigarettes be modified to contain less nicotine, and therefore be less addictive. In a 1999 review, Australian researchers floated the idea of a single regulatory framework for tobacco and all other nicotine delivery systems; one that reduced secondhand exposure to tobacco products, reduced the risk of young people becoming addicted to nicotine, and changed the design of existing cigarettes and alternative nicotine products so that they were less harmful and/or addictive. This regulatory approach has also been advocated in the UK, but has not been adopted in either Australia or the UK.

In the context of tobacco control, smokefree laws, which reduce the exposure of non-smokers to secondhand smoke, and mandatory standards for reduced ignition propensity cigarettes, which reduce the risk of fires caused by discarded cigarettes, are examples of harm reduction approaches that have been universally supported and widely adopted. Harm reduction for the individual smoker would be achieved by reducing their exposure to carcinogens and other toxins to the greatest extent possible. For smokers who are unable or unwilling to quit, options to potentially reduce their health risks might include attempts to make cigarettes less harmful—see Section 18.2, or individuals switching to alternative products that may carry fewer risks than traditional cigarettes—see InDepths 18A and 18B.

Some smokers believe they will reduce the risk of harm by switching to products such as cigars, waterpipe tobacco or smokeless tobacco. Cigars may be associated with a lower risk of lung cancer if used infrequently and not inhaled, but, like waterpipes, still pose similar health risks to those associated with smoking cigarettes—see Chapter 3, Section 3.27.
Some types of smokeless tobacco such as low-nitrosamine Swedish snus would appear to be less toxic (see InDepth 18A) and, like dissolvable nicotine products, might be regarded as an ‘alternative nicotine delivery systems’ (ANDS).

Products that have been developed for their tobacco harm reduction potential are frequently referred to as Potential Reduced Exposure Products (PREPs). Examples of PREPs include modified cigarettes that may be less toxic and carcinogenic (see 18.2), and electronic nicotine delivery systems (ENDS) or e-cigarettes, referred to by some marketing commentators now as ‘personal vapourisers’ including ‘cigalikes’ and tank systems (see InDepth 18B). Another harm reduction strategy might be for smokers to reduce the number of cigarettes they consume each day. Unless supported by nicotine replacement products (NRT), this approach has not proved to be feasible in reducing intake of the harmful constituents of tobacco smoke, and consequently is widely discredited as an approach to reducing harm (see 18.3).

Other strategies that can be considered ‘harm reduction’ include chemoprevention (see 18.5) and screening (see 18.6). A contrasting or possibly complementary approach to harm reduction would be to reduce the addictiveness of cigarettes gradually over time; either as a ‘mass weaning’ strategy, or in order to facilitate switching to less harmful tobacco products or cigarette alternatives (see 18.4).

Harm reduction has been a contentious and divisive issue within the tobacco control community. Proponents argue that it is a necessary option for those who are unable to stop using tobacco products, and that substituting cigarettes with lower-risk nicotine or tobacco products offers enormous individual and public health benefits. They argue that failing to provide smokers with accurate information and access to alternative sources of nicotine is unethical, and dissuades smokers from quitting the most harmful method of consuming nicotine—inhaling smoke. An additional argument is that having less harmful alternatives more widely available could provide justification for greater regulation of (and perhaps even eventually a complete phase out of) smoked tobacco.

Opponents believe that the harm reduction approach diverts smokers from the safest option—complete cessation. They argue that prevalence rates have continued to fall using proven effective population based approaches, including making tobacco products expensive, highly regulated, non-advertised, plain packaged, and out of consumers’ sight in retail outlets. Tobacco harm reduction, they argue, may be an ‘unnecessary distraction’ from these strategies. There is also hesitancy in trusting tobacco companies to develop and market a less harmful alternative, given the history of ‘harm reduction’ products ultimately proving to cause enormous harm. For example, the introduction of supposedly safer low tar and filter cigarettes led to greater numbers of smokers, deeper inhalation patterns, and/or higher daily consumption. Continuing use of any smoked tobacco is harmful, with the risk of cardiovascular disease elevated for even low levels of use, thus greatly compromising potential reductions in harm if smokers engage in dual use (of smoked products along with alternative products) instead of complete switching.

The possibility of dual use and the potential for alternative products to act as a gateway to traditional products raises concerns whether harm reduction approaches would ultimately result in a net reduction of harm at the population level. Proponents counter that smokers have a right to information to assist them make the best possible choice about their own health regardless of the wider consequences to public health, and that regulation, such as tighter controls and disincentives to smoke, can be used to minimise this risk.

These issues have led to fierce debates about the most ethical and appropriate way to communicate public health messages regarding the risks and efficacy of potentially harm reducing products, and a lack of consensus about the most appropriate ways to regulate their sale and use.

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18.1 Assessing the harmfulness of tobacco and tobacco-like products

Most diseases caused by tobacco take many years to develop. Real-world effectiveness in reducing harm can be assessed with certainty only after several decades have elapsed. To assess the potential of a product to reduce exposure or harm, reduction in risks to both individuals and populations need to be assessed for all major types of disease, and against an appropriate baseline (i.e., non-smokers, former smokers, current smokers in the context of host susceptibility and previous level of smoke exposure). Measuring constituents of tobacco products and tobacco smoke can provide information on the relative risks to health of tobacco, flavours and additives, and can be used to inform product regulations. At the individual level, exposure to tobacco can be quantified through biomarker measurements. A good deal is known about the toxic and carcinogenic constituents of tobacco products and tobacco smoke, and the mechanisms by which harm is caused to human physiology over many years. Reducing exposure to such constituents, it is argued, should reduce physiological harm; however, so far little is known about the effectiveness of measures designed to regulate toxicants in tobacco products. For a detailed discussion of the constituents of tobacco products in Australia, see chapter 12. For a discussion of proposed regulations, see section 18.2.

18.1.1 Constituents of tobacco products

Tobacco constituents include substances that are naturally present in tobacco, while tobacco ingredients are substances that are added to tobacco during the manufacturing process (i.e., flavours and additives). Although it is the chemicals in cigarette smoke that are responsible for the harmful health effects of smoking, understanding the constituents of the products themselves (before burning) is also important, including the nature of the additives. There are several hundred additives in cigarettes, many of which affect the flavour and smell, and hence the palatability of the product and its tolerability to both smokers and bystanders. Some are also used to raise the pH of the smoke, which increases nicotine absorption and therefore addictive potential.

18.1.2 Constituents of cigarette smoke

Cigarette smoke comprises a highly complex mixture of a vast number of chemicals, many of which are known to be toxic or carcinogenic, and likely many more that have not yet been evaluated. Reducing concentrations of these constituents, which typically have been measured via smoking machines, has been suggested as a method of reducing health risks; however, using these measures to compare the relative harmfulness of cigarettes is problematic. Machine measurement is useful for comparing products and brands under standard conditions, but fails completely in terms of determining actual deliveries to a smoker (for a detailed discussion, see 12.2). Proposed regulations in some jurisdictions would mandate lowering of toxicants in cigarette smoke (see 18.2); however these would also depend on machine measurements, albeit using protocols designed to attempt take into account the ways that consumers smoke (see 12.x for further details). Some experts have suggested that validated tobacco carcinogen and toxicant biomarkers may be a possible solution to the shortcomings of machine measurements (see 18.1.3).

18.1.3 Biomarkers
Biomarkers of tobacco exposure measure the effects of tobacco in a person’s body fluids (including exhaled air) or organs.¹ Exhaled carbon monoxide (CO) is one of the most commonly used biomarkers to quantitate exposure to tobacco smoke because it does not undergo metabolic activation; however, limitations include that non-tobacco sources of exposure such as vehicle exhaust can affect measurements, and that levels can change following physical activity or with the presence of lung disease. Other widely used biomarkers include blood nicotine level and its metabolite cotinine, with cotinine used more frequently due to its longer half-life.⁴ A limitation of cotinine is that it measures exposure to nicotine, rather than the main toxins in tobacco and cannot distinguish between someone who is using a clean form of nicotine (e.g. gum or e-cigarette) and someone who is smoking tobacco.

Biomarkers are affected by inter-individual differences in metabolism,⁴ and it is unlikely that a single biomarker can sufficiently provide all necessary data regarding the effects of tobacco. Rather, a panel of biomarkers that includes biomarkers of exposure, biologically effective dose, and potential harm can provide more comprehensive information. The usefulness of new products in reducing harm should also be tested in people who differ in their susceptibilities (i.e., people who differ in their behaviour, sex, age, genetics, and history of tobacco use).⁴

Carcinogen biomarkers provide an objective measure of carcinogen uptake and metabolic activation and detoxification in people who consume or are exposed to tobacco products, and include DNA adducts, protein adducts and urinary metabolites. Some people more efficiently convert carcinogens to DNA adducts, and may therefore be at higher risk for developing cancer. Carcinogen biomarkers are important in establishing carcinogen dose in people who are exposed to tobacco products and in understanding mechanisms of carcinogenesis, and might ultimately be useful in predicting cancer risk.⁵ For example, a study in 2014 found an association between low levels of the biomarker serum bilirubin and higher risks of lung cancer incidence and mortality in male smokers, suggesting that it is a useful identifier of smokers at higher risk for lung cancer.⁶

Researchers have validated a specific panel of tobacco carcinogen and toxicant biomarkers, which they propose can be applied to product regulation and cancer prevention. They suggest that first, a panel of target biomarker levels can be set based on studies of their relationship with cancer risk. Next, the product constituent levels that correspond to the target biomarker levels in the panel should be determined. Finally, regulations could be developed based on these determined constituent levels.⁷

References


18.2 Regulation to disclose or reduce harm from tobacco products

For smokers who are unable or unwilling to quit, reducing the health risks of tobacco products themselves has been proposed as a pragmatic option. Modification of the cigarette so that the inhaled smoke is less carcinogenic, toxic, and inflammatory might represent a major opportunity for harm reduction.1 This approach was first proposed in the 1970s with, for example, the suggestion of low-tar medium-nicotine cigarettes as a strategy for 'safer smoking'.2 Some public health experts assert that the regulation of potentially reduced exposure products is necessary and feasible, and should be part of comprehensive public health policy toward tobacco. They argue that effective regulation would allow a better understanding of the toxicology and health effects of products, as well as ongoing monitoring of individual and public health risks. Regulation could also ensure that labelling and advertising of products accurately convey risk, or levels of certainty about risks from consumption, allowing more informed choices by consumers and potential reduction of harm. Regulation could also foster clear and consistent policies regarding scientific testing, labelling, and advertising of products.3 Researchers recently suggested that lung cancer risks from smoking may be increasing in the US due to changes in the design of cigarettes since the 1950s, and proposed that regulatory control over cigarette design may therefore reduce health risks from smoking.4,5

In 2003, WHO convened a formal Study Group on Tobacco Product Regulation (TobReg) to examine the scientific basis for regulation. Its 2007 report recommended establishing levels for selected smoke toxicants per milligram of nicotine, as well as banning the importation or sale of products with yields above these levels. Toxicants were chosen based on animal and human toxicity data, hazard indices, variability of the toxicants across brands, the potential for the toxicant to be lowered, inclusion of constituents from both particulate and gas phases of smoke and from different chemical classes in cigarette smoke.6 The TobReg group has suggested that the upper limit for these toxicants should be set at the median level of products presently on the market based on existing data, with regular reviews of these levels.7

The WHO and Scientific Advisory Committee on Tobacco Regulation developed a statement of principles to guide the evaluation of new or modified tobacco products, and concluded that:

1. Existing scientific evidence is not sufficient to assess the differences in health risk potential between newly engineered tobacco products and existing products for composition, exposure, toxicity, or harm.
2. Regulatory oversight of cigarette and cigarette-like products should include examination of at least five separate aspects of the new products: physical chemical characteristics of the tobacco and tobacco smoke, uptake of toxicants (both by smokers and by non-smokers), toxicity, addiction potential, and disease risk.
3. Regulatory oversight of smokeless tobacco products should also include examination of at least five separate aspects of the new products: physical chemical characteristics of the product and its constituents, uptake of toxicants, toxicity, addiction potential, and disease risk.
4. Claims of reduced exposure or reduced harm should be supported by adequate scientific data provided by the manufacturer who intends to make the claim.
5. Each type of claim requires a substantive body of evidence; an independent regulatory body capable of examining the claims should determine whether the claims are valid.
6. No claim should be permitted for any tobacco product unless found to be valid by an independent regulatory body on the basis of adequate scientific data submitted by the manufacturer.
7. Regulatory oversight, including post-market surveillance, is necessary to assess and monitor changes in newly modified tobacco products.
8. Demonstration of reductions in smoke emissions or reduced uptake of toxicants alone is not sufficient to support claims or implications of reduced toxicity or harm.
9. Claims of reductions in smoke emissions or reduced uptake of toxicants need to be examined in post market surveillance to determine what smokers and non-smokers actually understand from those messages.
10. Evidence supporting a reduction in carcinogenicity must be interpreted in light of the potential effects of the changes in the product on the other major diseases caused by cigarette smoking. 8

Although establishing regulations is a slow and complex process, supporters of tobacco product regulation have contended that swift action is needed in the face of a massive epidemic of tobacco-related disease, and to reduce harm to young people taking up smoking. They argued that mandating and widely publicising TobReg’s recommendations would be sufficient, and countries that do not manufacture cigarettes could ban the importation of products that fail to meet the standards. The tobacco industry would be responsible for testing products and providing data, with spot checks that are funded by tobacco taxes ensuring the accuracy of such data. Although international standards would be ideal, given the difficulty of this goal, it is likely that national legislation will be the starting point with the hope that it spreads to other countries. They suggested that countries such as Australia, New Zealand, and Singapore, which have total advertising and promotion bans, might be ideal, as such countries could prohibit any attempts the tobacco industry would likely make at marketing the regulated cigarettes as ‘safer’. 7

In the meantime, Australia became a Party to the WHO Framework Convention on Tobacco Control (FCTC) on February 27, 2005. The FCTC aims to regulate some of the causes of the tobacco epidemic, including trade liberalisation and direct foreign investment, illicit trade, and tobacco advertising, promotion and sponsorship beyond national borders. The FCTC recognises the need for tobacco product regulation, and under Articles 9 and 10, parties will be developing systems to regulate the contents, design and emissions of products and to require reporting on the same from manufacturers. 9 Partial implementation guidelines have been adopted for Articles 9 and 10, with further guidelines for the testing, measuring, and regulation of tobacco smoke constituents to be elaborated on in a step-by-step process. 10 A number of jurisdictions, including the EU, Brazil, South Africa, and Egypt, have implemented limits on tar and nicotine emissions. Other countries requiring regular reporting of tar and nicotine emissions and ingredients include Canada, US, and Hong Kong. 11

For a detailed discussion of the current state of the construction and labelling of Australian cigarettes, see chapter 12.

18.2.1 FDA regulation

In 2009, US President Barack Obama signed into law the Family Smoking Prevention and Tobacco Control Act (FSPTCA) granting the US Food and Drug Administration authority to regulate the manufacture, distribution, and marketing of tobacco products. The FSPTCA aims to provide basic consumer protections and to promote public health and safety from the harmful effects of tobacco products. 12

Among its many provisions, the Act established requirements for tobacco product ingredient submissions. Section 904(a)(1) of the Act requires each tobacco product manufacturer or importer to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and sub-brand. For tobacco products on the market as of June 22, 2009, the list of ingredients had to be submitted by December 22, 2009. For tobacco products not on the market as of June 22, 2009, section 904(c)(1) requires that the list of ingredients be submitted at least 90 days prior to delivery for introduction into interstate commerce. The act also requires submission of information whenever any additive, or the quantity of any additive, is changed. 13 In March 2012, the FDA issued draft guidance on reporting harmful and potentially harmful constituents in tobacco products and tobacco smoke constituents in tobacco products, with the criteria that they are a carcinogen, toxicant, or addictive. The FDA intends to publically display the list of constituents by brand and by quantity in each brand and sub-brand, in a format “that is understandable and not misleading to a lay person.” 14

The Act also prohibits tobacco companies from making reduced harm claims such as ‘light,’ ‘low,’ or ‘mild,’ without filing an application for a modified risk tobacco product and obtaining an order to market as such, and bans cigarettes with characterising flavours (such as fruit, candy, and clove), except menthol and tobacco. 15 Effective August 8th 2016, the FDA extended its regulatory authority to all tobacco products, including e-cigarettes, cigars, and hookah and pipe tobacco. These products are therefore now subject to each of the above requirements. 15

A national survey in the US in 2014–15 examined perceptions of tobacco constituents and FDA regulation. Over one-quarter of adults, and over one-third of smokers, reported having looked for information about tobacco constituents in cigarette smoke; however, the vast majority had little awareness of the actual constituents. More than half of respondents indicated that they would like relevant information to be available on cigarette packs, while just over one-quarter preferred to access that information online. Two-thirds felt that the FDA can effectively regulate tobacco products. 16
In 2001, the European Union (EU) established maximum yield limits for cigarettes for tar (10mg), nicotine (1mg) and carbon monoxide (10mg). In April 2014, the EU adopted a revision of the Tobacco Products Directive (TPD), which regulates the manufacture, presentation, and sale of tobacco products, and aims to homogenise approaches to tobacco regulation across the 28 EU member states. The revision states that the maximum emission limits remain valid, and also highlights that it could be necessary and appropriate at a later date to reduce the emission levels for tar, nicotine and carbon monoxide, or to establish maximum levels for other emissions from tobacco products, taking into consideration their toxicity or addictiveness.

The TPD has also specified minimum rules and regulations regarding:

- Health warnings. Combined graphic and text health warnings must cover 65% of the front, back and top of pack.
- Ingredients. Mandatory reporting on ingredients is now required for all tobacco products through a standardised electronic format.
- Flavourings. Flavourings in cigarettes and RYO tobacco products that give the product a ‘characterising’ flavour other than tobacco are banned (e.g. candy, alcohol, vanilla, fruit, spice, herbs), including menthol from 2020.
- Snus. Remains illegal in all Member States except Sweden.
- Packaging. Cigarette packs are to be a cuboid shape and contain at least 20 cigarettes per pack, with no promotional or misleading messages.
- Cross-border sales. Cross border distance sales will not be banned at EU-level, but member states may choose to ban such sales.
- E-cigarettes. E-cigarettes will be regulated as consumer products if containing 20mg/mL or less of nicotine unless the manufacturer chooses to make therapeutic claims, in which case they will be required to seek a medicinal licence.
- Illicit trade. An EU-wide tracking and tracing system for the legal supply chain will be introduced.

The introduction of this directive was fiercely opposed by the tobacco industry, which spent enormous amounts of time and money attempting to delay and amend the TPD. In particular, the proposed introduction of plain packaging, an ingredients ban, and a point-of-sale display ban faced high levels of resistance. Philip Morris International alone employed more than 160 lobbyists, and spent millions trying to subvert the TPD. Though ultimately it was successfully adopted, these attempts by the tobacco industry resulted in delays to implementation and some weakening (e.g., two provisions were removed: plain packaging and a retail display ban).

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A strategy often adopted by smokers who are trying to reduce their risk of adverse health outcomes is cutting down on the number of cigarettes smoked each day. The validity of this approach as a strategy for reducing harm is drawn from large amounts of research showing a dose–response relationship between level of consumption and health risks; that is, the association between smoking and many diseases becomes stronger with more cigarettes smoked each day. However, despite this relationship, the evidence does not support cutting down as an effective method to alleviate risk. One explanation for this lack of risk reduction is compensation: smokers who cut down tend to take more and deeper puffs from each cigarette, and smoke more of it. In turn, there is a much smaller proportional reduction in intake of nicotine, tar, and other toxins than the amount of cutting down might predict. Further, the relationship between exposure to tobacco smoke and harm is not linear. For example, a low level of tobacco exposure (4–7 cigarettes per day) has about 70% of the effect of heavy smoking (at least 23 cigarettes per day) on risk for cardiovascular disease. A longitudinal study of health outcomes in light smokers found that smoking 1–4 cigarettes per day was associated with a significantly higher risk of dying from ischaemic heart disease and from all causes, and from lung cancer in women. Light smoking women were five times more likely and men three times more likely to develop lung cancer compared with non-smokers.

A 2007 systematic review that examined the health effects of reducing smoking found a small health benefit following a substantial reduction in smoking, but concluded that further studies are needed to determine any long-term effects. A Korean study found no association between smoking reduction and all cancer risk except for a significant reduction in risk of lung cancer, but the reduction in risk was disproportionate to the reduction in consumption, and smaller than expected. Other studies have found no evidence that smoking reduction is an effective means of reducing mortality risk.

The primary benefit of cutting down seems to be its role as a step toward quitting, although this may be a less effective strategy than going ‘cold turkey’. A 2015 review exploring the usefulness of cutting down determined that smokers who reduce the number of daily cigarettes smoked are more likely to attempt and actually achieve smoking cessation, particularly when combined with NRT. It should also be noted that the existing epidemiological evidence on cutting down providing no health benefit is generally in the context of no additional source of nicotine, such as NRT or e-cigarettes. Obtaining nicotine from an alternative source may reduce some of the compensatory smoking behaviour that would otherwise limit the benefit from cutting down. Studies of smokers cutting down while using NRT have found that while blood nicotine levels generally remain stable or slightly higher, carbon monoxide readings decreased. This has led some to advocate concomitant use of NRT while smoking as a harm reduction strategy. Evidence suggests that use of NRT to ‘cut down to quit’ is effective and cost effective compared to no quit attempt, but data on the health risks/benefits of long-term dual use of NRT and cigarettes are lacking.

References


18.4 Low nicotine – nicotine reduction

It is well established that addiction to nicotine maintains most smokers’ use of tobacco products. Once addicted, quitting can be extremely difficult, with many smokers repeatedly relapsing following their cessation attempts. Young people have a very poor understanding of addiction, often believing that they will be able to stop smoking at will. However, once they take up smoking, the nicotine addiction sustains the behaviour into adulthood, dramatically increasing their risk of tobacco-related harm.

The regulation of the level of nicotine in tobacco products has been suggested as a potential strategy for avoiding the transition from experimental smoking to addiction. Reducing the nicotine content in cigarettes so that they are non-addictive could prevent adolescents and occasional smokers from becoming addicted. A gradual reduction could also allow smokers to slowly decrease their intake of nicotine, thereby weaning themselves off the product and making quitting substantially easier. Unlike ‘low tar and light’ cigarettes promoted by tobacco companies, which did not actually reduce delivery of tar and instead involved design features that allowed smokers to easily compensate for the reduced nicotine content by drawing harder (see section 12.4), reduced nicotine cigarettes could be manufactured the same as regular cigarettes except with tobacco that has a lower nicotine content. If the nicotine content was low enough, it would be virtually impossible to absorb significant levels of nicotine by using these products. Research comparing gradual with immediate nicotine reduction in cigarettes found that neither led to compensatory smoking, while both strategies reduced levels of cotinine. However, another trial of gradually reducing the nicotine content of cigarettes found no long-term benefit for level of dependence or cessation among a sample of smokers who were not interested in quitting. A larger randomised trial found that, among another sample of adult smokers with no interest in quitting, abrupt switching to reduced-nicotine cigarettes versus standard-nicotine cigarettes for six weeks reduced nicotine exposure and dependence and the number of cigarettes smoked.

Developing low-nicotine cigarettes has been a prominent approach in considerations of tobacco endgame strategies; it is endorsed by the American Medical Association, the British Medical Association, the US Food and Drug Administration (FDA) and the US Surgeon-General, and is also supported within the WHO Framework Convention on Tobacco Control. The approach more broadly calls for research, government regulation, gradual reduction, consumer education, and increased availability of lower-risk options, in order to combat addiction and eliminate gateway risks. Health Canada issued a tender in 2016 calling for research into the possibility of forcing tobacco companies to make their cigarettes less addictive. The FDA included in its 2009 tobacco law the authority to reduce nicotine, potentially advancing the possibility of low-nicotine cigarettes. However, critics of the approach have argued that it may not be practicable within the confines of FDA law. Or, if it is, it may take many years to implement, and would require mandatory low nicotine content to succeed. They contend that resources would be better allocated to more pleasurable and likely less harmful forms of nicotine use, such as vaping and snus. Alternatively, others have suggested a combination of these strategies; that is, reducing the nicotine content of smoked tobacco products while allowing non-combustible recreational nicotine products to be sold.

References


18.5 Chemoprevention of tobacco–related disease

The global incidence of cancer has been steadily increasing over time, and with its high personal, social, and healthcare costs, researchers have increasingly focused their efforts on prevention.1 The identification of risk factors including tobacco, obesity, family history, sedentary lifestyle, viruses, and sun exposure have prompted the development of strategies that might hinder the carcinogenic pathway.2 One such approach is chemoprevention, which is the use of natural, synthetic (made in a laboratory), or biologic (from a living source) substances to reverse, suppress, prevent, or delay the development of cancer.1 An improved understanding of the biology of carcinogenesis along with the identification of potential molecular targets that can disrupt this process has led to a marked increase in attention to this approach.1 Chemoprevention may target a variety of steps in tumour initiation, promotion and progression. Compounds that prevent cancer initiation are traditionally termed ‘blocking agents’. Once initiation has happened, chemopreventive agents that may hinder the promotion and progression of initiated cells are often called ‘suppressing agents’.1

Positive outcomes have been shown for the chemoprevention of a number of cancers, such as breast, prostate and colon cancer, and as at 2011 in the US there were 10 FDA-approved agents for the treatment of precancerous lesions or cancer risk reduction. For example, the HPV vaccine has been approved to reduce the risk of cervical cancer; cervical precancerous lesions, vulvovaginal cancer, and anal cancer and its precursor lesions. There are also many more published clinical trials in the literature that have reported positive results, but most have not received regulatory approvals.2

The vast majority of lung cancers are caused by smoking, with current smokers and even those who have successfully quit being at high risk. In light of the high mortality and suffering caused by lung cancer, chemoprevention of lung carcinogenesis has been suggested as a way forward.3 To date, no agent has been identified as effective in those at high risk for lung cancer. Two large chemoprevention trials have evaluated the effects of beta-carotene on the prevention of lung cancer, but both resulted in higher rates of lung cancer and lung cancer mortality in participants treated.2 Some researchers have suggested that the target for chemoprevention should be tobacco smoke carcinogens and toxicants, the cause of lung cancer in smokers and ex-smokers.3 Others have suggested focusing on former smokers in chemoprevention trials, due to current smokers’ great risk of many other tobacco-related diseases that may mask any potential benefits of the approach.4

References


Screening is used to promote the early detection of cancer. Australia currently has three national cancer screening programs: BreastScreen, which recruits and scans women aged 50–74 for early signs of breast cancer; the National Bowel Cancer Screening Program, which offers people over the age of 50 a free screening test that tests for blood in the bowel movement and can be undertaken in their own home; and The National Cervical Screening Program, which recommends regular pap tests for women aged between 18 and 70. There is considerable interest, both in Australia and internationally, in the potential for population based screening using low-dose CT scans to detect nodules that might be lung cancer early, when it is still treatable. Research has suggested that annual spiral CT screening can detect lung cancer that is curable. The largest study performed to date, the US National Lung Cancer Screening Trial (NLST), showed a 20% reduction in lung cancer mortality after screening high risk individuals (heavy smokers) using low dose computed tomography, leading to recommendations that support screening in the US. A number of expert reviews have concluded that while annual screening of individuals at a substantially elevated risk of lung cancer may be a promising way forward, there is still too much uncertainty for large-scale population-based implementation. They have suggested that further investigation is needed in the areas of: over-diagnosis and false positives; weighing up the potential benefits versus harm; at risk population to screen; frequency and duration of screening; the most appropriate diagnostic work-up of screen detected abnormalities; and implications for public policy. A similar conclusion has been reached in Australia, where decisions regarding screening programs are guided by criteria set out in the Population Based Screening Framework. Due to screening having the potential to cause both harms and benefits, high-level evidence is required prior to the establishment of a screening program. Potential harms include the financial costs of the program and personal costs to the person such as anxiety, discomfort, adverse effects, follow-up investigations, over-diagnosis and possible treatment (which can carry its own risks). Among high-risk Australians, research has shown that there is high willingness for lung cancer screening and surgical treatment. However, Australian researchers have argued that national lung screening is likely to strain health care expenditure, and that the cost of systematic screening may be equivalent to the annual expenditure on all lung cancer care. They suggest that a more cost- and outcome-effective method of reducing mortality is smoking cessation programs. The Standing Committee on Screening concluded that further evidence is needed before a national lung cancer screening program might be considered for implementation in Australia.

References


18A.1 Forms of smokeless tobacco and how they are regulated

Smokeless tobacco refers to tobacco products that are consumed by means other than smoking/burning, and can be used nasally or orally. Common forms of smokeless tobacco include:

- Snuff, which is finely ground tobacco that can be purchased moist or dry. It is available loose, in dissolvable lozenges or strips, or in tea bag-like sachets. Moist snuff, or ‘snus’, is placed between the user’s cheek and gums or behind the upper or lower lip allowing nicotine to be absorbed through the oral mucous membranes.2 Dry snuff can be inhaled into the nose.3

- Chewing tobacco, which consists of shredded tobacco in the form of loose leaves, plugs (bricks), or twists of rope. A piece of tobacco is placed between the cheek and lower lip, usually toward the back of the mouth, and can be chewed or held in place.4

Oral tobacco was briefly marketed in Australia during the 1980s, however all smokeless tobacco products were subsequently banned in several states during the late 1980s. A permanent federal ban on the manufacture, importation and commercial supply of the products came into effect in June 1991,4 although consumers are able to privately import up to 1.5 kilograms of smokeless tobacco into Australia.5 In mid-2006 there was a significant increase in taxation on these products, from $2.30/kg to $300.39/kg,6 taking the customs duty into line with that in all other tobacco products.

This regulatory framework allows current users to access smokeless tobacco, while discouraging uptake by non-tobacco users (especially young people).7 Some health experts advocate wider availability of smokeless tobacco, arguing that these products have the potential to reduce tobacco-related disease, and that it is nonsensical that the most harmful form of tobacco product (cigarettes) is subject to far fewer restrictions. Reducing taxes and allowing commercial importation and supply could potentially promote reduced harm among smokers who switch to smokeless products.8,9 Others are more wary, citing potential for dual use (i.e., the use of smokeless products in smokefree areas) and concern that the tobacco industry may use covert advertising techniques to promote uptake by young people.10

References


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18A.2 Prevalence of use of smokeless tobacco in Australia

The prevalence of use of smokeless tobacco varies widely across countries and regions, with particularly high rates of consumption in some areas of South-East Asia. For example, in Bangladesh and India, levels of use of smokeless tobacco surpass cigarette smoking. In Sweden, use of smokeless tobacco is also common, and in 2010 was about 10 times higher than the rest of Europe. In contrast, use of these products in Australia is very low; results from the 2013 National Drug Strategy Household Survey showed that only 0.3 – 0.4% of Australians aged 14 years or older reported using chewing tobacco, snus, or snuff in the past 12 months. However, prevalence of use among some minority groups is much higher. A 2014 survey of South Asian residents in Sydney found rates of having ever used smokeless tobacco products, using it more than 100 times, and current use at 72.1%, 65.9% and 17.1%, respectively. Chewing tobacco is also used in some Indigenous communities, particularly in Central Australia. Aboriginal Australians may chew commercially available tobaccos mixed with ash from certain trees, or native tobaccos (pituri). Tobacco chewing among the Australian Indigenous population is discussed in greater detail in Chapter 8, Section 5.3.

References


18A.3 Health effects of various forms of smokeless tobacco

The health effects of using smokeless tobacco, and the wider public health impact, are a source of debate among the tobacco control community and healthcare professionals. Many smokeless tobacco products contain high concentrations of nicotine and deliver comparable daily systemic doses to those obtained from cigarette smoking, therefore use of smokeless tobacco can be as addictive as smoking cigarettes. Treatment of addiction to smokeless tobacco has proven difficult, with clinical trials of pharmacotherapies often suggesting ineffectiveness; though, a trial of varenicline in smokeless tobacco users has shown promise, with participants reporting high cessation rates.

Smokeless tobacco also contains a number of known carcinogens, with levels varying based on product characteristics including tobacco type, additives, alkalinity, and processing methods. Exclusive smokeless tobacco users can be exposed to even higher levels of nicotine and toxicants than exclusive cigarette smokers. Plant materials such as areca nut or tonka bean, along with other additives, are frequently present in smokeless tobacco products and may also be carcinogenic and have other detrimental health outcomes.

A 2014 report by the National Cancer Institute and Centers for Disease Control and Prevention summarised the available evidence on the health effects of use of smokeless tobacco, drawing the following conclusions:

- The associations between smokeless tobacco use and adverse health effects differ by type of product.
- Smokeless tobacco products cause addiction, precancerous oral lesions, and cancer of the oral cavity, oesophagus, and pancreas, as well as adverse reproductive developmental effects including stillbirth, pre-term birth, and low birth weight.
- The evidence suggests that some, but not all, smokeless tobacco products are associated with increased risk of fatal ischemic heart disease, fatal stroke, and type 2 diabetes; more studies are needed to clarify any causal associations.
- There is insufficient evidence to assess whether smokeless tobacco products are associated with increased risks of lung cancer, cervical cancer, and hypertension.

A 2016 systematic review and meta-analysis similarly concluded that there is an association between ever use of smokeless tobacco and risk of fatal ischaemic heart disease and stroke. Another 2016 systematic review and meta-analysis—this time exclusively of studies in India, which faces the largest burden of smokeless tobacco-attributable health effects—found significant associations between smokeless tobacco use and oral, pharyngeal, laryngeal, oesophageal, and stomach cancers. It has been estimated that globally in 2010, smokeless tobacco use led to 1.7 million years of healthy life lost and 62,283 deaths due to cancers of mouth, pharynx and oesophagus, as well as 4.7 million years of healthy life lost and 204,309 deaths from ischaemic heart disease. Over 85% of this burden was in South-East Asia.

The smokeless tobacco products that are most relevant to the harm reduction debate are those that have been produced to be relatively low in toxins, such as carcinogenic nitrosamines. For example, studies of health effects of using Swedish snus—a product with relatively low nitrosamine levels—have found an increased risk of pancreatic and, possibly, esophageal cancer but not of oral or other cancers. This risk of pancreatic cancer associated with use of smokeless tobacco is significantly lower than that associated with cigarette smoking. Similarly, most studies in
Sweden show little or no increased risk of cardiovascular disease in snus users\textsuperscript{14, 15} and markedly lower rates of lung cancer as a total population compared with other countries. These findings have often formed the basis of arguments for the wider availability of snus as a method of harm reduction; i.e., as a substitute for cigarettes for smokers who are unable to stop using nicotine.\textsuperscript{1}

It is also important to note that—in comparison with the extensive research linking smoking with adverse health outcomes—evidence on the health effects of smokeless tobacco is far less comprehensive. Information on dose–response relationships, prevalence estimates, and confounding variables is often sparse, while the novelty of some products may not allow for a full understanding of long-term risks. Comprehensive monitoring of use of smokeless tobacco and its short- and long-term effects on health outcomes are required, particularly in regions with high prevalence.\textsuperscript{4}

References


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18A.4 Snus as a potential harm reduction strategy

18A.4.1 The ‘Swedish experience’

Sweden has a similar prevalence of tobacco use to its neighbours, but one of the world’s lowest tobacco-attributable mortality rates. Some observers have suggested this phenomenon, known as ‘the Swedish experience’ is explained by the increasing use of smokeless tobacco, a trend that has corresponded with a decline in smoking prevalence, particularly among Swedish men who are the greatest users of smokeless tobacco. However, this interpretation has been debated. The most common form of smokeless tobacco used in Sweden is a moist oral snuff called snus, which is available either as loose tobacco or pre-packaged portions that resemble teabags. Unlike other smokeless tobacco products marketed in the US and other countries, snus is pasteurised rather than fermented and stored under refrigeration to minimise bacterial growth. These processes greatly reduce the formation of nitrosamines, the main carcinogens in tobacco. This, and the absence of the combustion products associated with smoking (e.g. carbon monoxide, small particulate matter) reduces the risks of cardiovascular disease, chronic obstructive pulmonary disease and cancer compared to smoking. Unlike cigarettes, snus does not produce secondhand smoke or carry a risk of causing accidental fires.

Long-term prospective cohort studies have observed a lower risk of many tobacco-related diseases and overall lower mortality in snus users compared to smokers. A recent study measured changes in biomarkers, representing toxicants commonly associated with tobacco-related morbidity and mortality, in cigarette smokers who switched to smokeless tobacco products (Camel Snus, Sticks, Strips or Orbs). After 5 days, substantial reductions of most biomarkers, including nicotine, were observed, and toxicant exposures were similar to being tobacco abstinent.

Compared to no tobacco use, use of snus does appear to carry some residual risks, albeit lower than for smoking, of pancreatic cancer, and cardiovascular disease. Snus use is also associated with dental disease and gum lesions, called leukoplakia, but these appear to disappear on discontinuation of use. Past studies suggested an association between snus use and diabetes, however a recent study in Sweden found no such increased risk among users.

In Sweden, among people who have ever smoked regularly, those who use snus are more likely to have quit smoking than those who do not. A similar relationship is also seen in Norway among currently daily and former snus users. In the past few decades, the market share for snus has increased by over 20% and cigarette consumption has decreased at a comparable level, with snus the most commonly cited cessation aid. When Finland joined the EU in 1995, it was subject to a ban on oral tobacco products and smoking rates subsequently increased, leading researchers to conclude that the availability of snus was associated with lower rates of smoking prevalence. The Swedish experience has prompted some researchers to suggest that smokers who are unable to quit should use low nitrosamine smokeless tobacco products such as snus to reduce tobacco-related harm. This proposal is contentious.

Some health professionals do not feel that the existing epidemiological studies showing a lower risk of tobacco-related disease in snus users are sufficient to support snus use as a harm reduction strategy. Others are concerned that the difference in potential harm between snus and smoking has not been fully described in existing studies. Some believe that any health risk from snus, no matter how small, is too great for its use to be encouraged. However, the difference in healthy life expectancy and overall mortality risk between smokers who quit all tobacco and smokers who
switch to low nitrosamine smokeless forms appears to be small.\textsuperscript{28, 29} Sweden has also achieved substantial reductions in tobacco-attributable mortality despite a high prevalence of use of snus among men.

18A.4.2 Cultural adaptability

Snus has been used extensively for many decades in Sweden, where it was known as ‘the poor man’s luxury’. Whether the Swedish experience would transfer to Australia, which has never had a significant smokeless tobacco tradition, is uncertain. A growing smokeless tobacco market in Australia during the 1980s was halted by the introduction of a commercial sales ban in 1991, but it is unknown whether these products would have become widespread without the ban.\textsuperscript{30} A survey of Australian smokers in 2008 found that about half were interested in purchasing low-nitrosamine varieties of smokeless tobacco.\textsuperscript{31} However, the survey participants were only provided with pictures and written descriptions of the products rather than samples to try, and most had no previous experience of using smokeless tobacco. In contrast only 13% of smokers in a Californian survey stated they would probably or definitely switch to smokeless tobacco if they thought it was less harmful than smoking.\textsuperscript{32}

There are also behavioural aspects of smoking that may not be adequately replaced by snus use. For example, smoking offers something to do with the hands and is easy to do while engaging in other social activities such as drinking and talking. Snus is simply placed under the top lip and left there until it is removed. Talking and drinking while using snus requires more skill than smoking to keep the tobacco portion in place. The small bulge visible in the upper lip during snus use may also lack the supposed glamour of smoking.

18A.4.3 Ethical issues

Low nitrosamine smokeless tobacco products are not harmless and can be as addictive as smoking.\textsuperscript{33} Many health professionals feel it is unethical to promote the use of a substance that offers no direct benefit to the user (the indirect benefit is the absence of smoking), is addictive, and still carries risks. Proponents of tobacco harm reduction with smokeless tobacco counter that it is unethical to deny smokers access to products with substantially lower risks than smoking and to deny them accurate information about the benefits of switching to them, particularly as cigarettes, the most harmful tobacco product, are readily available.\textsuperscript{34}

Opponents argue that quitting all tobacco use is the only health advice that doesn’t carry any risk. Proponents argue that many smokers fail to follow this advice and that ‘quit’ or ‘keep smoking’, sometimes described as ‘quit or die’, should not be the only options available.\textsuperscript{35} While it is debatable whether health professionals should recommend low nitrosamine smokeless tobacco products to smokers, it is arguably unethical to provide inaccurate information about the relative harms of these products and cigarettes due to the mistrust such misinformation can create.\textsuperscript{36, 37} This may be further confounded by a lack of understanding of relative harms; a survey of GPs in Sweden and the US found that they erroneously ranked nicotine above smoke and tobacco in terms of health risks.\textsuperscript{38}

The lower harmfulness of low nitrosamine smokeless tobacco compared to cigarettes is likely to be an important motivator for smokers to switch products. For example, in a survey of Australian smokeless tobacco users, just over half stated they used smokeless tobacco because it was less harmful than smoking\textsuperscript{30} and users of non-cigarette tobacco products are more likely to believe they are less harmful than cigarettes than non-users.\textsuperscript{39-41} Surveys of smokers in Australia, Canada, the UK and the US suggest that few smokers believe that smokeless tobacco is less harmful than cigarettes.\textsuperscript{39, 42} Misperceptions about the relative harmfulness of smokeless tobacco products compared to cigarettes could be an important barrier to smokers switching to these less-harmful products. The challenge is avoiding messages that products such as snus are ‘less harmful’ being misinterpreted as meaning that they are ‘harmless’.

18A.4.3 Individual and population level harm

Using low nitrosamine smokeless tobacco products may reduce tobacco-related disease in individual smokers who make the switch, but widespread use could still result in population level harm in a number of ways. Firstly, if these products proved more popular among non-smokers than smokers, then overall harm could increase. Secondly, their promotion could keep current smokers smoking (instead of quitting) or lead some non-smokers to commence smoking. This is the most likely way in which smokeless tobacco promotion could produce population harm because the large difference in health risk between smoking and use of low nitrosamine smokeless tobacco means that a very large number of non-smokers need to use these products to offset the health gain achieved from a smoker switching to them.\textsuperscript{25, 43} In Sweden, snus use very rarely leads to smoking in non-smokers,\textsuperscript{2} although dual use is relatively common among adolescents who smoke in Sweden\textsuperscript{44} and Finland.\textsuperscript{45} It is unknown whether similar patterns of use would occur in Australia.
Tobacco manufacturers have argued that they should be able to market and promote reduced harm smokeless tobacco products in order to inform smokers of the benefits of switching. This is an important issue because if these products are to have a population-level benefit, a sufficient number of smokers need to make the switch. However, promotion of smokeless tobacco via tobacco industry advertising may increase overall tobacco use, possibly including smoking among current non-smokers. Some cigarette manufacturers have also produced ‘snus versions’ of their most popular brands of cigarettes.\textsuperscript{46} Allowing these products to be promoted for tobacco harm reduction would simultaneously facilitate the promotion of the corresponding cigarette brand.

In April 2015, an FDA advisory panel voted against the smokeless tobacco manufacturer Swedish Match’s application to change the warning labels on snus. Swedish Match sought to remove the warnings stating that snus causes mouth cancer, gum disease and tooth loss, arguing that there isn’t sufficient scientific evidence to support them. It also wanted the new warning to read: ‘No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes.’ Although the panel was split on certain issues, it ultimately disagreed with Swedish Match’s claims, voting that the proposed label fails to adequately communicate the potential health risks from using snus.\textsuperscript{47}

In countries where tobacco advertising is allowed, cigarette manufacturers have promoted dual use of smokeless and smoked tobacco products as a way to get around public smoking bans.\textsuperscript{48} Such ‘dual use’ could reduce or even negate any health benefit from snus use by deterring quitting. Public smoking bans not only protect non-smokers from environmental tobacco smoke, but have the added benefit of encouraging smokers to quit due to the inconvenience these bans produce. Some of these quitters may therefore be encouraged to keep smoking as they can get through the inconvenient times with a short-term alternative.\textsuperscript{49}

In Norway, while current daily or former snus use is associated with quitting smoking, current occasional snus use is not.\textsuperscript{21} This may be evidence of a specific pattern of dual use that deters quitting smoking. Alternatively, these dual users may be in a process of gradually moving from one product to another or of quitting all tobacco use. In the US and Sweden, dual use of smoked and smokeless tobacco is uncommon and does not appear to be a stable pattern of tobacco use.\textsuperscript{50, 51} Some harm reduction advocates have suggested that dual use is not necessarily a negative if it encourages smokers to try smokeless tobacco and leads to some switching completely. Indeed, epidemiological evidence (albeit with some limitations) has suggested that dual use of snus and cigarettes might increase smoking quit rates.\textsuperscript{52, 53} Clearly, addressing the need to inform inveterate smokers of the benefits of switching to low nitrosamine smokeless tobacco without deterring would-be quitters or encouraging smoking in non-smokers requires careful regulation of information to avoid these potential negative consequences.

18A.4.4 An unnecessary distraction?

Some tobacco control professionals view tobacco harm reduction with smokeless tobacco as a distraction from the main task of encouraging smokers to quit tobacco use and discouraging uptake.\textsuperscript{25} Tobacco smoking, they point out, has declined in Australia without these products. Supporters of harm reduction argue that it offers an additional strategy that may hasten the decline in smoking and may reach those smokers who have been resistant to traditional tobacco control strategies or have been unable to quit tobacco use despite repeated efforts.\textsuperscript{31, 54}

18A.4.5 How does smokeless tobacco compare to nicotine replacement therapy?

Long-term use of nicotine replacement therapy (NRT) products, such as gum, lozenges or inhalers, has also been suggested as an alternative to smoking. Because these present lower risk than smokeless tobacco, it has been argued that there is no need for smokeless tobacco products as a harm reduction alternative.

This argument ignores the possibility that smokeless tobacco may be more attractive to smokers than NRT. Smokeless tobacco is a purely recreational tobacco product that can deliver nicotine in similar amounts to the user as smoking. It may, therefore, be a better substitute for cigarettes for smokers who want to continue using tobacco recreationally. NRT is also primarily marketed as a medicine for short-term assistance during cessation. Currently available NRT products are low dose, which prevents them from providing a sufficient ‘buzz’ for smokers who want to use nicotine recreationally. Higher dose, recreational, ‘clean’ nicotine products face substantial regulatory barriers because of their addictiveness. Australia’s drugs and poisons regulatory system also does not provide for nicotine to be sold for recreational use, unless it is contained within tobacco intended for smoking.\textsuperscript{55} Pharmaceutical companies, who manufacture NRT, are unlikely to see the marketing of a recreational, addictive product as their core business. Pharmaceutical companies may also be concerned that long-term use of high-dose nicotine products may carry a higher health risk than short-term use of low-dose NRT, which has been established as safe.

In 2010, former smokers in Sweden were significantly more likely to use smokeless tobacco than never smokers.\textsuperscript{56} In Sweden and Norway, snus is a more popular smoking cessation aid than NRT gum or patches and smokers who use
snus are more likely to quit than smokers who use NRT. Among the possible reasons for this greater popularity and higher success rate are the social acceptance of snus use in Sweden, its lower cost (before 2007, snus was taxed at a lower rate than cigarettes), the higher nicotine delivery from snus compared to NRT, and possibly longer use of snus after quitting compared to NRT. Using NRT to quit smoking may also be stigmatised by some smokers who see the use of a medication to quit as a sign of drug addiction. Snus, which is not a medication, may be seen as a ‘smarter choice’ rather than a sign of weakness. As uptake of NRT in Australia remains relatively low, a product that may be more attractive to smokers and more effective, even if marginally riskier, could increase the number of quitters and therefore produce a greater population level benefit.

Smokeless tobacco products appear to be less effective at reducing withdrawal symptoms than cigarettes. However, some small-scale trials suggest that smokers may prefer moist oral snuff over NRT and that snuff reduces cigarette cravings more than NRT. There is also some evidence from population surveys that switching to smokeless tobacco may be more effective than using NRT. A small clinical trial found that smokers who were given smokeless tobacco products reduced their cigarette intake and increased their interest in quitting smoking compared to those who were not given these products.

When presented with a range of hypothetical policy options, a sample of Australian smokers stated they would be more likely to quit if smokeless tobacco were made less expensive than cigarettes and if there were a substantial price increase on cigarettes, than if there were a cigarette price increase alone. The option of switching to smokeless tobacco appeared most attractive to those who were resistant to quitting rather than those who indicated they would quit with just a price increase. These results suggest that a lower tax on smokeless tobacco compared to smoked tobacco could produce a greater reduction in the number of smokers than simply increasing cigarette taxes. Similarly, a Californian survey found that smokers with greater intentions of quitting were less likely to be interested in switching to smokeless tobacco, but smokers who were trying to cut down their cigarette intake and smokers who had made unsuccessful quit attempts were more likely to be interested in switching to smokeless tobacco. However, a recent study comparing snus and NRT found that US-marketed snus performed similarly to nicotine gum in cigarette smokers who were interested in completely switching to these products, but was associated with greater toxicant exposure and less satisfaction than nicotine gum. The authors suggest that the harm reduction effects observed in Sweden may have limited generalisability to other countries.

Another clinical trial in the US compared abstinence outcomes among smokers who were randomised to receive free samples of snus versus not. Overall, wide-scale provision of snus to smokers not ready to quit resulted in minimal uptake, and appeared to undermine quit attempts. There were no differences between groups on abstinence. However, the small number of participants who became regular users of snus were more likely to try and succeed in quitting. RJ Reynolds Tobacco reportedly carried out a randomised control trial in 2009–14 comparing Camel Snus to Nicorette NRT for cessation, but the results appear to not have been published. Researchers have called for release of the findings.

Overall, more research is needed to determine whether the option of using smokeless tobacco translates to fewer smokers without detrimental effects on quitting.

18A.4.6 What should the public health response be?

The epidemiological evidence and the Swedish experience suggest that low nitrosamine smokeless tobacco may be an important tobacco harm reduction opportunity. With uncertainty about its potential effect on other tobacco control policies, most Australian commentators have been cautious about such proposals.

References


Electronic cigarettes (e-cigarettes) provide users with aerosolised nicotine for inhalation. These devices usually comprise a battery to heat an element that vapourises a solution, typically containing nicotine, propylene glycol or glycerine, and flavourings, which is held in a cartridge/tank in the device. Users of e-cigarettes, or ‘vapers’, breathe in the aerosol. The action of inhalation and exhalation mimics the use of conventional cigarettes, and provides some of the same cues or sensory effects such as hand to mouth action, taste and throat rasp. Many e-cigarettes are designed to look like traditional tobacco products, such as cigarettes, cigars, cigarillos, and pipes. Others more closely resemble other everyday items such as pens, USB memory sticks, and larger cylindrical or rectangular devices. E-cigarettes are also commonly referred to in the literature as electronic nicotine delivery devices (ENDs), alternative nicotine delivery devices (ANDs), and personal vapourisers (PVs). E-cigarettes that do not contain nicotine but deliver a flavoured aerosol (commonly fruit, confectionary, tobacco, or other food and drink flavours) are also available.

There is ongoing debate within the public health community as to whether e-cigarettes have a potential role in smoking cessation; whether use of e-cigarettes can reduce harm for individual users; whether widespread use of the devices has the potential to reduce or increase population-level harm; and how best to regulate e-cigarettes to minimise both individual and population-level harm. Producing nicotine aerosol from a solution rather than by burning tobacco gives rise to fewer harmful substances than cigarette smoke does to users and non-users, but the long-term effects of e-cigarette use are not known. Because of the likely lesser health risks associated with vaping, some experts advocate wider availability and softer regulation, and see e-cigarettes as holding great potential to help smokers quit or switch to a harm-reducing way to consume nicotine. Others call for the application of the ‘precautionary principle’ in public health, and argue that it is not sound public health policy to allow e-cigarettes onto the market until such time as robust evidence is available supporting the safety of e-cigarettes and their efficacy in reducing harm. They cite the addictiveness of nicotine, and the potential for harm from ongoing use of e-cigarettes compared with complete cessation of all nicotine and tobacco products. There are also concerns that e-cigarettes will be used in combination with tobacco products (‘dual use’), or that ex-smokers will re-initiate their nicotine addiction or return to smoking, particularly if exposed to glamorous e-cigarette advertising. Other serious issues include the possibilities that e-cigarette use might promote nicotine use among non-smokers, especially children; serve to renormalise smoking; or serve as a gateway to the use of combustible cigarettes or illicit drugs.

For a background and overview of harm reduction as an approach within public health and tobacco control, see Section 18.0

References


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18B.1 Development of products

Although the concept of an electronic cigarette was first patented in the USA in 1965,\(^1\) it was not until 2003 that the first commercialised e-cigarette product was developed in China.\(^2\) E-cigarettes generally comprise four parts: the battery, the heating element, the vapourising chamber, and the solution cartridge. The battery supplies the power to the heating element, in order for it to become sufficiently warm to aerosolise the solution. The heating element is housed in a chamber, which also holds the aerosol until the user inhales. Some types of e-cigarettes allow users to control the voltage so they can select the amount of aerosol produced and nicotine concentration.\(^3\)

There are a growing number of varieties of e-cigarettes and solutions, with evidence of large variability between the labelled content and the actual content and concentrations.\(^4\) Differences in battery voltage and unit circuitry can create significant variances in the products’ ability to aerosolise the solution, and consequently the amount of nicotine and other constituents delivered to the user. Individual user behaviour, such as the length, depth, and frequency of puffs might also affect nicotine absorption. Users can also modify many of the products, allowing them to alter delivery of nicotine and/or other drugs.\(^5\)

In 2014, the market for e-cigarettes globally was estimated to be worth six billion US dollars.\(^6\)

18B.1.1 Start-up companies

Historically, the e-cigarette market was highly fragmented and largely dominated by small start-up companies.\(^7\) This is changing with large manufacturers and big tobacco companies entering the market (see section 18B.1.2, below); in 2014, approximately 70% of the market in the US reportedly belonged to 10 companies.\(^8\) The number of companies is increasing. A comprehensive search of English-language websites in 2014 found that there were 466 brands of e-cigarettes with their own websites and 7,764 unique flavours. It is estimated that 30–50% of sales of global e-cigarettes are conducted online.\(^9\)

18B.1.2 Major international companies

Although initially slow to enter the market, the major international tobacco companies have invested heavily in e-cigarettes in recent years. Acquisitions and investments by the tobacco industry in the past few years include the following:\(^7\)

- In December 2012 British American Tobacco (BAT) acquired CN Creative, a start-up that developed the Intellicig e-cigarette and ECOpure eliquid brands. It went on to launch the Vype brand in August 2013. Vype is now marketed by Nicoventures, a BAT subsidiary.
- Lorillard, the third-largest cigarette manufacturer in the US, acquired the e-cigarette company blu eCigs for a reported $135 million in 2012. It also acquired Skycig, a leading brand of e-cigarettes in Britain, for $48.5 million, allowing it to enter the UK market. Skycig then became blu eCigs in May 2014, with the support of a £20 million marketing campaign. When RJ Reynolds acquired Lorillard in 2014, Imperial Tobacco purchased its blu line to avoid antitrust concerns that RJ Reynolds owning both Vuse and blu would give it an unfair advantage in the market.
Japan Tobacco International (JTI) acquired UK e-cigarette brand Elites in June 2014 from previous owner Zandera. JTI also invested in the start-up Ploom in 2011, and agreed to commercialise its vapourisers outside the USA. In February 2015, JTI acquired the patents and trademarks from Ploom Inc., allowing it to develop new products and markets.

Fontem Ventures (a subsidiary of Imperial Tobacco) acquired Dragonite in August 2013, which was previously owned by the Chinese pharmacist who invented the modern e-cigarette. In early 2014, Imperial presented its own e-cigarette called Puritane. Imperial also purchased the blu e-cigs line as part of the merger between Reynolds and Lorillard in 2014. In February 2015, Imperial announced the launch of its new e-cigarette, Jai, in France and Italy.

Philip Morris International (PMI) announced in December 2013 that it was joining with Altria to market e-cigarettes and other ‘reduced risk’ tobacco products. PMI gained the right to exclusively sell Altria’s e-cigarettes outside the US. In 2014, PMI acquired UK-based Nicocigs, the owner of the Nicolites brand, claiming that it would provide immediate entry to the UK market for these and any other e-cigarette products.

Altria, which owns Philip Morris USA and controls about one half of all cartons sold in America, launched its e-cigarette ‘MarkTen’ in 2013. In 2014, Altria also acquired the e-cigarette manufacturer Green Smoke.

Reynolds American launched its e-cigarette ‘Vuse’ through its subsidiary RJ Reynolds Vapor Company in 2013.

References


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18B.2 Development of markets

18B.2.1 Lobbying for favourable regulation

The introduction of increasingly strict regulations on e-cigarettes has led to fierce lobbying, both in favour of and against proposed new laws. Smaller e-cigarette companies have tended to fight new restrictions, while big tobacco companies have pushed for a range of controls on e-cigarettes, including detailed health warnings (e.g., the health warning on a MarkTen electronic cigarette package is 116 words long), reduced product ranges, restricted sales, and onerous and costly testing requirements. The tobacco companies argue that these restrictions will ensure product safety, but others have suggested that the industry’s support for the laws comes from a desire to maintain dominance and minimise competition. Strict regulations might give large companies an advantage in the e-cigarette market, as they are much more likely than small start-up companies to have the resources to go through potentially lengthy and expensive approval processes.\(^1\)\(^,\)\(^2\) For example, RJ Reynolds, the owner of Vuse, submitted a 119-page document to the US Food and Drug Administration (FDA) arguing for a ban on products with ‘tanks’ that users can fill themselves, as it claims the liquid cannot be safely regulated. Its own disposable products come pre-loaded with the cartridge. However, outright banning of refillable products would be likely to wipe out many smaller companies that are independent of the tobacco industry as they are the primary manufacturers of modifiable devices. It has also been argued that the FDA’s proposed new rules favour the tobacco industry’s products, as the process to gain approval for a new product is time-consuming and expensive.\(^3\)\(^,\)\(^4\)

Similarly, several commentators have claimed that the initial move to classify e-cigarettes as medicinal products under early drafts of the EU Tobacco Products Directive (since changed, see 18B.9) was influenced by lobbyists from both the pharmaceutical and tobacco industries.\(^5\) GlaxoSmithKline, one of the major providers of pharmaceutical smoking cessation aids and thus a competitor of e-cigarettes, has lobbied vigorously for stringent e-cigarette regulation in the EU.\(^6\) Johnson & Johnson, which markets the Nicorette line of products, expressed strong support for regulating all non-tobacco nicotine products, including e-cigarettes, as medicines.\(^7\) Tobacco and e-cigarette lobbyists reportedly sent gifts and offers of hospitality to members of the European Parliament. While the extent to which these were accepted is not known, all member states are signatory to article 5.3 of the World Health Organization’s Framework Convention on Tobacco Control, which obliges parties to protect the processes of development and implementation of tobacco control policies from interference by the tobacco industry and associated interests.\(^5\)

E-cigarette users have also attempted to fight regulations. For example, there were two candidates in the UK’s general election in March 2015 for the ‘Vapers in Power’ party, which was established to campaign against EU rules on the sale of electronic cigarettes.\(^8\)

18B.2.2 Promotion

The increasing popularity of e-cigarettes has been largely attributed to aggressive promotion over the Internet.\(^9\) Even prior to major promotion by tobacco companies, one study found that a large proportion of people in the US were aware of the existence of e-cigarettes, naming television, word of mouth, and the internet as their top three sources of information.\(^10\) Between 2009 and 2010, awareness doubled from 16.4% to 32.2%.\(^11\)
Revenue spent on advertising of e-cigarettes in the US is estimated to have trebled between 2011 and 2012 (from $US6.4 million to $18.3 million) and reached $88.1 million in 2014.12 Almost 40% of this expenditure was attributed to Altria's promotion of Markten.13 Other research has shown that between 2011 and 2013, exposure to television advertisements for e-cigarettes increased among US youth (aged 12-17) by 256%, and in young adults (aged 18-24) by 321%.14

The advertising of e-cigarettes is frequently aimed at smokers, often comparing electronic and tobacco cigarettes. E-cigarettes are frequently marketed online as healthier, cheaper, more socially acceptable, and more amenable to use with indoor smoking restrictions in comparison with tobacco cigarettes. Despite mixed evidence on their efficacy for this purpose, they are also frequently marketed as a useful cessation aid.15 A study of smokers' reactions to such advertising has found that smokers' interest in trying e-cigarettes is highest after viewing ads with messages about differences between regular and electronic cigarettes, such as claims about e-cigarettes' lower cost, greater 'healthfulness' and utility for smoking cessation, as well as when they see advertisements showing someone actually using the product.16

An analysis of print advertisements in the US found that the advertisements typically implied use for harm reduction, or as a partial alternative to cigarettes (dual use) and often incorporated the theme of individuality, sociability, and sexuality. Particular demographics were targeted depending on the publication; for example, a blu ad in Rolling Stone magazine showed a shirtless man lying in bed next to an overweight, semi-naked woman with the words 'no regrets' boldly highlighted. In contrast, a blu ad in Us Weekly showed a stylish, attractive woman with the text: 'Freedom never goes out of fashion… blu produces no tobacco smoke and no ash, only vapor, making it the ultimate accessory….Step out in style with blu.'17

References


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18B.3 Extent of use

The National Drug Strategy Household Survey asked respondents about e-cigarettes for the first time in 2013: detailed characteristics e-cigarette usage among Australians 14 years and over are set out in table 18B.3.1.

Table 18B.3.1
E-cigarette use by demographics and smoking status, 2013

<table>
<thead>
<tr>
<th>Total population aged 14+</th>
<th>Used e-cigarettes in last 12 months</th>
<th>Used, but not in last 12 months</th>
<th>Never used e-cigarettes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3.2%</td>
<td>1.2%</td>
<td>95.5%</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>4.0%</td>
<td>1.5%</td>
<td>94.6%</td>
</tr>
<tr>
<td>Female</td>
<td>2.5%</td>
<td>1.0%</td>
<td>96.5%</td>
</tr>
<tr>
<td>Age group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14–17 years</td>
<td>4.3%</td>
<td>1.7%</td>
<td>94.0%</td>
</tr>
<tr>
<td>18–24 years</td>
<td>7.3%</td>
<td>2.2%</td>
<td>90.5%</td>
</tr>
<tr>
<td>25–29 years</td>
<td>5.4%</td>
<td>2.6%</td>
<td>92.0%</td>
</tr>
<tr>
<td>30–39 years</td>
<td>3.8%</td>
<td>1.3%</td>
<td>94.9%</td>
</tr>
<tr>
<td>40–59 years</td>
<td>2.3%</td>
<td>0.8%</td>
<td>96.9%</td>
</tr>
<tr>
<td>60+ years</td>
<td>0.9%</td>
<td>0.6%</td>
<td>98.6%</td>
</tr>
<tr>
<td>Socioeconomic status*</td>
<td>Low SES</td>
<td>3.9%</td>
<td>1.2%</td>
</tr>
<tr>
<td></td>
<td>Mid SES</td>
<td>3.0%</td>
<td>1.2%</td>
</tr>
<tr>
<td></td>
<td>High SES</td>
<td>2.6%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Smoking status</td>
<td>Daily smoker</td>
<td>15.3%</td>
<td>4.0%</td>
</tr>
<tr>
<td></td>
<td>Weekly smoker</td>
<td>14.7%</td>
<td>4.0%</td>
</tr>
<tr>
<td></td>
<td>Less than weekly smoker</td>
<td>10.7%</td>
<td>4.0%</td>
</tr>
<tr>
<td></td>
<td>Ex-smoker</td>
<td>1.8%</td>
<td>1.2%</td>
</tr>
<tr>
<td></td>
<td>Never smoker (&lt;100 cigs)</td>
<td>0.8%</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

Source: Centre for Behavioural Research in Cancer analysis of 2013 National Drug Strategy Household Survey data.¹

* From Index of social disadvantage of place of residence

About 3.2% of the general population aged 14 and over reported using e-cigarettes in the past twelve months, with 1.2% reporting having ever used e-cigarettes but not in the last 12 months. At 7.3%, past-year use was highest among young adults aged between 18 and 24 years. Having used an e-cigarette in the previous year, and ever use of e-cigarettes was much more common among smokers than non-smokers. Fewer than 1% of never-smokers reported having used e-cigarettes at least once in the last 12 months, compared with 15.3% of Australians 14 years and over who were daily smokers.
Demographics, smoking characteristics, and cessation history of current smokers aged 18 and over who have used an e-cigarette are presented in table 18B.3.2.

<table>
<thead>
<tr>
<th>Current smokers* aged 18+</th>
<th>Using e-cigarettes in last 12 months</th>
<th>Used, but not in last 12 months</th>
<th>Never used e-cigarettes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>14.4%</td>
<td>4.1%</td>
<td>81.5%</td>
</tr>
<tr>
<td>Female</td>
<td>13.6%</td>
<td>3.5%</td>
<td>82.9%</td>
</tr>
<tr>
<td><strong>Age group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–24 years</td>
<td>27.1%</td>
<td>3.7%</td>
<td>69.2%</td>
</tr>
<tr>
<td>25–29 years</td>
<td>18.0%</td>
<td>8.0%</td>
<td>74.0%</td>
</tr>
<tr>
<td>30–39 years</td>
<td>14.4%</td>
<td>4.9%</td>
<td>80.7%</td>
</tr>
<tr>
<td>40–59 years</td>
<td>10.2%</td>
<td>2.5%</td>
<td>87.3%</td>
</tr>
<tr>
<td>60+ years</td>
<td>6.7%</td>
<td>2.2%</td>
<td>91.2%</td>
</tr>
<tr>
<td><strong>Socioeconomic status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low SES</td>
<td>14.9%</td>
<td>3.2%</td>
<td>81.9%</td>
</tr>
<tr>
<td>Mid SES</td>
<td>12.6%</td>
<td>4.2%</td>
<td>83.3%</td>
</tr>
<tr>
<td>High SES</td>
<td>15.7%</td>
<td>5.0%</td>
<td>79.3%</td>
</tr>
<tr>
<td><strong>Type of tobacco smoked</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factory-made cigarettes (FMC) only</td>
<td>13.2%</td>
<td>3.5%</td>
<td>83.3%</td>
</tr>
<tr>
<td>Roll-your-own (RYO) only</td>
<td>15.1%</td>
<td>3.0%</td>
<td>81.9%</td>
</tr>
<tr>
<td>FMC and RYO</td>
<td>18.4%</td>
<td>6.0%</td>
<td>75.5%</td>
</tr>
<tr>
<td>Neither FMC or RYO</td>
<td>8.2%</td>
<td>1.6%</td>
<td>90.2%</td>
</tr>
<tr>
<td><strong>Cigarettes per day</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fewer than 10 per day</td>
<td>13.9%</td>
<td>3.8%</td>
<td>82.4%</td>
</tr>
<tr>
<td>10–20 per day</td>
<td>13.5%</td>
<td>4.0%</td>
<td>82.5%</td>
</tr>
<tr>
<td>More than 20 per day</td>
<td>16.3%</td>
<td>4.1%</td>
<td>79.6%</td>
</tr>
<tr>
<td><strong>Intention to quit tobacco cigarettes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 30 days</td>
<td>21.4%</td>
<td>3.6%</td>
<td>75.0%</td>
</tr>
<tr>
<td>Within 30 days–3 months</td>
<td>16.4%</td>
<td>3.8%</td>
<td>79.8%</td>
</tr>
<tr>
<td>Yes, but not within 3 months</td>
<td>14.3%</td>
<td>3.8%</td>
<td>82.0%</td>
</tr>
<tr>
<td>Not planning to quit</td>
<td>12.0%</td>
<td>3.7%</td>
<td>84.3%</td>
</tr>
<tr>
<td><strong>Attempted to quit in past 12 months</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not attempt to quit</td>
<td>11.6%</td>
<td>4.2%</td>
<td>84.1%</td>
</tr>
<tr>
<td>Quit for 1+ month</td>
<td>12.3%</td>
<td>2.7%</td>
<td>85.0%</td>
</tr>
<tr>
<td>Unsuccessfully tried to quit</td>
<td>20.6%</td>
<td>3.6%</td>
<td>75.8%</td>
</tr>
<tr>
<td><strong>Attempted to reduce consumption in past 12 months</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not reduce consumption</td>
<td>12.7%</td>
<td>3.5%</td>
<td>83.8%</td>
</tr>
<tr>
<td>Reduced consumption</td>
<td>14.6%</td>
<td>4.3%</td>
<td>81.1%</td>
</tr>
<tr>
<td><strong>Attempted to switch to lower tar/nicotine brand</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not switch brands</td>
<td>13.8%</td>
<td>3.8%</td>
<td>82.4%</td>
</tr>
<tr>
<td>Successfully switched</td>
<td>19.3%</td>
<td>3.8%</td>
<td>76.9%</td>
</tr>
<tr>
<td>Unsuccessfully tried to switch</td>
<td>22.4%</td>
<td>5.2%</td>
<td>72.4%</td>
</tr>
</tbody>
</table>
More than 14% of current smokers aged 18 or older reported using an e-cigarette in the last year, and younger smokers were more likely to have used an e-cigarette than older smokers (27.1% for those aged 18–24 compared with 6.7% for those over 60). Recent e-cigarette use among male smokers tended to be slightly higher than females smokers. Different rates of use among groups with varying smoking behaviours are difficult to interpret from this cross-sectional survey. For instance, the higher rates of use among those who had unsuccessfully tried to quit or cut down may be a result of higher levels of addiction among such smokers compared to those who had successfully quit or reduced consumption.

Data from the International Tobacco Control policy evaluation study reported slightly higher rates of use among Australian smokers and recent quitters interviewed in 2013. Approximately 24% of current cigarette smokers and 16% of recent quitters said that they had ever tried e-cigarettes; 9% of current cigarette smokers and 2% of recent quitters reported currently using them (with current use defined as any use of e-cigarettes, ranging from daily to less than monthly). A more recent study undertaken in NSW in 2014–15 found a prevalence of use of 9%. Users were more likely to be aged 18–29, and were more likely to be current smokers.

International Tobacco Control Surveys data show wide variation between countries surveyed, which may be attributable to a range of factors, including but not solely differences in regulatory approaches. Current use of e-cigarettes among adult never-smokers appears to be much less common than among smokers, with reported prevalence of less than 1% in the UK, Australia and the US. In some countries the use of e-cigarettes is growing, with the majority of users being current smokers. Between 2010 and 2013 in the US, current e-cigarette use (use in the past 30 days) among adults increased from 1.0% to 2.6% and over the same time period, current usage among smokers increased from 4.9% to 9.4%. A more recent US adult survey suggests that this upward trend has continued, finding that in 2014, about 3.7% of adults were current users (using e-cigarettes every day or on some days). Among these current e-cigarette users, 15.9% were current cigarette smokers (using 22% were recent former smokers, 2.3% were long-term former smokers and 0.4% had never smoked cigarettes.

In the UK, overall use of e-cigarettes remained has remained stable since 2013, with 5.6% of adults reporting use in 2016. Use among smokers, recent ex-smokers, and long-term ex-smokers has grown, with 13.3% of daily smokers reporting e-cigarette use. The majority of e-cigarette users were dual users. Among European Union member countries, ever-use in 2012 ranged from 7.9% of smokers in Slovakia to more than 36.3% in Denmark. In the EU in 2014, ever-e-cigarette use was reported by 31.1% of current smokers, 10.8% of former smokers, and 2.3% of never smokers.

Awareness of and experimentation by children and adolescents also appear to be growing in some countries, and it is of note that experimentation with e-cigarettes may be more common among non-smoking youth than non-smoking adults. National data from the US show that use of e-cigarettes in the last 30 days among high-school students increased from 1.5% in 2011 to 13.4% in 2014 and the number of never-smokers who had ever used an e-cigarette more than trebled over that time (although still comprised fewer than one per cent of never smokers). Results from 2015 similarly showed that e-cigarette use continued to grow among middle and high school students, with 16% of students reporting current use. Between 2011 and 2013, use appeared to be increasingly characterised by current rather than experimental use. In the US state of Florida, prevalence of use of e-cigarettes trebled between 2011 and 2014 by which time 20.5% of high school students had used e-cigarettes, with 10.8% reporting use in the last month.

Among 11–18-year-olds in the UK, ever use of e-cigarettes increased from 4.6% in 2013 to 12.7% in 2015. Approximately 4% of adolescent never-smokers had tried e-cigarettes in 2015, up from 2% in 2014. Regular sustained use of e-cigarettes among young people in the UK appears to be rare—in 2014, 1.7% of adolescents reporting using cigarettes once a month or more, while in 2015, 2.4% of respondents used e-cigarettes once a month or more, with 0.5% using them weekly.

In New Zealand, ever use of e-cigarettes among teenagers tripled from 7% in 2012 to 20% in 2014. In the large Canadian province of Ontario in 2015, 12% of high school students reported using e-cigarettes in the past year. In Poland, ever-use and current use of e-cigarettes in teenagers aged 15-19 increased from 16% and 5.5% respectively in 2010-2014, to 62% and 30% in 2013-2014. Current use of e-cigarettes (use in past 30 days) in teenagers aged 15-19 increased from 5.5% in 2010–11 to 29.9% in 2013–14. In 2015, 54% of French 16-year-olds had tried e-cigarettes, and 20% of those who experimented with e-cigarettes had never tried tobacco cigarettes.
References


18B.4 Public perceptions of products

Current and former smokers surveyed in 2010–11 in the US, UK, Australia, and Canada indicated that e-cigarette users were predominantly smokers, the majority of whom perceived the products as less harmful than tobacco cigarettes, and as helpful in their attempts at smoking reduction or cessation.\(^1\) (Refer Section 18B.6 for findings of research on efficacy for smoking cessation.) Survey research in NSW found that the most common reasons for using e-cigarettes among smokers over 30 was “to help me quit” and to “cut down” smoking; for younger adults it was “because they are not as bad for your health as cigarettes”.\(^2\) An analysis of Australian and UK data from the 2013 International Tobacco Control Four-Country project found that, consistent with the country’s less stringent regulations, smokers and recent ex-smokers in the UK were more likely to perceive e-cigarettes as less harmful than cigarettes, compared to those in Australia.\(^3\)

A study of smokers in the US found that they viewed e-cigarette use as less likely to cause lung cancer, oral cancer, or heart disease compared to smoking regular cigarettes. By contrast with consumer views on e-cigarettes, other tobacco products, such as smokeless tobacco and snus, were viewed as more likely to cause oral cancer than smoking cigarettes but less likely to cause lung cancer. The authors suggest that these perceptions might help explain the rapid growth in e-cigarette use among smokers.\(^4\) A systematic review of the perceived effects of e-cigarettes by users similarly found that most users perceive they are less harmful to health than traditional cigarettes, and one reason for use is smoking cessation.\(^5\)

Nonetheless, perceptions of harm appear to be increasing. Research in the EU found that between 2012 and 2014, the perception that e-cigarettes are harmful increased from 27.1% to 51.6%, although there were major differences between member states.\(^6\) An online poll in the US similarly found that about half of respondents said vaping was not healthier than smoking conventional cigarettes in 2016, compared with 38 percent in the 2015 poll. The proportion of people who did not think vaping could help people quit, that thought vaping was addictive, and that vape was comparable to secondhand smoke also increased.\(^7\)

References


Due to the recency of their introduction to the market, there are no controlled studies on the safety of long-term use of e-cigarettes; however, since e-cigarettes do not generate the smoke that is produced by burning tobacco, their use is generally accepted as likely to be less harmful than smoking conventional cigarettes.\(^1\)\(^-\)\(^3\) Immediate short term adverse effects of exposure to e-cigarettes are usually mild and transient, and may include nausea, vomiting, mouth and airway irritation, chest pain, and palpitations.\(^4\)

E-cigarettes deliver nicotine by creating an aerosol of ultrafine particles, but due to the variability and chemical complexity of fine particles and uncertainty regarding the specific components responsible for toxicity, it is unknown whether e-cigarettes have health effects and toxicity similar to the ambient fine particles generated by conventional cigarette smoke or secondhand smoke.\(^5\) This uncertainty is further confounded by the lack of regulation and manufacturing standards, leading to potentially harmful and widely varying ingredients, and significant inconsistency between the labelled content and the actual content and concentrations.\(^6\) It has become apparent in Australia that some e-cigarettes which are claimed to be free of nicotine, do in fact contain the substance.\(^7\)

A 2016 systematic review of available studies on the health risks of using e-cigarettes concluded that such studies are limited, and findings to date are inconsistent. Limited results suggest use may have the potential to contribute to non-carcinogenic health risks.\(^9\)

### 18B5.1 Nicotine addiction

Nicotine is among the most addictive of substances known.\(^10\),\(^11\) While some research suggests that e-cigarettes may be no more addictive than nicotine gum,\(^12\) other research has found that in the hands of experienced users, e-cigarettes may deliver systemic nicotine concentrations in a similar range to,\(^13\) or even in excess of,\(^14\) those delivered by combustible cigarettes.

Nicotine addiction is discussed further in Chapter 6 - Addiction.

### 18B5.2 Nicotine toxicity

The nicotine content of e-cigarettes typically ranges between 0 and 34mg/mL;\(^13\) although several studies have reported discrepancies between labelled and measured nicotine content.\(^15\),\(^16\) At high enough doses, nicotine has acute toxicity.\(^17\) Vaping is unlikely to cause nicotine overdose or intoxication, since the amount consumed and absorbed is quite low and comparable to smoking.\(^18\)\(^-\)\(^20\) However, some e-liquid cartridges contain nicotine doses that are potentially toxic in adults and children if used in ways other than intended.\(^21\) In recent years there have been increasing numbers of calls to poison information centres due to unintended ingestion of the e-liquid,\(^22\),\(^23\) particularly by children,\(^24\)\(^-\)\(^26\) with a baby in the US\(^27\) and a toddler in Israel\(^28\) reportedly dying after drinking from an e-cigarette refill bottle. There have also been limited reports of intentional intoxication by injection and ingestion and a small number of suicide attempts.
associated with the cartridges. E-cigarettes may also leak, presenting a hazard as nicotine can be absorbed through the skin.

For further information, refer to Chapter 6, section 2.

18B.5.3 Nicotine exposure in pregnancy

Nicotine adversely affects maternal and foetal health during pregnancy, contributing poor outcomes including preterm delivery, still birth, neonatal apnoea, and sudden infant death syndrome. Nicotine exposure during pregnancy also has lasting adverse consequences for brain and lung development. There is currently no clinical knowledge of the efficacy and safety of e-cigarette use in pregnancy, but no amount of nicotine is known to be safe during pregnancy. The US Surgeon General notes that ‘the evidence is already sufficient to provide appropriately cautious messages to pregnant women and women of reproductive age... about the use of nicotine-containing products such as smokeless tobacco and electronic cigarettes, and newer forms of nicotine-containing tobacco products, as alternatives to smoking.

18B.5.4 Nicotine exposure in adolescence

There is evidence that adolescents who are exposed to nicotine may become addicted more rapidly, and at lower or more intermittent levels of consumption than adults. Evidence suggests that nicotine exposure during adolescence, a time during which the brain undergoes rapid development, may have a long-term negative impact on higher cognitive function. The US Surgeon General notes that ‘the evidence is already sufficient to provide appropriately cautious messages to ... adolescents about the use of nicotine-containing products such as smokeless tobacco and electronic cigarettes, and newer forms of nicotine-containing tobacco products, as alternatives to smoking.

18B.5.5 E-cigarette use and possible cardiovascular disease risk

Conflicting findings have been reported about the potential health effects of e-cigarette use on the cardiovascular system. A 2016 review of the evidence regarding the cardiovascular effects of e-cigarettes concluded that the current body of research is limited and short-term, with a lack of high-quality studies and adequate follow-up. Some evidence suggests that e-cigarettes have sympathomimetic effects (i.e., mimicking the action of the sympathetic system) related to nicotine exposure. Limited data suggests that vascular injury may be another concern. Another review suggested that, given the non-linear relationship between smoking and cardiovascular mortality (i.e., even light smoking can cause significant cardiovascular health effects), reductions in exposure to certain constituents (such as carbonyls and nicotine) through switching from tobacco to e-cigarettes may not result in proportional harm reduction. Overall, existing evidence is limited and further research is needed to establish the cardiovascular risks of using e-cigarettes long-term.

18B.5.6 E-cigarette use and possible cancer risk

The effects of long-term e-cigarette use on cancer risk are unknown. Small amounts of formaldehyde and acetaldehyde, both established carcinogens, have been detected in e-cigarette cartridges. In June 2016, the Australian Competition and Consumer Commission commenced action in the Federal court against two online e-cigarette retailers, alleging that their products contained carcinogens and toxic chemicals including formaldehyde, acetaldehyde and acrolein. Aerosol produced from some products has also been found to contain traces of carcinogenic nitrosamines, and some toxic metals such as cadmium, nickel and lead. However, the carcinogen levels were nine to 450 times lower than those found in conventional tobacco products. A study commissioned by the US Food and Drug Administration in 2009 also detected carcinogens diethylene glycol and nitrosamines at very low levels. Some recent studies have suggested that newer products with higher voltage capabilities might produce the same or even higher levels of carcinogenic formaldehyde than tobacco smoke, but their findings have been challenged.

In terms of nicotine exposure, the US Surgeon General’s most recent report concluded that there is insufficient data to conclude that nicotine causes or contributes to cancer. However, the International Agency for Research on Cancer Advisory Group has recommended that nicotine’s potential as a carcinogen be reassessed as a matter of high priority, because of increased population exposure to nicotine from e-cigarettes, and recent mechanistic data that ‘suggest an association with DNA damage and other pathways of carcinogenesis.' Overall, although levels of carcinogens are
significantly lower than tobacco cigarettes, regular e-cigarette use over many years is likely to result in some level of harm. Further research is needed to quantify this risk.\textsuperscript{51}

18B.5.7 E-cigarette use and possible respiratory disease risk

Other than nicotine, the main ingredient in e-cigarettes is propylene glycol, which is generally considered to be safe for human consumption if swallowed. However, it has not been tested in the manner that e-cigarette use involves; that is, repeated inhalation over a long period of time.\textsuperscript{51} Frequent exposure to fine and ultrafine particles, such as tobacco smoke, air pollution, and dusts, can contribute to pulmonary and systemic inflammatory processes and increase the risk of cardiovascular and lung diseases.\textsuperscript{5} The thresholds for human toxicity of potential toxicants in e-cigarette vapour are so far unknown.\textsuperscript{5} There have been rare reports of exposure causing irritation to the upper and lower respiratory tract mucosa.\textsuperscript{52} The level of emissions of compounds such as formaldehyde, acetaldehyde, and acrolein appears to increase with the temperature and age (i.e., number of uses) of the device, and for single-coil vs. double-coil e-cigarettes.\textsuperscript{53} E-cigarettes have been implicated in individual case reports of exogenous lipoid pneumonia, bronchiolitis, acute eosinophilic pneumonia, pneumonia with bilateral pleural effusions, and inhalation injury and suspected acute hypersensitivity pneumonia.\textsuperscript{40} A recent study in mice suggested that chronic inhalation of nicotine-containing e-cigarette liquid could promote the development of obstructive airways disease.\textsuperscript{54}

Researchers have also raised concerns regarding the potential harm of inhaled flavourings used in e-cigarettes on the respiratory system.\textsuperscript{55-58} They suggest that respiratory toxins in the more than 7,000 unique flavourings might pose a threat to the respiratory health of users, particularly as the flavours have primarily been tested in regard to ingestion, rather than inhalation.\textsuperscript{56} A 2015 study found that the concentrations of some flavour chemicals in e-cigarette fluids are sufficiently high for inhalation exposure by vaping to be of toxicological concern. The authors suggest that regulatory limits should be considered for levels of some of the more worrisome chemicals as well as for total flavour chemical levels, and that ingredients should be labelled.\textsuperscript{59}

18B.5.8 Exposure to second-hand vapour

An additional concern regarding the use of e-cigarettes is bystanders’ exposure to second-hand vapour (as exhaled by the user), particularly if the products are used indoors. Several reviews have concluded that e-cigarettes do emit toxicants; however, these emissions are markedly lower than those from conventional cigarettes.\textsuperscript{60, 61} The most recent systematic review has reported that exhaled e-cigarette vapour can contain emissions at a level which affects indoor air quality, including nicotine, particulate matter, glycerine, propylene glycol, formaldehyde, acetaldehyde, polycyclic aromatic hydrocarbons (PAHs) and metals, but mostly to a lesser extent than combustible tobacco products. The authors conclude that while the health impacts of exposure to second-hand vapour are likely to be less than the impact of combustible tobacco, e-cigarettes do have the capacity to produce environmental pollutants, and in sufficient quantities to potentially harm health. Long term studies on the health effects of exposure to second-hand vapour do not yet exist; nor studies on how vapour might impact on the health of vulnerable populations, including children, pregnant women, and people with chronic lung or heart disease.\textsuperscript{52}

18B.5.9 Explosions and fires

A number of fires have been attributed to e-cigarettes.\textsuperscript{1} These have resulted in several burn injuries, some particularly serious when devices exploded in users’ mouths.\textsuperscript{53} A man was reportedly killed in late 2014 when a charging e-cigarette exploded and ignited his oxygen equipment.\textsuperscript{64} Following several fires, in 2015 the International Civil Aviation Organization prohibited airplane passengers and crew from carrying e-cigarettes and other battery-powered portable electronic smoking devices in checked baggage, and from recharging the devices in aircraft cabins.\textsuperscript{65}

Most of the reported explosions have occurred due to lithium-ion battery failure when the device was charging, largely due to the use of non-approved power adaptors. Although many e-cigarettes have a USB port, plugging an e-cigarette into a USB port or power adapter not supplied by the manufacturer can subject the battery to a higher current than is safe, leading to an explosion and/or fire.\textsuperscript{53}

18B.5.10 Environmental impact
Little is known so far regarding the environmental impact of e-cigarettes, and potential hazards relating to their manufacturing, use and disposal require further investigation. For example, the environmental impact of manufacturing will likely vary based on factory size and the nicotine extracting method used, while disposal of nicotine residue-containing cartridges and battery-containing e-cigarettes represent further potential concerns for the environment. There are currently no methods for proper disposal of e-cigarettes or their cartridges.

Cigarettes are also a major cause of burns (see Section 3.19) and a significant hazard for users of medical oxygen. There have also been reports of other devices with lithium-ion batteries, such as smartphones, exploding due to faulty charging or overheating; thus, this risk is not limited to e-cigarettes.

Cigarette manufacturing also has a substantial environmental impact, and cigarette butt litter remains a major environmental pollutant that poisons waterways and wildlife and causes bushfires (see Section 10.16).

References


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18B.6 Usefulness in quitting

Consumers of e-cigarettes, the majority of whom are smokers, report mixed reasons for their use. Some use them as a substitute for cigarettes, either in an attempt to reduce consumption, or to enable nicotine use in situations where use of traditional cigarettes would not be allowed or acceptable. Others report using e-cigarettes as a step toward complete cessation of tobacco cigarettes. Despite some manufacturers promoting e-cigarettes as a cessation aid, there is currently insufficient evidence to conclude that the products are helpful for quitting.

Several evidence reviews have been published in recent years, with mixed findings. The Cochrane Collaboration published a review in 2014 that considered the effectiveness of e-cigarettes for smoking cessation. Assessing the two randomised controlled trials conducted to that date, the reviewers found that participants using e-cigarettes were more likely to have abstained from smoking for at least six months compared with participants using a placebo. However a number of limitations with the data including the small number of trials, low event rates, and wide confidence intervals led to the authors' rating their confidence in the results of the review as 'low.' A subsequent systematic review published in 2015 concluded that all included studies (four randomised controlled trials) supported e-cigarettes as an effective smoking cessation tool.

Rahman et al.’s systematic review and meta-analysis of 2015 concluded that use of e-cigarettes is associated with smoking cessation and reduction. Products containing nicotine appeared to be more effective for cessation than those without nicotine. A 2016 systematic review found that while most studies show a positive relationship between e-cigarette use and quitting, the low quality of evidence means that no firm conclusions can be drawn.

On the other hand, Grana, Benowitz and Glantz’s meta-analysis in published in 2014 concluded that “ENDS use in the real world is associated with significantly lower odds of quitting smoking cigarettes.” A 2016 systematic review and meta-analysis of e-cigarette use and smoking cessation in real-world and clinical settings identified 38 studies (20 with control groups) and found that the odds of quitting cigarettes were 28% lower in those who used e-cigarettes compared with those who did not use e-cigarettes.

18B.6.1 Usefulness in reducing consumption of conventional tobacco products

Large declines in daily consumption of conventional cigarettes in users of e-cigarettes have been noted in several studies, and reviews. However, evidence suggests that the health benefits of reducing consumption of conventional tobacco products are minimal. Several large cohort studies have found that smokers who reduce their consumption do not significantly reduce their risk of premature death. Smoking just 1–4 cigarettes per day significantly increases a person’s risk of dying from smoking-related disease. This lack of health benefits is often attributed to compensatory smoking: those who cut down tend to inhale each cigarette more deeply, and smoke more of it. (See Section 18.3 for further detail).

A number of studies have shown that dual use of NRT and cigarettes can help alleviate the issue of compensation, leading some to advocate for long-term use of NRT in combination with cutting down as a harm reduction strategy. Researchers have suggested that it may be possible that the use of e-cigarettes while smoking could similarly reduce intake from each cigarette. However, data on the long-term safety of e-cigarettes is lacking, and they may be less safe than existing, licenced NRT products.
The main benefit of cutting down seems to be its role as a step toward quitting, although this may be a less effective strategy than going ‘cold turkey’. A 2015 review exploring the usefulness of cutting down determined that smokers who reduce the number of daily cigarettes smoked are more likely to attempt and actually achieve smoking cessation, particularly when combined with NRT. The authors conclude that smoking reduction is a promising intervention; however, the benefits are only observed when it leads to permanent cessation. They suggest that e-cigarettes may prove to be a useful form of NRT in combination with smoking reduction as part of ‘cutting down to quit’, but further research is needed on the efficacy of the products in this context.

References


18B.7 Potential public health impact

At the heart of the debate over the utility of e-cigarettes is the tension between whether the potential benefits of making a less harmful alternative to tobacco widely available to smokers is worth the potential risks of uptake by non-smokers, gateway effects, dual use, discouragement from cessation, and renormalising smoking.1, 2

Modelling of the potential health effects of increasing e-cigarette use and taking into account the epidemiology of the diseases caused by tobacco use, it is clear that any benefits to overall public health are dependent upon most e-cigarette users being current smokers interested in quitting who are now approaching the critical years of middle age, or—somewhat more controversially—young people who would have otherwise become long-term tobacco cigarette users. Other scenarios, such as e-cigarette use renormalising smoking, dual use, or significant uptake by young people (who would otherwise never have smoked tobacco cigarettes) have the potential to increase population-level harm.3

Uptake among non-smokers and a ‘gateway effect’ to tobacco smoking

Experimentation with electronic cigarettes among non-smoking adults appears to be relatively rare.4, 5 Among young people, use is increasing, in some countries quite rapidly (see Section 18B.3). Initial reports indicated that e-cigarette use appeared to occur predominantly among adolescents who had also experimented with tobacco.6 In 2015 in the UK, 77% of 11–18 year old regular smokers had tried e-cigarettes compared to only 4% of never smokers. However, 36% of young people using e-cigarettes had not tried tobacco prior to taking up e-cigarettes.7 A large longitudinal study of Californian high school students has suggested that e-cigarettes are attracting users who would not have taken up combustible tobacco products.8 Others have observed an association between e-cigarette use and intention to smoke in the future, and subsequent tobacco use.9-17 Further longitudinal studies will continue to explore whether e-cigarettes act as a ‘gateway’ to smoking, or whether young people who experiment with e-cigarettes are those who are also likely to experiment with cigarettes.

Regardless, use of e-cigarettes by children is a concern to public health specialists and regulators. Exposure to nicotine during adolescence may have significant and lasting health consequences18 (see Section 18B.5.4), including long-term addiction.19 Some adolescents are also using e-cigarettes for vaping of cannabis and other substances.20 As with tobacco cigarettes, exposure to e-cigarette marketing and promotion is associated with greater e-cigarette use among young people,21-23 and the wide range of flavours is particularly appealing to children.24 Together, these issues have led to calls for strict regulations that would minimise use among young people and non-smokers, including restrictions on advertising and promotion, prohibiting use in smokefree areas, banning flavours that could appeal to youth, raising taxes, implementing health warnings, and prohibiting sales to minors.25, 26

Dual use

Dual use refers to the concurrent use of conventional tobacco products and e-cigarettes. Dual use is actively promoted by some e-cigarette manufacturers, especially those that also manufacture tobacco products, as a way for smokers to by-pass smokefree regulations.27 Other smokers use both products as a means of reducing their exposure to tobacco smoke, and/or as an intended pathway to smoking cessation.28 A 2016 meta-analysis concluded that cigarette smoking increases the probability of e-cigarette use, especially among current smokers and adolescents.29
While a reduction in risk seems likely for smokers who completely substitute tobacco cigarettes,\textsuperscript{30, 31} the benefits for those who continue to use some tobacco cigarettes are much less certain. Among those who exclusively smoke tobacco cigarettes, cutting down the number of cigarettes consumed may not reduce toxic exposure if smokers compensate by drawing more deeply on the cigarettes they do smoke. There is some evidence that supplementing reduced cigarette consumption with an alternative source of nicotine might reduce toxicant exposure and hence mortality among smokers who continue to smoke at a reduced rate—see Section 18B.6.\textsuperscript{32-34} However, there are no long-term studies to measure whether long-term dual use translates into measurably better health outcomes compared to continued smoking of cigarettes alone. So far, research on the likelihood of dual use of cigarettes and e-cigarettes prompting or supporting cessation is limited. While cutting down cigarettes has been associated with later increased success in quitting, the evidence for improved cessation rates among those who supplement tobacco cigarettes with e-cigarettes is mixed (see Section 18B.6).

Discouragement from cessation

Smokers taking up e-cigarettes while still smoking tobacco cigarettes, who might otherwise have quit altogether had they not commenced e-cigarette use, might represent missed opportunities for complete cessation. Smoking poses a very significant risk to health both in the immediate and the longer term, but the most serious diseases emerge only with long-term use. While two of every three long term smokers in Australia will die from smoking, quitting prior to age 45 reduces mortality risk close to that of never smokers.\textsuperscript{35} Given that complete cessation of use of any nicotine product is the option associated with least harm, it follows that the optimal approach for younger smokers at least in the first instance would be to attempt to quit without continuing use of nicotine.

The renormalisation of smoking

Decades of successful public health campaigning have profoundly denormalised smoking. As evidence has accumulated about the hazards of tobacco to smokers and non-smokers alike, stronger public health measures including restrictions on smoking have been widely adopted.\textsuperscript{36} Those advocating caution about e-cigarettes have characterised these new products as having the potential to weaken these tobacco control efforts and help to renormalise smoking, particularly if they are used in smokefree areas.\textsuperscript{36, 37}

It has also been argued that e-cigarettes could revive the behaviour of smoking in public, undermining increasingly stringent restrictions on smoking in both indoor and outdoor areas.\textsuperscript{1} Along with cessation, a study of older adults in the US found that they reported using e-cigarettes as a way to circumvent no-smoking policies, and perceived e-cigarette marketing as a way to renormalise smoking.\textsuperscript{38} An alternative view is that e-cigarettes are easily distinguishable in appearance and smell from tobacco cigarettes, and that widespread use of e-cigarettes is more likely to normalise alternative nicotine devices than smoking, and may benefit and support smokefree environments.\textsuperscript{6}

Involvement of the tobacco industry

Although e-cigarettes were originally developed and marketed independently from the tobacco industry, some of the world’s largest tobacco companies have entered the market—see Section 18B.1.2. Given its history of unethically promoting and defending tobacco cigarettes, the tobacco industry’s involvement in e-cigarettes is of great concern to public health experts. The tobacco industry is said to be pursuing five goals: promoting widespread dual use; hindering smoking cessation; renormalising public smoking; conveying to young people that nicotine is a benign drug; and welcoming back lapsed smokers.\textsuperscript{1} Concerns have also been raised regarding the quality of research on e-cigarettes, with one systematic review finding many serious methodological shortcomings. In 34% of the papers reviewed, the authors had a conflict of interest. Most studies were funded or otherwise supported/influenced by manufacturers of e-cigarettes, which appeared to influence the conclusions of the papers.\textsuperscript{39}

As well as enjoying commercial gains from investing in e-cigarettes, it has been argued that tobacco companies are likely to be keen to exploit opportunities for advertising and promotion that will promote tobacco and/or e-cigarette use. By becoming involved in alternative nicotine delivery products, companies may be able to evade current restrictions on engagement in policy imposed by Article 5.3 of the Framework Convention on Tobacco Control (FCTC).\textsuperscript{6} In response to concerns regarding the possibility of e-cigarettes interfering with existing tobacco control efforts, the WHO has invited FCTC Parties to “protect tobacco-control activities from all commercial and other vested interests related to [electronic nicotine delivery systems], including interests of the tobacco industry.”\textsuperscript{40}


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18B.8 Legal status in Australia

In Australia, the regulation of e-cigarettes is encompassed by a number of laws relating to tobacco control, therapeutic goods, poisons and consumer protection laws, and is shared between the Commonwealth and the states and territories. Their current status in Australia is as follows:

E-cigarettes that contain nicotine

Under the Standard for the Uniform Scheduling of Poisons (Cth) (‘the Poisons Standard’), nicotine is classed as a schedule 7 ‘dangerous poison’, except where it occurs (1) in tobacco products prepared and packed for smoking or (2) in preparations for human therapeutic use.

When in preparations for human therapeutic use, nicotine is considered a schedule 4 ‘prescription only medicine’. Generally speaking, in order to be legally supplied as a ‘prescription only medicine’, an e-cigarette containing nicotine would first need to be approved by the Therapeutic Goods Administration (TGA) for use as an aid to smoking cessation. To date, no e-cigarette has been TGA approved as a cessation aid. Therefore, as a general rule, the retail sale of e-cigarettes containing nicotine is illegal in every Australian state and territory.

There are, however, some very limited exceptions to the general requirement that nicotine e-cigarettes would first need to be approved by the TGA for therapeutic use before they could be supplied in Australia. In particular, individual users may be able to lawfully buy and use e-cigarettes that contain nicotine by importing them (or nicotine refill capsules) for personal use under the TGA personal importation scheme, subject to certain restrictions (including that they must be for personal/family use, adhere to quantity limitations, and meet restrictions on prohibited imports). Personal importation requires a medical prescription from an Australian doctor. Even if imported under this scheme, however, consumers still need to comply with the poisons laws that operate in their particular state or territory, which would require their being granted the appropriate permit to purchase and/or use the nicotine. The extent (if at all) to which Australian doctors have prescribed nicotine is not known. Given that there are already a number of TGA-approved nicotine-containing therapeutic products available without restriction for smoking cessation, it may well be that in practice, Australian doctors would not choose to prescribe an unapproved and untested product for this purpose. It is also of significant concern that nicotine sourced from overseas may not be produced to a consistent standard (strength, consistency, purity, quality), be appropriately packaged and labelled, and that use of these products may therefore expose the user to additional unknown risks.

E-cigarettes that do not contain nicotine

E-cigarettes that do not contain nicotine can be sold by retailers in Australia in some jurisdictions as long as the manufacturers do not make therapeutic claims (i.e., they cannot claim that the product is a cessation aid). Non-nicotine e-cigarettes may be possessed in all jurisdictions. Individuals can also import non-nicotine e-cigarettes for personal use without a prescription. However, if the products are marketed as a cessation aid (and are therefore classed as a therapeutic good), their importation is subject to the restrictions outlined above under the TGA Personal Importation Scheme.

It is worth noting that there is no way to determine whether or not an e-cigarette contains nicotine, short of subjecting it to laboratory analysis. This may have implications for effective law enforcement.
In the ACT, the sale of electronic cigarettes that do not contain nicotine is currently allowed provided the business holds a tobacco licence, the person purchasing the product is over 18 years, and no therapeutic claim is made about the product. Use of e-cigarettes is also banned in smokefree areas, and the advertising, display, and marketing of products is strictly regulated.  

**Western Australia**

In Western Australia, the Tobacco Products Control Act 2006 (s. 106) states that a person must not sell any food, toy or other product that is designed to resemble a tobacco product or package. In a Western Australian Supreme Court decision on 10 April 2014, e-cigarettes were found to resemble a tobacco product and the seller of these e-cigarettes was convicted of this offence. The seller subsequently made an application to appeal the decision of the Supreme Court, and have the matter heard before the WA Court of Appeal. The matter was heard by the Court of Appeal in November 2015 and the appeal was unanimously dismissed in a decision handed down on 10 March 2016.  

**New South Wales**

In NSW, the Public Health (Tobacco) Amendment (E-cigarettes) Act 2015 prohibits the sale or supply of e-cigarettes and accessories to minors; restricts vending machine locations for e-cigarettes; and provides NSW police with powers to seize e-cigarettes from minors. It also restricts the display of e-cigarettes and accessories and bans the use of electronic cigarettes in cars carrying children. E-cigarettes are permitted to be used in areas where smoking is banned, but establishments and workplaces may choose to impose their own restrictions or bans if they wish.  

**Queensland**

Queensland’s Tobacco and Other Smoking Products Act 1998 was extended from 1 January 2015 to apply to e-cigarettes (defined as personal vaporisers). These products may not be sold to minors, used in smokefree areas, or advertised, promoted or displayed at retail outlets.  

**South Australia**

In South Australia, the Tobacco products Regulation Act 1997 (s. 36) states that ‘A person must not sell by retail any product (other than a tobacco product) that is designed to resemble a tobacco product.’ In 2015 the SA Government established a Select Committee to investigate and report on e-cigarettes and any legislative and regulatory controls that should be applied to their advertising, sale and use. The Select Committee’s final report was tabled in February 2016, and recommended a regulatory approach that would see the products regulated in much the same way as tobacco products.  

**Tasmania**

The Tasmanian Government released a discussion paper, Options for a public health response to electronic cigarettes, in mid-2015. At the time of writing, no report on the paper’s findings has been released.  

**Victoria**

In Victoria, the Tobacco Act 1987 gives the Minister for Health the power to ban certain products, including something which is ‘not a tobacco product but resembles a tobacco product’ (s. 150). This authority has not been applied to e-cigarettes to date. However in May 2016 the Government announced its intention to introduce restrictions on advertising e-cigarettes, prohibit their use in smokefree areas, and ban sales to minors.  

**Northern Territory**

There is currently no legislation in the Northern Territory which specifically relates to e-cigarettes. It was reported in the NT media in October 2014 that the government was considering regulation.  

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1. Except when used as an aid for withdrawal from smoking in preparations for oromucosal or transdermal use (e.g., nicotine patches or inhalers). Such products fall outside of the Poisons Standard altogether and are therefore available without a prescription.
References


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18B.9 International regulatory overview

Internationally, at least 71 countries have legislation in place which applies to various aspects of use, sales, promotion and taxation of e-cigarettes. About two-thirds of large countries have implemented some type of e-cigarette regulation, usually using existing laws relating to tobacco or nicotine.

European Union

In February 2014, the EU Tobacco Products Directive (TPD) was passed by the European Parliament and became law in April 2014. Member States had until May 2016 to transpose the new rules into national law. E-cigarettes containing up to 20mg/ml of nicotine come under the TPD and are permitted to be made available as general consumer products (rather than under a medicines framework); but products containing a higher level of nicotine, or that are marketed with therapeutic claims will require marketing authorisation as medicines. It also prohibits many forms of advertising and promotion of e-cigarettes. Additional regulations include:

- A size limit for e-liquids of 10ml for dedicated refill containers and 2ml for electronic cigarette cartridges and tanks
- Safety mechanisms (such as childproof fastening and opening) for e-liquid containers, cartridges and tanks
- Warnings on the two largest surfaces of the packs and any outside packaging covering at least 30% of the external area. These must state either ‘This product contains nicotine which is a highly addictive substance’ or the above plus ‘It is not recommended for use by non-smokers’.
- Consumer information must also include instructions on use, information on addictiveness and toxicity, a list of all ingredients and information on nicotine content, and promotional materials on packs are prohibited.
- Manufacturers and importers bear full responsibility for the quality and safety of their product and must notify detailed information about their products to competent authorities in each Member State.
- Prohibition on cross-border advertising promotion and sponsorship in line with that for tobacco products.
- Member States will be able to introduce extra safeguards, for example on age-limits and flavourings in electronic cigarettes.

United States of America

In the US, the Food and Drug Administration (FDA) formalised its arrangements so that all electronic delivery systems, including e-cigarette and vape pens, are now regulated under the Federal Food, Drug and Cosmetic Act (as amended by the Family Smoking Prevention and Tobacco Control Act) in August 2016. This rule gives the FDA regulatory control over the manufacture, import, packaging, labelling, advertising, promotion, sale and distribution of these products. Products which make a therapeutic claim (such as being an aid in cessation) are regulated as pharmaceutical products and are required to undergo assessment by the US FDA’s Centre for Drug Evaluation and Research, which oversees the safety and efficacy of pharmaceutical products.

18B.9.1 Bans on sales

As of June 2016, sale of all types of e-cigarettes was banned in Argentina, Bahrain, Brazil, Brunei Darussalam, Cambodia, Colombia, Greece, Jordan, Kuwait, Lebanon, Lithuania, Mauritius, Mexico, Nicaragua, Oman, Panama,
Qatar, Saudi Arabia, Seychelles, Singapore, Suriname, Thailand, Turkey, United Arab Emirates, Uruguay and Venezuela.\(^1\) A two-tier system is in place in some other countries, whereby non-nicotine e-cigarette sales are permitted, but nicotine e-cigarettes face additional restrictions or bans. Examples of this system include Canada, Hong Kong, Hungary, Japan, Mexico, New Zealand, and Norway.\(^4\) As with traditional cigarettes, pharmacy chain CVS in the US has banned the sale of e-cigarettes in its stores.\(^5\)

### 18B.9.2 Bans on sales to minors

Sales to people aged under 18 are banned in the USA.\(^3\) Other countries with a similar ban in place include the United Kingdom, Norway, Vietnam, France, Spain, Italy and Ecuador.\(^6\) In the Republic of Korea\(^6\) and Ontario\(^7\) e-cigarettes must not be sold to anyone younger than 19 years old, while Honduras restricts sales to those 21 and over.\(^1\)

Regulations such as these might not be completely effective in preventing use by teenagers. Several studies in the US have demonstrated that despite laws banning the purchase of e-cigarettes by minors and requiring online vendors to verify customer age, teens can easily buy e-cigarettes online.\(^8,\ 9\) In the UK, recent compliance testing found that almost 40 per cent of retailers illegally sold nicotine e-cigarettes and vaping liquids to minors.\(^10\)

### 18B.9.3 Bans on use in public places

Use of e-cigarettes is banned in Cambodia, Jordan and the United Arab Emirates.\(^1\) A number of other countries, such as Belgium, Greece, South Korea, and Turkey, have banned their use in enclosed public spaces and on public transportation.\(^1\)

In the US, many states and local councils have adopted their own laws regarding the use of e-cigarettes. As of April 2016, there were eight states and 352 local laws that restrict e-cigarette use in some or all types of smokefree venues. There were also 16 states and over 500 local laws that restrict e-cigarette use in other venues, such as schools, universities, hospitals, or prisons.\(^11\)

In the UK, electronic cigarettes are generally not regulated under smokefree laws, although this has been considered in Wales.\(^12\) However, individual premises may ban their use.\(^13\) In Scotland, patients and visitors may not use electronic cigarettes in hospital grounds.\(^14\)

### 18B.9.4 Product safety

The North Carolina Senate passed a bipartisan bill in April 2015 that would make child-resistant packaging and warning labels mandatory for liquids used with e-cigarette vaporizers.\(^15\) New York State has also introduced childproof packaging.\(^16\) The EU Tobacco Products Directive mandated that e-cigarettes sold in Member States must adhere to safety standards (such as childproof fastening and opening) for e-liquid containers, cartridges and tanks by May 2016.\(^2\)

### 18B.9.5 Taxation

When privately importing e-cigarettes into Australia, because they are not classed as tobacco products, they are not subject to customs duty. They are also not subject to GST if their customs value is at or below A$1,000.\(^17\) Togo’s tobacco excise tax (which covers e-cigarettes) is 45 per cent, and South Korea also applies a special tax to e-cigarettes.\(^1\) Italy adopted a new tax in January 2015 that doubles the price of e-liquid, and is set at half the tax rate of that on traditional cigarettes. Electronic cigarette firms claim that the new levy unfairly helps tobacco giants and will hurt their industry.\(^18\) Tax policy makers in Europe are considering whether e-cigarettes should be covered by excise duty, which would drastically increase their cost.\(^19\) New York State has also proposed taxing and regulating e-cigarettes the same way as tobacco cigarettes.\(^20\)

Some researchers have suggested that lower taxes on e-cigarettes (and other non-combustible nicotine-yielding products) that are determined or deemed likely to pose significantly fewer risks than combustible tobacco products could significantly hasten the move away from cigarette smoking.\(^21\)
18B.9.6 Advertising and promotion

Many countries have introduced restrictions or bans on the advertising, promotion or sponsorship of e-cigarettes, including Canada, Japan, New Zealand, and Norway. In the USA, the Food and Drug Administration has the power to regulate advertising and promotion of e-cigarettes. In the EU, the Tobacco Products Directive prohibits most advertising and sponsorship associated with e-cigarettes.

References


18B.10 Key Australian and international position statements on e-cigarettes, health, and options for regulation

A number of authoritative Australian and global health agencies have issued position statements on e-cigarettes. Excerpts from some of these are included below: it is not practicable to provide an exhaustive list, or to reproduce them in full. Readers should refer to the original position statements for further detail.

For the most part, position statements express caution about e-cigarettes, generally acknowledging that while they could have the potential to benefit public health, there is currently insufficient evidence to be sure that e-cigarettes assist smokers in quitting, do not cause some level of physical harm, and will not serve to undermine long-standing and effective tobacco control measures.

18B.10.1 Australian agencies

The Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods, including prescription medicines. This includes regulating supply, import, manufacturing and advertising of therapeutic goods; and ensuring that therapeutic goods meet required standards of safety, quality and efficacy.1

The TGA notes that:2

Unlike Nicotine Replacement Therapy (NRT) products, which have been rigorously assessed for efficacy and safety and, therefore, approved by the Therapeutic Goods Administration for use as aids in withdrawal from smoking, no assessment of electronic cigarettes has been undertaken and, therefore, the quality and safety of electronic cigarettes is not known.

The Australian Government is concerned about the use of electronic cigarettes in Australia. The impact of wide-scale use of these devices on tobacco use is not known, and the outcome in the community could be harmful.

National Health and Medical Research Council

Among other roles, the National Health and Medical Research Council (NHMRC) has responsibility for developing health advice for the Australian community, health professionals and government.3

The NHMRC reviewed the evidence about the risks and benefits of personal vapourisers in early 2015, and concluded that:4

There is currently insufficient evidence to conclude whether e-cigarettes can benefit smokers in quitting, or about the extent of their potential harms. It is recommended that health authorities act to minimise harm until evidence of safety, quality and efficacy can be produced. NHMRC is currently funding research into the safety and efficacy of e-cigarettes for smoking cessation.

Public Health Association Australia

The Public Health Association of Australia has endorsed the position adopted by the World Federation of Public Health Associations,5 which supports the World Health Organization’s ‘call for caution and seeks the application of the precautionary principle by governments’ in relation to ENDS. Statements from the World Federation of Public Health Associations and the World Health Organization are included in Section 18B.10.2 – Global agencies, below.

Cancer Council Australia and Heart Foundation

These agencies issued a joint position statement in 2015.7 In their Overview, the agencies state that:

...based on past experience in tobacco control and early research on electronic cigarettes, there is sufficient information to act on three particular regulatory gaps in order to prevent uptake and use of electronic cigarettes by young people and other risks to public health. Areas in need of priority attention for this purpose include the proper regulation of: (a) non-nicotine electronic cigarettes; (b) use in smoke-free environments; and (c) advertising.

The agencies make the following recommendations:

1. Ban the retail sale of non-nicotine electronic cigarettes (unless the product has been approved by the TGA). It is currently unlawful to sell electronic cigarettes that contain nicotine in any form. This is because nicotine is a scheduled poison and can only be lawfully sold in the form of legal tobacco products (a historical anomaly) and approved nicotine replacement products. This position could change in the future for individual nicotine electronic cigarette products that receive approval from the TGA. Similar restrictions should also apply to non-nicotine electronic cigarettes, which come in a variety of fruit, confectionery and other flavours that appeal to children. Laws in South Australia, Western Australia and Queensland prohibit the sale of products that resemble tobacco products. There are no such laws in other states and territories, meaning that non-nicotine electronic cigarettes (when marketed without therapeutic claims) can be lawfully sold, including to young people.

2. Ensuring smoke-free laws in each state and territory cover electronic cigarette use. The purchase, possession or use of electronic cigarettes containing nicotine is currently unlawful under state and territory poisons and public health laws. However, these laws are complicated and difficult to enforce. Prohibiting use of all electronic cigarettes under smoke-free laws would make the law clear for the community and ensure that both nicotine and non-nicotine electronic cigarettes are not used in places where smoking tobacco is prohibited.

3. Prohibiting advertising and promotion of electronic cigarettes, consistent with tobacco advertising prohibitions. Electronic cigarettes are being aggressively promoted, with young people and children clearly identified as a target market. Electronic cigarette advertising should be subject to similar restrictions as tobacco products.

Australian Medical Association

The Australian Medical Association (AMA) released Tobacco smoking and e-cigarettes in December 2015.8 The statement notes that ‘the AMA has significant concerns about e-cigarettes. E-cigarettes and the related products should only be available to those people aged 18 years and over and the marketing and advertising of e-cigarettes should be subject
In support of the WHO approach, the WFPHA calls for regulations to:

- Protect health-care staff, consumers and the environment from harm caused by ENDS,
- Ensure that smoke-free measures are applied to ENDS products in all situations where they apply to smoking.
- Prohibit unproven health claims about ENDS
- Ensure that ENDS are not marketed as cessation aids as such claims are not supported by evidence at this time.

Elsewhere in the document, they state that:

The evidence supporting the role of e-cigarettes in cessation is mixed and low level, and e-cigarettes are not currently recognised as cessation aids by the National Health and Medical Research Council, the Therapeutic Goods Administration or the World Health Organisation. In fact, using an e-cigarette may significantly delay the decision to quit smoking. In addition, there is uncertainty about the longer term health implications of inhaling the vapours produced by the illegally imported (and unregulated) solutions.

There are legitimate concerns that e-cigarettes normalise the act of smoking. This has the potential to undermine the significant efforts that have been dedicated to reducing the appeal of cigarettes to children, young people and the wider population. These concerns are supported by research findings that young people using e-cigarettes progress to tobacco smoking. Currently there is no medical reason to start using an e-cigarette.

Lung Foundation Australia

In its statement of June 2014, Lung Foundation Australia declared that:

There is currently not enough evidence to suggest the use of e-cigarettes as an effective smoking cessation tool over current recommended strategies including pharmacotherapy and clinical counselling. This could change as more research is published on this subject.

While the number of toxins in an e-cigarette is fewer than those in traditional cigarettes, there are no long-term studies on the safety of e-cigarettes and concern has been expressed about the small particles inhaled when "vaping" and their health impact, particularly on youth.

Lung Foundation Australia strongly urges relevant government agencies to further regulate access to e-cigarette devices and components, nicotine-filled cartridges, and non-nicotine cartridges.

**18B.10.2 Global agencies**

**The World Health Organization and the Framework Convention on Tobacco Control**

In response to the increase in e-cigarette use, in 2009 the WHO Study Group on Tobacco Product Regulation reviewed the evidence to date, and recommended that ENDS should be "regulated as combination drugs and medical devices and not as tobacco products." At the Fifth Session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control (FCTC) in November 2012, the WHO was invited to report on the "control and prevention of smokeless tobacco products and electronic nicotine delivery systems, including electronic cigarettes," and to present this report to the Sixth Session of the Conference of Parties, to be held in 2014.

In the lead-up to the release of this report, Dr Margaret Chan, Director-General of the WHO, was sent a letter signed by 53 "specialists in nicotine science and public health policy," urging the WHO to consider the potential for tobacco harm reduction products to reduce the burden of smoking-related disease. In the following weeks a second letter signed by 129 "public health and medical authorities from 31 countries" was sent to Dr Chan, countering the arguments put forward in the first letter and encouraging the WHO to maintain its evidence-based approach to shaping an appropriate regulatory framework for ENDS.

In October 2014, the WHO presented its report Electronic nicotine delivery systems to Sixth Session of the FCTC Conference of the Parties in Moscow. The report included the following clauses:

**General considerations (clauses 33–38)**

33. Smokers will obtain the maximum health benefit if they completely quit both tobacco and nicotine use. In fact, Article 5.2(b) of the Convention commits Parties not only to preventing and reducing tobacco consumption and exposure to tobacco smoke but also to preventing and reducing nicotine addiction independently from its source. Therefore, while medicinal use of nicotine is a public health option under the treaty, recreational use is not.

34. The rapid growth of ENDS use globally can neither be dismissed nor accepted without efforts to appropriately regulate these products, so as to minimize consequences that may contribute to the tobacco epidemic and to optimize the potential benefits to public health. Thus it is important to identify public health concerns and to consider these concerns when undertaking regulation and surveillance.

35. Regulation of ENDS is a necessary precondition for establishing a scientific basis on which to judge the effects of their use, and for ensuring that adequate research is conducted, that the public has current, reliable information as to the potential risks and benefits of ENDS, and that the health of the public is protected. Public health authorities need to prioritize research and invest adequately to eludiate evidentiary uncertainties as soon as possible. However, the greater probability to prove claims about ENDS scientifically should remain with the industry.

36. When designing a regulatory strategy for ENDS, governments should bear in mind the following general regulatory objectives:

(a) impede ENDS promotion to and uptake by non-smokers, pregnant women and youth;
(b) minimize potential health risks to ENDS users and non-users;
(c) prohibit unproven health claims from being made about ENDS; and
(d) protect existing tobacco-control efforts from commercial and other vested interests of the tobacco industry.

37. Because the product, the market and the associated scientific evidence surrounding ENDS are all evolving rapidly, all legislation and regulations related to ENDS should be adaptable in response to new scientific evidence, including evaluation of different models for ENDS regulation, as evidence accumulates.

38. Governments should consider that if their country has already achieved a very low prevalence of smoking and that prevalence continues to decrease steadily, use of ENDS will not significantly decrease smoking-attributable disease and mortality even if the full theoretical risk reduction potential of ENDS were to be realized.

The Conference of the Parties accepted the WHO report and requested that the WHO be further invited to prepare an expert report, with independent scientists and concerned regulators... with an update on the evidence of the health impacts of ENDS/ENDS, potential role in quitting tobacco usage, impact on tobacco control efforts, and to subsequently assess policy options for the prevention and control of ENDS. The updated report is to be presented to the Seventh Session of the Conference of the Parties due to take place in Noida, India, in November 2016.

**World Federation of Public Health Associations**

The World Federation of Public Health Associations (WFPHA) has announced its support for the recommendations provided by the WHO in their 2014 report, Electronic nicotine delivery systems. In their position statement, the WFPHA emphasizes the following points:

- Endorses WHO’s call for caution and seeks the application of the precautionary principle by governments
- Calls for further evidence and research
- Emphasizes that ENDS/e-cigarettes should not be used as a means of bypassing Article 5.3 of the FCTC or re-normalizing smoking behaviour.

In support of the WHO approach, the WFPHA calls for regulations to:

- Ban all forms of advertising and promotion for ENDS to ensure both that children, young people and non-smokers are not exposed to ENDS promotions and that any commentary about ENDS is made by governments and health authorities, not by those with a commercial interest in these products and tobacco promotion
- Ensure strict emission and control measures for e-cigarettes
- Prohibit unproven health claims about e-cigarettes
- Ensure that smoke-free measures are applied to ENDS products in all situations where they apply to smoking
Electronic cigarettes and other electronic nicotine delivery systems, 

Key messages of the updated statement include that:

- The safety of electronic cigarettes (ECs) or electronic nicotine delivery systems (ENDS) has not been scientifically demonstrated.
- Adverse health effects for third parties exposed (second-hand exposure) cannot be excluded because the use of ECs leads to the emission of fine and ultrafine inhalable liquid particles, nicotine and cancer-causing substances into indoor air.
- The benefits of ECs have not been scientifically proven. To date, few studies have assessed ECs/ENDS as a harm reduction and cessation aid; those that do exist have conflicting findings.
- Marketing, awareness and use of ECs or ENDS are growing rapidly.
- The tobacco transnationals have increasingly entered the EC/ENDS marketplace with a strong presence.
- A range of current and proposed legislative and regulatory options exists; some countries (such as Brazil, Norway, Indonesia and Singapore) have banned ECs/ENDS completely. Other countries are considering banning them.
- ENDS could undermine the implementation of the WHO Framework Convention on Tobacco Control (FCTC) Article 12 (de-normalisation of tobacco use); use of ENDS could also hamper the implementation of Article 8 (protection from exposure to tobacco smoke), as ENDS users in public places may claim that their electronic cigarette does not contain tobacco and/or does not produce second-hand tobacco smoke.
- The Union strongly supports regulating the manufacturing, marketing and sale of ECs or ENDS, preferably as medicines.

Forum of International Respiratory Societies

The Forum of International Respiratory Societies (FIRS) is composed of professional organisations and experts in respiratory disease. Member societies include Asociacio’n Latinoamericana del To­rax, the American College of Chest Physicians, the American Thoracic Society, the Asian Pacific Society of Respirology, the European Respiratory Society, the International Union Against Tuberculosis and Lung Disease and the Pan African Thoracic Society. FIRS’ position on electronic nicotine delivery devices includes the following statements:

- There is concern that the use of electronic cigarettes is growing rapidly, especially among young people and women. Their acceptance may be attributed in part to the perception created by marketing and the popular press that they are safe.
- The health risk of electronic cigarettes has not been adequately studied.
- The addictive power of nicotine and its untoward effects should not be underestimated.
- The potential benefits of electronic nicotine delivery devices, including harm reduction and enhancing smoking cessation, have not been adequately studied.
- Potential benefits to an individual smoker should be weighed against harm to the population of increased social acceptability of smoking and use of nicotine.
- Health and safety claims regarding electronic nicotine delivery devices should be subject to evidentiary review.
- Adverse health effects for third parties exposed to the emissions of electronic cigarettes cannot be excluded.
- Parties to World Health Organization Framework Convention on Tobacco Control should consider whether allowing use of electronic cigarettes is consistent with the requirements of the treaty.
- Electronic nicotine delivery devices should be restricted or banned, at least until more information about their safety is available.

World Medical Association

The World Medical Association (WMA) is an independent federation of 111 national medical associations, including the Australian Medical Association. In their 2012 statement Electronic cigarettes and other electronic nicotine delivery systems, the WMA recommended:

- That the manufacture and sale of e-cigarettes and other electronic nicotine delivery systems be subject to national regulatory bodies prior approval based on testing and research as either a new form of tobacco product or as a drug delivery device.
- That the marketing of e-cigarettes and other electronic nicotine delivery systems as a valid method for smoking cessation must be based on evidence and must be approved by appropriate regulatory bodies based on safety and efficacy data.
- That e-cigarettes and other electronic nicotine delivery systems be included in smoke free laws.
- Physicians should inform their patients of the risks of using e-cigarettes even if regulatory authorities have not taken a position on the efficacy and safety of these products.

18B.10.3 Overseas agencies

Many overseas agencies have issued position statements. Some of these include:

- American Association for Cancer Research and the American Society of Clinical Oncology
- American Heart Association
- British Medical Association
- Canadian Cancer Society
- Cancer Society New Zealand
- Public Health England
- Royal College of Physicians (UK) and 10 other UK health agencies writing in support of Public Health England’s position
- US Food and Drug Administration
- US National Institute on Drug Abuse
- US Preventive Services Task Force

Use of e-cigarettes as a device for harm reduction is more widely supported by health agencies in the UK than in most other countries (see also Section 18B.9).

References
