

Tobacco smoking, harm reduction, and nicotine product regulation



John Britton, Richard Edwards

Cigarette smoking is highly addictive, widely prevalent, and very hazardous. Smoking killed 100 million people in the 20th century,¹ and is predicted to kill 1 billion in the 21st century.¹ Worldwide, there are about 1.1 billion smokers, and there are expected to be 1.6 billion by 2025.² Half of all smokers will die prematurely, unless they stop smoking.³

In the 50 years since the health risks of smoking first became widely recognised, the political and public health responses to smoking at national and international levels have been grossly inadequate. Although the main components of current recommended tobacco control policy^{4,5} (panel 1) have changed little from those first proposed in 1962,⁶ they have still not been widely applied⁷ and, in any case, achieve a reduction in smoking prevalence of typically about 0.5,^{8–10} and at best 1.0,¹¹ percentage point per year. Full implementation of these policies might be sufficient to prevent smoking in countries in which the smoking epidemic has yet to take hold, but this is only part of the necessary solution for countries with an established smoking population. In the UK, for example, where 24% of adults still smoke,¹² at a reduction rate of 0.5 percentage point per year it would take more than 20 years to reduce the prevalence of smoking by half. Even then, there will be more than 5 million smokers in the UK alone, predominantly from the most socioeconomically disadvantaged sectors of society,¹³ bearing a vast burden of avoidable morbidity and mortality. In fact most of the 150 million deaths from smoking that are expected over the next 20 years will occur in current smokers who are alive today. Since millions of these are unlikely to stop smoking in the near future, we argue, on the basis of a new report from the Royal College of Physicians,¹⁴ that in addition to conventional tobacco control policies, the application of harm reduction principles to nicotine and tobacco use could deliver substantial reductions in the morbidity and mortality currently caused by tobacco consumption. However, achievement of these reductions will require radical structural reform of the way in which nicotine and tobacco products are regulated and used.

Most people continue to smoke because they are addicted to nicotine.¹⁵ Inhaled tobacco smoke is especially addictive because it delivers high doses of nicotine to the brain very rapidly,¹⁵ and because nicotine confers rewarding properties on other stimuli associated with smoking.¹⁶ Exposure to high nicotine concentrations at an early age might also determine the intensity of addiction through effects on nicotinic receptor numbers in the brain.^{17,18}

Nicotine is available from a wide range of products: smoked tobacco, of which the cigarette is pre-eminent;

medicinal nicotine, currently available as nicotine replacement therapy; and smokeless tobacco products, of which oral tobacco is the most widely used. Cigarettes and other smoked tobacco products, such as cigars and pipes, are by far the most harmful because they deliver nicotine in conjunction with hundreds of other toxins and carcinogens. It is these toxins and carcinogens that are mainly responsible for the major adverse health effects of smoking—particularly lung cancer, chronic obstructive pulmonary disease (COPD), heart disease, and stroke. By contrast, the safety record of medicinal nicotine products is very good.

Nicotine is not a recognised carcinogen and does not cause COPD. It has effects on blood pressure and heart rate that might be expected to increase risk of cardiovascular disease,¹⁹ but these effects are not seen in practice.^{19–21} Nicotine reduces placental blood flow, but medicinal nicotine does not reduce birthweight as much as smoking does.²² Therefore, although medicinal nicotine is not wholly safe, for practical purposes, and certainly when compared with smoking, the hazard associated with medicinal nicotine use is very low.

The risk profile of smokeless tobacco products is more wide ranging and includes oral cancer, other gastrointestinal cancers, and heart disease.²³ These risks vary substantially between different smokeless products, but are low for products low in nitrosamine, such as Swedish snus. Snus use increases the risk of pancreatic cancer,^{24,25} but not of lung²⁵ and oral cancers,^{25,26} or COPD. Use of other smokeless products has been linked to an increased risk of cardiovascular disease,²⁷ but snus has little, if any, effect.²⁶ The risk of adverse effects associated with snus use is lower than that associated with smoking,²⁸ overall by an estimated 90%.²⁹ Whatever the true overall hazard, use of low nitrosamine smokeless products is clearly substantially less harmful than tobacco smoking.

The rationale behind harm reduction is that although the best option would be to avoid the harmful behaviour

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Division of Epidemiology and Public Health, University of Nottingham, City Hospital, Nottingham, UK (Prof J Britton MD); and Department of Public Health, University of Otago, Wellington, New Zealand (R Edwards MD)

Correspondence to:

Prof John Britton, University of Nottingham, Clinical Sciences Building, City Hospital, Nottingham NG5 1PB, UK
j.britton@virgin.net

Panel 1: Essential components of tobacco control policy⁴

- Use of price, tax increases, or both to reduce consumption
- Prevent smoking in public places and in workplaces
- Health warnings on packets of tobacco products
- Health promotion and public information campaigns
- Prohibition of advertising and other promotion
- Provision of smoking cessation services
- Prevention of smuggling
- Prohibition of sales and reduction of availability to people under age 18 years

completely, the next best option, if the behaviour is likely to continue, is to ensure that the harm caused is kept to a minimum. A logical harm reduction approach for the millions of smokers who are unlikely to achieve complete abstinence in the short-term or medium-term future is to promote the substitution of tobacco smoking with an alternative, less hazardous means of obtaining nicotine.

The least hazardous alternative is medicinal nicotine. Since their development around 20 years ago, medicinal nicotine products have been promoted as cessation therapies, for use as short-term substitutes for smoking in the context of attempts to stop smoking. In clinical trials, use of medicinal nicotine increases the likelihood of stopping smoking by around 80%,³⁰ but the absolute increase in quit rates is modest because the baseline success rates are low. Thus, in a quit attempt using medicinal nicotine in conjunction with best-practice behavioural support, only about one in five smokers succeed in stopping for 6 months.^{31,32} These products are not strongly effective or competitive substitutes for smoking because they deliver nicotine in lower doses and more slowly than do cigarettes. Medicinal nicotine products are also much less available than cigarettes in most countries; are marketed and advertised as smoking cessation therapies (rather than long-term smoking substitutes); are expensive to buy; and are widely perceived as harmful by smokers.³³

Anecdotally, smokeless tobacco products have a history of use as temporary substitutes for smoking by occupational groups, such as coal miners, who cannot smoke while at work. In Sweden at least some of the substantial reduction in daily smoking prevalence in the past 20 years or so seems attributable to substitution of smoking by snus use, especially by men.³⁴ Although there has been uptake of regular smoking by smokeless users who might not otherwise have smoked (gateway progression), the extent to which this progression has happened is much less than that from regular smoking to snus.³⁵ However, this pattern of use has not been replicated elsewhere. In the USA, where other forms of smokeless tobacco have also been available for some time, the prevalence of smokeless tobacco use has fallen progressively in conjunction with that of smoking³⁶—to below 5% in men and 1% in women by 2000.³⁶ In Norway, snus use has increased recently to about 11% of all men, and 18% of men aged 16–24 years, with no evidence yet of effect on the rate of decline in smoking prevalence [Erik Dybing, personal communication].

The effectiveness of smokeless tobacco as a substitute for smoking, and the relative extent to which wider availability and promotion of smokeless products would result in gateway progression into or out of smoking, are controversial topics. Some argue that health professionals should not condone any use of nicotine, and also that encouraging use of alternative nicotine products, particularly smokeless tobacco, would invite abuse of the

market by their commercial producers. Others argue that if smokeless products are an effective and less hazardous substitute for smoking it would be in the public interest to harness that potential to public health benefit, particularly if the Swedish pattern of predominant gateway progression from smoking to smokeless use could be realised in other countries.

The arguments are finely balanced. However, on the basis of the Swedish data we believe that the potential role of smokeless products at least merits further consideration and investigation to find out whether and to what extent these products can act as substitutes for smoking; whether tobacco products are more effective smoking substitutes than medicinal nicotine; and, if so, whether the product characteristics responsible can be identified and used to develop more acceptable low-risk medicinal products. We also believe that the development of such products should happen only within an overall strategy of radical reform of the regulatory systems that apply to nicotine products, including much stronger regulation of smoked tobacco, to ensure that the harm caused by all nicotine use is kept to a minimum.

Effective harm reduction strategies, and particularly the option of providing nicotine without smoke as an acceptable long-term or even lifelong substitute for smoking, have not been widely applied to tobacco smoking. The pharmaceutical companies have not evidently engaged in the development of medicinal devices that are strongly competitive with cigarettes. Use of smokeless tobacco is actively discouraged by many health professionals and by WHO.³⁷ This opposition to smokeless products is despite predicted benefits from modelling studies. If a product such as snus were marketed in the USA with a health warning stating that it is addictive and might increase risk of disease, but that it is substantially less harmful than cigarettes, the prevalence of smoking in the USA would be reduced by an estimated additional 1.3% to 3.1% over 5 years³⁸ (ie, by about 0.44% per year). In a study modelling the effect of the introduction of snus as an alternative to smoking in Australia, the investigators concluded that the overall net effect would be beneficial to public health.³⁹

We believe that the absence of effective harm reduction options for smokers is perverse, unjust, and acts against the rights and best interests of smokers and the public health. Addicted smokers have a right to choose from a range of safer nicotine products, as well as accurate and unbiased information to guide that choice.⁴⁰ There are, however, several obstacles to the development of an effective harm reduction strategy for tobacco smoking in the UK and many other countries, and particularly to the development and marketing of more effective medicinal products. Paramount among these is the current system of regulations that apply to different nicotine products in most countries.

A major reason why tobacco products have remained exempt from consumer protection regulation in most

countries is that the logical and proportionate application of existing regulations would result in their immediate withdrawal from sale. Thus, the most dangerous and addictive nicotine products remain only slightly regulated, in great disproportion to their hazard, and are freely available and widely used. Tobacco companies are also free to develop or modify, and bring to market, new smoked tobacco products and other tobacco derivatives with little regulatory control.

By contrast, medicinal nicotine products, which are the safest source of nicotine, are generally subject to the highest levels of regulation since they are generally classified as drugs. This is almost certainly a major disincentive to new product development and innovation, and to market competition to create better and more effective cigarette substitutes. The present regulatory system also discourages innovation through the real or perceived likelihood that most effective smoking substitutes, which would almost certainly be more addictive than the present range of medicinal products, would be subject to even stricter controls on marketing and supply, or perhaps even prevented from coming to market.

Current regulation of smokeless tobacco products is also inconsistent, since most products are subject to minimal regulatory controls, whereas the supply of snus, which is one of the least hazardous of such products, is prohibited in most European countries. Extension of that prohibition across the range of smokeless products would resolve this inconsistency, but at the expense of the loss of a potentially effective alternative to smoking. On the other hand, removing the prohibition on snus would deal the tobacco industry a free hand to exploit the smokeless tobacco market with apparent endorsement by legislators. Neither of these options is ideal; hence, an alternative approach, designed to benefit public health rather than industry profit, is needed.

Our argument is that nicotine products should all be regulated rationally in relation to each other, in proportion to their level of hazard, in a system designed to reduce the overall harm caused by nicotine dependence and use. The regulatory framework should promote complete cessation of nicotine product use as the preferred option, but also encourage existing smokers who are unable to stop smoking to adopt a less hazardous source of the drug. An obvious prerequisite of this change would be an acceptance by society in general, and particularly by health professionals, that use of low-hazard nicotine products might be prevalent for many years.

Achievement of a rational nicotine regulatory framework needs a radical overhaul of existing systems to encourage the innovation, development, and use of new medicinal nicotine products at the least hazardous end of the spectrum, and to achieve the fastest possible reductions in use of products at the smoked tobacco extreme. The regulatory framework should therefore

Panel 2: Suggested roles and functions of a national nicotine regulatory authority

Functions at initiation

- Baseline measurement of all current nicotine product use
- Ensure full implementation of conventional tobacco control policies (panel 1)
- Permissive licensing of medicinal nicotine products for use as smoking substitutes
- Substantial relaxation of restrictions on marketing and sale of medicinal nicotine products
- Removal of tax on medicinal nicotine products
- Communication of objective health risk information for nicotine products and promotion of harm reduction principles to smokers and the public
- Establishment of ground rules for monitoring the use of health messages in promoting the use of lower hazard nicotine products as substitutes for smoking
- Imposition of generic packaging for all tobacco products
- Prohibition of retail display of smoked tobacco products
- Strong graphic health warnings on smoked tobacco products
- Setting of tax and consequently retail price of all nicotine products in relation to their probable relative risk to health
- Prohibition of all sale of nicotine products to individuals under age 18 years
- Introduce licensing of retailers of all smoked tobacco products
- Assume responsibility for overseeing nicotine product delivery and toxicity monitoring
- Mandate the introduction of reduced ignition propensity cigarettes
- Take expert advice on how current restrictions on smokeless nicotine products could be reformed to public health benefit

Continuing functions

- Regular monitoring of trends in nicotine product use, promotion, and availability
- Monitoring of effect of licensing and marketing relaxation on medicinal nicotine use, and revision as necessary to promote public health
- Progressive increases in tax on the most hazardous products
- Continued promotion of health information on different nicotine products and development and monitoring of mass communication strategies to prevent uptake, promote cessation, and reduce harm
- Progressive reduction in retail licences for smoked tobacco products
- Monitoring and policing of illicit and underage tobacco and nicotine trade
- Work with the commercial sector to promote competition and innovation in the medicinal nicotine market
- Monitoring and prevention of smoked product placement and new methods of marketing (eg internet, viral marketing)
- Act on expert advice to set framework for licensing of low-hazard smokeless products and possible test marketing
- Progressively incentivise minority, high risk smokeless tobacco users to quit or else migrate to safer products
- Identify and respond to new developments or threats to health from new or existing product development or promotion
- Control of expenditure on tobacco control interventions to ensure evidence-based and cost-effective interventions are used
- Support nicotine regulation and tobacco control approaches in resource-poor countries

apply the levers of affordability, promotion, and availability in direct inverse relation to the hazard of the product, thus creating the most favourable market environment for the least hazardous products while also strongly discouraging the use of smoked tobacco. The anomalies that inhibit market competition

to develop new and better rapid delivery, user-friendly medicinal nicotine products (eg, inhaled nicotine) that can compete with cigarettes for long-term use need to be removed; and there needs to be more widespread promotion and sale of existing or new lower-hazard products. The regulatory system should include a robust surveillance function so that potentially counterproductive trends in marketing or use of all nicotine products—particularly those that are tobacco-based—are promptly detected and resolved. The regulatory system should ensure that alternative nicotine products, medicinal or tobacco-based, are marketed with appropriate health information and, where appropriate, professional endorsement. Nicotine product regulation should also be applied over time to ensure that smoked tobacco products are subject to progressively increased restrictions—on availability and marketing, with the long-term objective of reducing and, in due course, eradicating all smoked tobacco use.

The options for rationalising nicotine regulation include making all nicotine product regulation the responsibility of an existing agency, such as a food or drug regulation agency, or by coordination and rationalisation of the activities of the different agencies that regulate nicotine products. We conclude, however, that meeting the challenges of implementing effective tobacco control and nicotine harm reduction policies (panel 2), both nationally and internationally, needs the creation of dedicated, autonomous, and fully resourced national (and where appropriate international) nicotine and tobacco product regulatory authorities. This approach might be unrealistic in many resource-poor countries, and less of a priority in those at the earliest stages of the smoking epidemic, but that is certainly not the case in those that already have a substantial population of established smokers, and hence the most to gain from this strategy.

The consequence of failing to intensify tobacco control efforts, and to address the current imbalance in nicotine product regulation, will be the unnecessary perpetuation of current smoking by millions of people, especially in disadvantaged communities, and a continued epidemic of avoidable death and disability. Specifically, cigarettes and other smoked tobacco products will continue to be freely available with few restrictions on their safety or content; the medicinal nicotine market will continue to focus on low-addiction, low-dose, low-effectiveness products while also stifling competition and innovation; and the current irrational regulation of smokeless products will continue. Most of the millions of smokers alive today will therefore continue to smoke tobacco, and half will die as a result.

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