Chapter 9
Harm reduction policies for tobacco

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Abstract

Tobacco smoking is the leading cause of preventable premature mortality and disability in European and other developed countries. This chapter first reviews strategies that (1) aim to reduce harm to non-smokers (public smoking bans and reduced ignition propensity cigarettes) and (2) aim to reduce harm to the smoker who is unable or unwilling to quit nicotine use, namely, regulating the harmfulness of cigarettes, and encouraging smokers to switch to less harmful nicotine products. The putative tobacco harm reduction products discussed include: modified tobacco cigarettes and cigarette-like devices, smokeless tobacco products and pharmaceutical nicotine products. The evidence for the harm reduction potential of each of these is discussed, as are adverse public health outcomes that may potentially arise from their promotion. The chapter concludes with a description of the most promising options for promoting tobacco harm reduction.

Keywords: smokeless tobacco, snus, reduced ignition propensity cigarettes, smoking bans, potential reduced exposure products, pharmaceutical nicotine.

Introduction

Tobacco can be smoked as cigarettes, in a pipe, or as cigars or used via non-smoked products such as chewing tobacco or oral and nasal snuff. Nicotine is the primary substance responsible for tobacco dependence but the majority of harm caused by tobacco use is not from nicotine but from the by-products of smoked tobacco (e.g. fine particulates, carcinogens, and noxious gases including carbon monoxide). Cigarettes are the most addictive and hazardous tobacco product, because cigarette smoke is readily drawn deep into the lungs where it is rapidly absorbed into the bloodstream and from which nicotine quickly reaches the brain (Benowitz, 2008).

In Europe, as in many regions of the world, the cigarette has become the dominant form of tobacco use over the past century (Berridge, 2007). The rise in the popularity of the cigarette was followed with a lag of several decades by increases in tobacco-caused diseases including cancers, pulmonary and cardiovascular diseases. By mid century tobacco smoking had become the leading cause of preventable premature mortality and disability in Europe and other developed countries. Cigarette smoking is currently responsible for around 730 000 deaths in the European Union (EU) each year (including 80 000 from passive smoking) (ASPECT Consortium, 2004).

Smoking prevalence has declined in most western European countries over the past 40 years, but prevalence remains high in many eastern European countries (ASPECT Consortium,

2004; WHO Regional Office for Europe, 2007). The disparities in smoking prevalence across Europe largely reflect differences in the intensity with which tobacco control policies have been implemented, such as increasing cigarette taxes, banning cigarette advertising, public mass media anti-smoking campaigns and restricting smoking in indoor public spaces (ASPECT Consortium, 2004; WHO Regional Office for Europe, 2003; WHO Regional Office for Europe, 2007).

Policies that encourage existing smokers to quit and discourage non-smokers from starting remain the most effective ways of reducing tobacco-related harm (World Bank, 2003). Nonetheless, even in countries that have most rigorously enforced these types of policies (Australia, the United States, Canada, the United Kingdom and Sweden), none have reduced overall smoking prevalence below one in six adults. Plausible projections show that more than 10 % of adults will be smoking in another 20 years if current rates of cessation and initiation continue (Gartner et al., 2009; Kemm, 2003; Mendez et al., 1998).

The persistence of smoking in a substantial minority of adults has prompted some to advocate tobacco harm reduction (THR) policies as an addition to conventional strategies that promote abstinence from tobacco. Harm reduction policies are generally those that 'attempt to prevent problems by targeting risky contexts or patterns of use, or by moderating the relation between use and problem outcomes, without necessarily affecting overall rates of use' (Toumbourou et al., 2007, pp. 1398–9). In the case of THR, this approach involves attempting to reduce the harmfulness of tobacco use without necessarily advocating cessation or abstinence, typically by advocating the use of much less harmful forms of tobacco or nicotine use.

Policies that reduce the harm to others

Public smoking bans

Non-smokers who are exposed to second-hand smoke (the emissions from the end of lit cigarettes and the exhaled smoke from a smoker) are at increased risk of many of the same diseases that affect smokers (US Department of Health and Human Services, 2006). Workers in smoky environments, such as bar staff, are particularly at risk due to their regular and prolonged exposure. Legislated bans on smoking in enclosed public spaces such as office buildings, restaurants, cafes, bars and clubs provide protection of employees and patrons and are the most widespread and non-controversial tobacco harm reduction policy. Research has shown that public smoking bans in countries like the United States and Australia have been effective in reducing exposure to second-hand smoke in these previously smoky environments (Hopkins et al., 2001). There is also evidence that these policies can provide immediate population health improvements, such as a reduction in the number of hospitalisations for acute coronary events (Pell et al., 2008).

A number of European countries have recently introduced indoor public smoking bans (for example, Republic of Ireland, United Kingdom), but many countries still do not have comprehensive smoking bans (Joossens and Raw, 2007). To be effective at reducing the

exposure of non-smokers, these bans need to cover all enclosed areas and should also extend to outdoor areas that are serviced by waiting staff. Smoking bans also have the added benefit of increasing cessation in the smoking population by reducing the opportunities to smoke and contributing to the de-normalisation of smoking (Fichtenberg and Glantz, 2002).

Reduced ignition propensity (RIP) cigarettes

Fires started by cigarettes cause substantial damage to property and loss of life. Internal tobacco industry documents show that the industry knew how to reduce the ignition propensity of cigarettes many years ago (Gunja et al., 2002) by reducing tobacco density, paper porosity and cigarette circumference, eliminating burn additives and by increasing the length of filters (Chapman and Balmain, 2004). Legislation requiring cigarettes to meet RIP performance standards has now been implemented in 22 US states and Canada (Arnott and Berteletti, 2008). In 2007, the EU Member States endorsed plans to develop a mandatory standard to reduce the ignition propensity of cigarettes sold in the EU (Arnott and Berteletti, 2008; Commission of the European Communities, 2008). An evaluation of New York's RIP standard (implemented in 2004), showed that it substantially reduced the ignition propensity of cigarettes sold in that state, largely via 'paper banding', without increasing the toxicity of the emissions (Alpert et al., 2005). There is as yet no evidence that the introduction of RIP standards has reduced cigarette-related fires. Nevertheless, implementation of a RIP performance standard in Europe would not be costly to the public, would have very little risk of producing adverse outcomes and could reduce the number of fires caused by discarded cigarettes.

Policies that reduce harm to the smoker

The main putative tobacco harm reduction products in order of decreasing relative harmfulness are modified tobacco cigarettes and cigarette-like devices, smokeless tobacco (SLT) products and pharmaceutical nicotine (PN) products (Stratton et al., 2001).

Modified tobacco cigarettes and cigarette-like devices

Regulating the harmfulness of cigarette emissions

The tobacco industry began developing a 'safer' cigarette in response to the emerging evidence of the harm from cigarette smoking in the 1950s (Glantz et al., 1996). The first example was the filtered cigarette, followed by so-called light, low-tar and low-nicotine cigarettes in the 1980s (Stratton et al., 2001). These cigarette modifications, which consisted of the addition of tiny ventilation holes in the side of the filter to dilute the smoke with air drawn in through these holes, were popular with smokers; however, they did not reduce the health risks of smoking as smokers compensated by drawing harder on the cigarette, covering the filter ventilation holes and smoking the cigarettes down to a shorter butt length. Research later revealed that the cigarette manufacturers knew these were not genuine

reduced harm products, but marketed them to reassure health-conscious smokers and discourage quitting (Glantz et al., 1996).

The World Health Organization's Study Group of Tobacco Product Regulation (TobReg) advocates mandatory maximum permissible levels of key toxicants in mainstream cigarette smoke (Burns et al., 2008) and the tobacco industry has developed and marketed cigarettes made with low nitrosamine tobacco and carbon filters, both of which are claimed to expose smokers to fewer toxins than regular cigarettes (Hatsukami et al., 2004; Rees et al., 2008). A major problem with this approach is that reductions in some toxins are often achieved by increasing others (King et al., 2007). Given that tobacco smoke contains more than 4 000 different chemicals, it will be difficult to achieve a substantial reduction in overall harmfulness (Stratton et al., 2001). Futhermore, there is no evidence that reducing or removing known toxins in cigarettes will produce observable reductions in smoking-related lung cancer (Pankow et al., 2007), yet publicity around mandating these changes may give consumers the impression that they do significantly reduce harm. Monitoring and enforcing a cigarette emissions standard will also require substantial laboratory and regulatory resources that may arguably be better used in other ways.

Cigarette-like devices

The tobacco industry has also marketed cigarette-like devices that aim to minimise tars and maximise nicotine by heating tobacco to produce an aerosol or vapour rather than smoke (for example, Eclipse, Premier, Accord and Heatbar) (Shiffman et al., 2002a; Stratton et al., 2001). Some of these products reduce emissions of one or more key toxins, but some studies report higher emissions of others (Breland et al., 2002; Breland et al., 2006; Fagerström et al., 2000; Stratton et al., 2001). Given the long latency of many tobacco-related diseases, it will take several decades before we know whether these products substantially reduce tobacco-related mortality and morbidity. Given these difficulties, we should arguably abandon attempts to reduce the harmfulness of cigarette emissions by modifying cigarettes or producing cigarette-like tobacco products in favour of harm reduction using non-smoked forms of tobacco and clean nicotine products (Stratton et al., 2001).

Smokeless tobacco (SLT) products

SLT products present greater opportunity for THR than smoked tobacco because there is no combustion/vaporisation and therefore no risk of respiratory disease, fire or passive smoking. SLT products include traditional chewing tobacco and snuff, and new products such as compressed tobacco lozenges, tobacco chewing gum and dissolvable strips (Hatsukami et al., 2007; Stepanov et al., 2006). Most policy attention has focused on a form of moist oral snuff used in Sweden, known as snus (see box on p. 262). It has much lower levels of tobacco-specific nitrosamines than snuffs marketed in the United States and elsewhere because it is produced by pasteurisation rather than fermentation (Hoffmann et al., 1995; Österdahl et al., 2004; Ramström, 2000). Levels of nitrosamines in Swedish snus have decreased over the past 20 or so years in response to the development of an

industry standard (Hatsukami et al., 2007; Österdahl et al., 2004). The development of portion snus in the 1970s (tea-bag-like sachets of snus) has produced a more user-friendly version that has increased prevalence of snus use among Swedish men. The fact that until recently snus was taxed at a much lower rate than cigarettes may also have contributed to its increased popularity. Increased snus use by Swedish men has been accompanied by decreased cigarette smoking and tobacco-related disease mortality (Foulds et al., 2003; Ramström, 2003).

A major barrier to the adoption of this form of harm reduction is the ban on the sale of the least harmful smokeless tobacco products in many countries. In Australia and New Zealand, for example, oral snuff and chewing tobacco products cannot be sold (Commonwealth of Australia, 1974; Parliament of New Zealand, 1990). With the exception of Sweden, the same is true in all EU Member States, where the sale of these tobacco products is prohibited, although chewing tobacco and nasal snuff can be sold (European Court of Justice, 2004).

Pharmaceutical nicotine (PN)

PN products in the form of gum, patches, inhalers and sprays have been available for many years. A new PN product under development is an oral nicotine pouch that mimics portion snus (Fagerström and Jiménez-Ruiz, 2008). PN is generally a safe (except perhaps in pregnancy), modestly effective and cost-effective way to help smokers to quit (Bertram et al., 2007; Stead et al., 2008), or, potentially, also as a long-term alternative to cigarette smoking (Warner et al., 1997). These products have minimal risk of abuse, in part because of their design. The long-term use of PN appears to be safe, as no treated morbidity or mortality was observed in five years of follow-up of nicotine gum users (Murray et al., 1996). Long-term use of PN in ex-smokers may also help prevent relapse to smoking (Hajek et al., 2007; Medioni et al., 2005).

The major disadvantages of PN are that, like other smoking cessation aids (bupropion, varenicline), most smokers who use it do not succeed in quitting (Nides, 2008; Shiffman et al., 2002b), and it has not been taken up by smokers as an alternative to smoking despite its wide availability in many developed countries. This seems to be because these products have been engineered for smoking cessation, with the aim of minimising their abuse by delivering a lower nicotine dose at a slower speed to cigarettes. They are also not marketed as long-term alternatives to tobacco smoking. For these products to gain popularity, PN regulation would need to be relaxed to allow these products to be made more attractive to inveterate smokers.

Recreational nicotine products

The marketing of the 'e-cigarette', a device that looks like a standard tobacco cigarette but contains only nicotine in a carrier vapour, is a recent attempt to commercialise a recreational nicotine product. Its similarity to cigarettes has led most tobacco control advocates to refer to it as a cigarette-like device. The e-cigarette produces a propylene

glycol vapour and has a glowing red tip to simulate a lit cigarette. The manufacturers have not marketed it as a smoking cessation aid and this has created regulatory barriers in some countries (for example, Australia and New Zealand) (National Drugs and Poisons Scheduling Committee, 2009; New Zealand Public Health Directorate, 2006). Some EU Member States have defined e-cigarettes as medical devices and require them to obtain a Confirmatory European (CE) mark before sale (e.g. Denmark, Austria) (Danish Medicines Agency, 2009; European Commission Health and Consumer Protection Directorate-General, 2008). A safety assessment of one brand of e-cigarette funded by the manufacturer suggests the product may be relatively safe (Laugesen, 2008; Laugesen et al., 2008), but there are no data on the patterns of use in smokers or uptake by non-smokers in countries where these products are sold, and there are no safety studies by groups that are independent of the industry.

There are claims in the popular media in the United Kingdom that the e-cigarette is being used in response to smoking bans in pubs and clubs (Sikora, 2007). Critics of the e-cigarette also argue that it maintains a visible smoking-like behaviour that may undermine the de-normalisation of smoking produced by public smoking bans (Chapman and Freeman, 2008). The substantial cost of the device and its replacement cartridges, the gimmicky nature of the smoke and glowing tip, and the regulatory hurdles in most countries will probably limit its use for THR (Arendt, 2008). However, more data is needed on whether smokers find these devices an acceptable substitute for smoking regular cigarettes.

The e-cigarette illustrates the inadequacy of current regulatory structures. Claims about aiding cessation would result in the e-cigarette being classified as a medicine and would require safety, quality and efficacy data before being marketed. If no such claims are made, the e-cigarette is likely to be regulated like tobacco cigarettes, and would then be subject to all the regulations that apply to tobacco products. Neither set of regulations are appropriate for e-cigarettes, the relative harmfulness of which is likely to fall somewhere between tobacco cigarettes and PN.

Will tobacco harm reduction products reduce harm to users?

There is no evidence that modified smoked tobacco products and cigarette-like devices substantially reduce harm. Experience with 'light' cigarettes also provides strong reasons for not allowing them to be promoted as THR products (Stratton et al., 2001; Warner, 2001). 'Light' cigarettes failed to reduce harm in smokers due to compensatory changes in the way they were smoked, such as inhaling more deeply, smoking a greater number of cigarettes and more of each cigarette, and blocking ventilation holes designed to dilute smoke exposure (Stratton et al., 2001). The mistaken image of a less harmful cigarette also provided reassurance to health-concerned smokers, which discouraged quitting. Similar compensatory changes, and/or 'risk swapping' by decreasing some toxins whilst increasing others, and false reassurance of safety, are likely to limit any benefits from THR products that involve the combustion or vaporisation of tobacco (e.g. Gray, 2004; Pierce, 2002; Stratton et al., 2001).

This argument does not apply to THR using PN and low nitrosamine SLT (LNSLT). The safety of PN is well established in the short to medium term with users having been followed for up to five years (Murray et al., 1996). PN may carry some residual health risks, such as an increased risk of cardiovascular disease arising from chronic nicotine intake, and adverse foetal outcomes if used in pregnancy, but these effects are small by comparison with those of cigarette smoking (Benowitz, 2000). Literature reviews of the health effects of SLT (Broadstock, 2007; Royal College of Physicians, 2007; SCENIHR, 2008) have concluded that some forms of SLT such as Swedish snus, which is low in nitrosamines, are significantly less harmful than smoking cigarettes. SLT use is not associated with respiratory diseases, including lung cancer and chronic obstructive pulmonary disease (COPD), but some potential health risks remain, namely oral and pancreatic cancer, cardiovascular disease and type 2 diabetes. Even so, these risks appear to be much lower than those of smoking. An expert panel estimated on the basis of the epidemiological literature that the overall risk of tobacco-related mortality in LNSLT users was 10 % of the risk of cigarette smokers (Levy et al., 2004). Epidemiological modelling of the aggregate health effects of quitting tobacco and switching from smoking to LNSLT suggest there is little difference in years of healthy life gained by those who quit tobacco and those who switch to LNSLT (Gartner et al., 2007b) (see box on p. 262).

Effects of tobacco harm reduction on aggregate harm

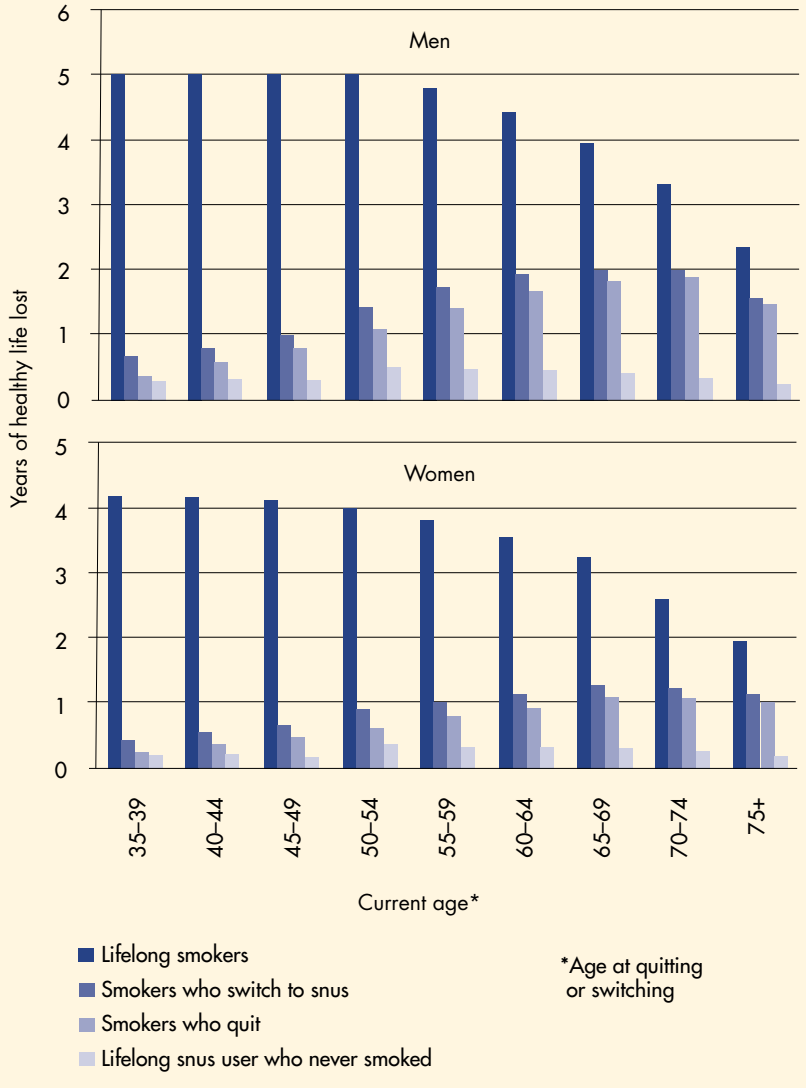
Whether THR produces a net benefit or harm depends on: the relative harmfulness of the THR product compared to regular cigarettes; how popular the THR product is among current smokers, ex-smokers and never smokers; and its effect on rates of smoking cessation and initiation. The risks of overall net harm are greatest for modified cigarettes and cigarette-like devices, because these produce the least reduction in risk and could discourage cessation in much the same way as 'light' cigarettes did.

Epidemiological modelling of the aggregate health effects of smoking and LNSLT use suggests that relaxations of bans on LNSLT use would only produce net harm if these products proved much more attractive to non-smokers than to smokers; led non-smokers to start to smoke; and/or maintained cigarette use in smokers by dual use rather than complete switching (Gartner et al., 2007a) (see box on p. 262). These putative effects of LNSLT have not been observed in Sweden and there are good reasons for thinking that they are unlikely to occur. As Kozlowski and colleagues (Kozlowski et al., 2001) have shown, PN would still produce a net population health gain, even if we made: (1) the most pessimistic assumptions about its residual health risks; and (2) we assumed that PN was used by the whole adult population (Kozlowski et al., 2001). A similar argument can be made for LNSLT.

Epidemiological modelling of the aggregate health effects of lifelong smoking, ex-smoking, switching to snus and lifelong snus use

Gartner et al (2007b) used multistate life tables and expert panel risk estimates to model the years of healthy life lost (YHLL) due to lifelong smoking, quitting tobacco use, switching from smoking to snus and lifelong snus use without smoking. The results showed that smokers who switched to snus would achieve health gains nearly as good as quitting all tobacco use. Men who switched from smoking to snus would lose 1.2–3.6 months of healthy life and women 1.2–4.8 months compared to smokers who quit tobacco altogether.

Figure 9.1: Years of healthy life lost by lifelong smoking, ex-smoking, switching to snus and lifelong snus use



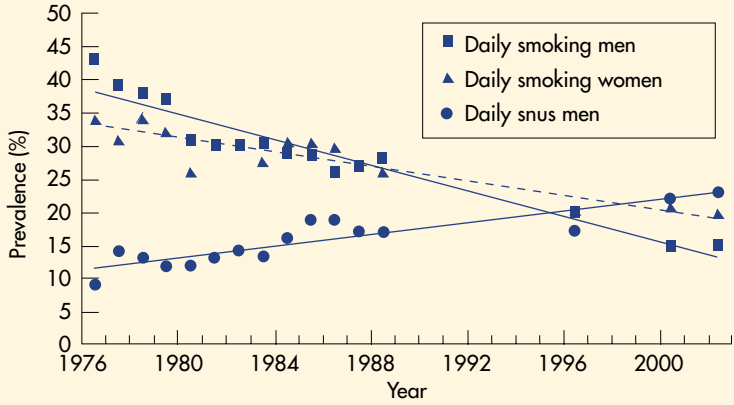
'Gateway' effects

There is no evidence that PN in its currently available forms encourages non-smokers to take up smoking (Gerlach et al., 2008; Klesges et al., 2003). This situation could change if PN was re-engineered to be more rapidly absorbed and produced higher blood nicotine, and if it were allowed to be marketed as a recreational nicotine product, like smoked tobacco. The current marketing of the e-cigarette in some countries may allow an assessment of the risks of more liberal regulation of the nicotine market, although the nicotine dose and delivery of currently marketed e-cigarettes may be too similar to existing PN cessation aids for a full assessment. The cost of the e-cigarette may also preclude its widescale uptake.

The Swedish experience

Snus is a traditional moist oral snuff used in Sweden. Snus use declined as cigarettes became popular. However, a marketing campaign that started in the 1970s reinvigorated the snus market and resulted in increased uptake among Swedish men, with as many Swedish men now using snus as smoking cigarettes (Ramström, 2000). The Swedish experience has been described as a natural experiment of tobacco harm reduction (Brandt, 2007; Henningfield and Fagerström, 2001) as the shift from cigarette smoking to snus use has occurred without the support of the Swedish health community.

Figure 9.2: Prevalence of daily smoking for men and women (ages 18–70 years) in Sweden 1976–2002 and prevalence of daily snus use for men (age 18–70 years) in Sweden 1976–2002

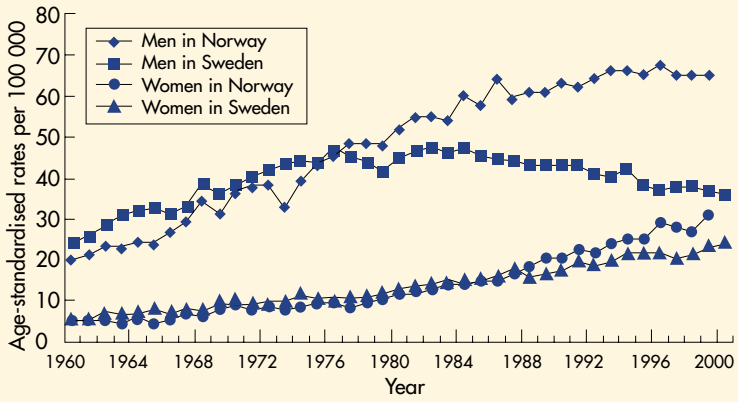


Source: Reproduced from Foulds et al., 2003.

The increase in snus use was accompanied by a decline in cigarette smoking from 40 % in 1976 to 15 % in 2002 (see Figure 9.2). Contrary to the gateway hypothesis, there were no increases in smoking among adolescent males, who were the heaviest users of snus. Instead, snus use appears to deter smoking initiation in young men and promote smoking cessation in

older men (Foulds et al., 2003; Furberg et al., 2005; Ramström, 2000). Most critically, the increase in snus use was accompanied by a decline in lung cancer mortality and the absence of an increase in either cardiovascular mortality or head and neck cancers (Foulds et al., 2003). The plausibility of a causal relationship between increased snus use and these good health outcomes was strengthened by the absence of any similar changes in smoking prevalence or lung cancer mortality in Swedish women, who did not adopt snus at the same rate as men (Foulds et al., 2003).

Figure 9.3: Lung cancer incidence for men and women in Sweden and Norway 1960–99 for age-standardised rates per 100 000 inhabitants based upon census population in each country



Source: Reproduced from Foulds et al., 2003.

Whether SLT serves as a gateway to smoking is a more contentious issue. The Swedish experience with snus contradicts the pessimistic view about the population impact of THR (Foulds et al., 2003) (see box on p. 263). The relationship between SLT use and smoking has been more varied in American studies. In some studies the same pattern has been reported as in Sweden (Ault et al., 2004; O'Connor et al., 2005). Other studies, however, have reported an apparent 'gateway' effect with young SLT users 'graduating' to smoking (Haddock et al., 2001). It is challenging to quantify how much smoking is attributable to prior SLT use because it is difficult to determine whether smokers who used SLT before cigarettes would have become smokers in the absence of SLT use. One analysis suggests that when the demographic and social factors associated with smoking initiation are taken into account, SLT does not appear to increase the uptake of smoking (Timberlake et al., 2009). In the United States, public health authorities may have also inadvertently encouraged SLT users to switch to cigarettes by claiming that the health risks of SLT are the same as those of smoking (Kozlowski and Edwards, 2005; Kozlowski and O'Connor, 2003; Waterbor et al., 2004).

'Dual use'

The use of PN to relieve nicotine withdrawal during periods of temporary abstinence is an approved use in some countries (for example, United Kingdom, Republic of Ireland, France, Austria, Denmark, Norway, Portugal, Brazil, Venezuela, New Zealand and Canada), as is its use to reduce smoking in preparation for quitting (ASH UK, 2008). Some studies have reported that users of PN often use it for purposes other than cessation (Hammond et al., 2008; Klesges et al., 2003). Such use does not appear to reduce quitting (Levy et al., 2007); indeed, such use may increase cessation in smokers who were not initially interested in quitting (Carpenter et al., 2004; Le Houezec and Sawe, 2003).

The tobacco industry has begun to market SLT for smokers to use when smoking is not permitted (Gartner et al., 2007a). This pattern of use could perpetuate smoking by reducing the incentive to quit provided by public smoking bans (Fichtenberg and Glantz, 2002). Alternatively, such use of SLT could lead some smokers to switch fully to SLT or even to quit tobacco use, as happens with PN. This pattern of short-term dual use as an intermediate step to full switching or quitting appears more common in Sweden than long-term dual use of SLT and cigarettes (Ramström and Foulds, 2006). It is a pattern that could be encouraged by a combination of policies, such as educating smokers about health risks, imposing differential tax rates on smoked tobacco and SLT products based on their relative harmfulness, and regulating the availability and accessibility of these products to favour SLT.

Ethical issues

Do public health practitioners have the ethical right to prevent smokers from being informed about THR products in order to reduce the possibility that THR may increase population nicotine use? Those who argue that smokers should not be told how to reduce their risks promote a paternalistic policy that sacrifices smokers' interests to the greater public good. Others argue that informing smokers about THR is an effective public health measure that properly respects their autonomy (Kozlowski, 2003; Kozlowski and Edwards, 2005; Waterbor et al., 2004).

Some opposition to THR reflects the belief that the goal of tobacco control policy should be the elimination of all nicotine use (for example, Pierce, 2002). Some opponents also argue that THR is morally wrong because it involves the long-term use of an addictive substance (Warner et al., 1997). These views contrast with the consequentialist ethical views of proponents who argue that the benefits of THR outweigh its harms (for example, Kozlowski, 2002).

The THR debate is complicated by the role of the tobacco industry whose interests conflict with those of public health. THR is seen as benefiting the tobacco industry by condoning continued tobacco use and thereby allowing the industry's continued existence (Bullen et al., 2006). Whilst the abolition of the tobacco industry would arguably be preferable, most THR proponents see this as an unrealistic goal, at least in the short to medium term (Hall and Gartner, 2009) and accept that enabling the tobacco industry to become part of the solution could accelerate change in the nicotine market over time.

Options for promoting tobacco harm reduction

Regulating the harmfulness of tobacco products

Mandating standards for RIP of cigarettes is unlikely to cause harm and may reduce cigarette-related fires. It is much less certain whether mandated maximum levels of key toxins in cigarette emissions will reduce aggregate harm because of the risk that any gains will be offset by compensatory smoking, higher levels of other toxins, and/or the impression of a significant reduction in harm. It will in any case take decades to assess. Mandated standards for toxins, such as tobacco-specific nitrosamines, in SLT should be less problematic to implement because the feasibility of this strategy has already been demonstrated (Österdahl et al., 2004; Stepanov et al., 2006) and, on Swedish experience, it is likely to minimise oral cancer risk.

Information about THR products

Harm reduction could be promoted through advising smokers to use less harmful products, such as LNSLT and PN. This could be done via product warning labels on cigarettes and less harmful tobacco and nicotine products that indicate the relative harmfulness of each product. This option is currently most relevant for non-EU countries and Sweden because of the sales ban on most of these products in EU Member States. Information provided by governments and health authorities could also clearly indicate the relative harms of each product, rather than misleadingly suggesting that all tobacco products are equally hazardous (Kozlowski, 2003; Kozlowski and O'Connor, 2003; Waterbor et al., 2004).

Regulation and promotion of THR products

Smokers who fail to quit after obtaining cessation assistance could be encouraged to use PN as a long-term alternative (Kozlowski, 2002; Kozlowski et al., 2003). This is one of the few THR strategies supported by the majority of US tobacco control advocates (Warner and Martin, 2003) and advocated by the Royal College of Physicians in the United Kingdom (Royal College of Physicians, 2007) and experts in the EU (ASPECT Consortium, 2004). It would probably have limited public health impact if it was aimed solely at high-risk smokers who failed to quit, because only a minority of these smokers seek help to quit, and probably few of whom find existing forms of PN attractive (Stratton et al., 2001; Warner et al., 1997).

In order to have a larger public health impact, THR requires as many smokers as possible to switch to either PN or LNSLT. The Swedish experience suggests that LNSLT may be more likely to achieve this goal than current forms of PN as more smokers in Sweden have switched to LNSLT than PN (Foulds et al., 2003; Ramström, 2000). This could change if regulators allowed more attractive forms of PN to be developed and marketed to smokers. In EU countries other than Sweden, consideration could be given to relaxing the sales ban on non-smoked, non-chewed oral tobacco products. More equal competition between cigarettes and less hazardous nicotine delivery devices could be achieved by making it harder to introduce new cigarette-like tobacco products and easier to introduce and promote the use of non-smoked THR products and recreational PN products (Stratton et al., 2001; Warner et al., 1997). Thought should be

given to the regulation of products that fall between current PN products and cigarettes. The e-cigarette could provide a test case for developing a more flexible regulatory structure that works in favour of public health, by regulating nicotine-containing products according to criteria that consider the relative harmfulness of each product.

A graduated policy sequence

We believe that exploring the use of LNSLT for THR is the most promising route facing regulators at the moment. The development of faster-acting PN is likely to take some time and e-cigarettes are probably too similar to PN products. The following steps could be used to explore the public health potential of THR using LNSLT in those countries in which their production and sale is prohibited, such as the EU, Australia and New Zealand (Commonwealth of Australia, 1974; European Parliament and Council of the European Union, 2001; Parliament of New Zealand, 1990).

First, the utility of LNSLT for smoking cessation could be cautiously trialled among smokers who had failed to quit with the use of PN and other smoking cessation medications by encouraging them to switch to LNSLT rather than return to smoking. Evaluations of this approach would provide information on how attractive these products may be to inveterate smokers.

Second, relaxation of PN product regulation could encourage the use of existing PN for long-term substitution if smokers fail to stop, and enable the delivery of nicotine doses in ways more like SLT, thereby encouraging smokers who failed to quit smoking to use these products instead.

Third, if there was sufficient interest in switching to LNSLT among inveterate smokers, permitting restricted sale of LNSLT products to these smokers (e.g. from specialist tobacconists) could provide an alternative to continued smoking. Legislation could impose differential taxes to reflect the relative harmfulness.

Fourth, the impacts of the sale of these products on: population smoking cessation rates; all forms of tobacco use among youth; and tobacco industry marketing should be rigorously evaluated.

Conclusions

Public smoking bans and mandatory reduced ignition propensity standards for cigarettes are strategies that reduce tobacco-related harm to non-smokers and should be implemented as a priority. The most promising strategy for reducing harm to tobacco smokers is to encourage smokers who are unable or unwilling to quit to switch to pharmaceutical nicotine or low nitrosamine smokeless tobacco products. There is good support for this policy from epidemiological studies in Sweden. Modelling studies indicate that this would very substantially reduce the risks of tobacco use. Nonetheless, this remains a controversial policy because the view of some in the tobacco control community is that our policy goal should be

elimination of all nicotine use. A major barrier to its implementation is that many states in the EU ban the sale of these products, and proposals to remove these bans have been opposed because of concerns that THR may increase the uptake of tobacco smoking and the harm that it causes.

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