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Editorial

Tobacco harm reduction: How rational public policy could transform a pandemic

Abstract

Nicotine, at the dosage levels smokers seek, is a relatively innocuous drug commonly delivered by a highly harmful device, cigarette smoke. An intensifying pandemic of disease caused or exacerbated by smoking demands more effective policy responses than the current one: demanding that nicotine users abstain. A pragmatic response to the smoking problem is blocked by moralistic campaigns masquerading as public health, by divisions within the community of opponents to present policy, and by the public-health professions antipathy to any tobacco-control endeavours other than smoking cessation. Yet, numerous alternative systems for nicotine delivery exist, many of them far safer than smoking. A pragmatic, public-health approach to tobacco control would recognize a continuum of risk and encourage nicotine users to move themselves down the risk spectrum by choosing safer alternatives to smoking – without demanding abstinence.
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Introduction

In efforts aimed at reducing the risk of death, injury or disease from any behaviour there are four broad areas of possible intervention. These include efforts to prevent the behaviour ever taking place, efforts aimed at ending the behaviour, efforts aimed at preventing the activity from harming third parties and efforts aimed at reducing the risks of those who engage in the behaviour. The interaction of these four pillars of public health intervention can be seen in everything from pharmaceutical policy, the rules of sport, automobile regulation, workplace safety standards and food processing and preparation regimes.

Interestingly, when dealing with issues of sexual behaviour and the use of licit and illicit drugs there is often strong opposition to efforts aimed at the reduction of risks among those who will engage in the behaviour in question. This schism appears to be the result of a persistent tension between a rational, scientific program and a behavioural, moralistic approach (Brandt, 1987, p. 182).

The conflict over means traces to a fundamental disagreement about aims: Is the purpose of an intervention to make people healthier or safer? Or is it to create better moral souls, to make people less "bad"? The availability of 'risk reduction' among accepted interventions can be seen as a key distinguishing feature between scientific public health interventions whose aims are pragmatic, and moralistic ones, whose aims are impossible to measure.

If the goal of public policy interventions on tobacco is to achieve the greatest possible reduction in deaths, injury and disease, then it is necessarily pragmatic. Therefore, it is necessary for policy makers to seriously consider the role of risk reduction for continuing users of tobacco/nicotine products. This does not mean that risk reduction strategies must replace other strategies any more than protection of third parties needs to replace cessation strategies. An ideal public health approach rationally combines the various possible interventions in pursuit of the greatest achievable reduction in deaths, injuries and disease.

The case for applying harm reduction strategies to public health interventions on tobacco

It is estimated that cigarette smoking resulted in the deaths of roughly 100 million people in the last century, and that at current trends in consumption will kill 10 times that many this century (Peto & Lopez, 2001). Roughly half of long-term smokers will die as a direct result of diseases caused by their smoking, and half of those deaths will occur during

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middle age. In terms of drug related deaths cigarettes dwarf the toll from other drugs.

The primary reason for smoking cigarettes is to obtain nicotine. The cigarette is an effective – but almost uniquely hazardous – delivery device for the drug, nicotine. As with the use of other drugs the pursuit of nicotine can be attributed to a combination of recreation, addiction and self-medication. The extent of each of these motivations will vary over time and between smokers just as the reasons behind the pursuit of alcohol or caffeine will vary between consumers and change over time.

We stress that nicotine is the primary cause of tobacco consumption. But it is not the nicotine that causes the harm: the inhalation of tobacco smoke is responsible for the pandemic of cancers, heart disease, respiratory diseases and other deadly results of tobacco consumption. Nicotine itself is comparatively benign. A fatal dose of nicotine would require roughly 60 mg for an average person, but, as with a fatal dose of caffeine, such a quantity is far more than is sought or attained by consumers (Fagerstrom, 2005). Were the world's 1.3 billion cigarette smokers acquiring their nicotine from clean delivery systems rather than through repeated inhalation of smoke, nicotine use would likely not rank much higher than caffeine use as a public health priority.

Given the projected death rates associated with smoking and the fact that these deaths can largely be explained by the recognition that 'it's the smoke, stupid', harm reduction interventions are essential. The case for harm reduction is made all the stronger when one considers that there already are various alternatives to cigarettes that are markedly less toxic and clearly acceptable to large numbers of consumers (See Table 1).

In Sweden a smokeless tobacco product known as 'snus' has come to dominate the tobacco market, with sales rising as cigarette sales have fallen. Many former smokers have switched to snus, far more males use snus than smoke, and snus sales amongst females – which had long lagged male usage – is now evidently growing rapidly. As a result Sweden has the lowest level of tobacco related disease in males among OECD countries, and has reported male smoking prevalence that has now hit single digit percentages in parts of the country.

Table 1
Examples of western world smoke-free alternatives to cigarettes

Transdermal nicotine patch (of various strengths and regimens)
Nicotine chewing gum (range of flavours and 2 strengths)
Nicotine inhaler ['puffers']
Nicotine nasal spray
Medicinal nicotine lozenges (range of flavours and 3 strengths, including sublingual)
Ultra-low nitrosamine tobacco lozenges [Ariva, Stonewall]
Swedish snus
Hard tobacco [Oliver Twist]
Moist snuff [Skoal, Copenhagen]
Spit-free tobacco pouches
Chewing tobacco

Norway and the United States have also in recent years seen a rapid increase in sales of smokeless tobacco products, and these sales trends are ascribed at least in part to growing awareness that non-combustible products are massively less hazardous than smoking (Morgan Stanley Research North America, 2006). Many countries also now have experience with medicinal nicotine (gum, patches, lozenges and 'inhalers') meeting the needs of smokers not just for short-term cessation efforts but for longer term use as a replacement for smoking.

Smokeless tobacco products do cause disease – but at very low rates compared to cigarettes. The disease risk of smokeless tobacco can be made lower still through changes in manufacturing techniques that reduce toxins such as tobacco-specific nitrosamines. It has been estimated that modern smokeless tobacco products are least 90%, and perhaps closer to 99%, less deadly than smoking cigarettes (Levy et al., 2004; RCP, 2002). While there is popular recognition that 'smokeless tobacco causes oral cancer' few recognize that the risk of oral cancer from the sort of high nitrosamine smokeless products that used to be on Western markets (and upon which the oral cancer risk was based) was actually considerably lower than the risk of the disease from smoking. Nor is there widespread recognition that low nitrosamine products such as Swedish snus do not appear to cause oral cancer at all.

Medicinal nicotine products appear to be significantly less hazardous even than smokeless tobacco. These products have been subjected to rigorous evaluation by drug regulatory authorities in many countries and been in use for decades. The major risk of such products is not inherent dangers, but the fact that they are not used at a sufficient dosage for a sufficient length of time and so result in users reverting to cigarette smoking. In part this underutilization of medicinal nicotine can be attributed to government regulations that restrict the nature and availability of such products out of an expressed concern that there is a potential for 'abuse'. This cautious approach to medicinal nicotine, combined with assorted attacks on tobacco and nicotine that demonize nicotine and fail to distinguish inter-product risks helps to explain why a vast number of smokers incorrectly believe that nicotine itself causes cancer.

Current cigarettes and cigarette-like products are at the high end of a continuum of risk. Moving down the continuum, but still very likely to be high risk are alternative 'cigarette' designs that primarily heat rather than burn tobacco. These products are undoubtedly more hazardous than non-combustion-based delivery, but very likely less hazardous than smoking. Even tinkering with the toxicity levels of cigarettes, through such things as lowering nitrosamine levels in the tobacco leaf, has potential to reduce mortality. Non-combustion products, and particularly low nitrosamine smokeless tobacco and medicinal nicotine products are at the least hazardous end of this risk continuum.

The relative safety of smokeless tobacco and other smoke-free systems for delivering nicotine demolishes the claim that

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abstinence-only approaches to tobacco are rational public-health campaigns. This is not to say that all smokers would or should necessarily switch to snus or current forms of medicinal nicotine. But it does mean that cigarettes need not be seen as the only way consumers can obtain their nicotine. This also means that it need not be that the only alternative to continued cigarette smoking must be complete cessation of nicotine in any form.

Alternative nicotine delivery devices will still entail risks. But as nothing in life is devoid of risks it is nonsensical to dismiss an alternative to a tremendously harmful activity by claiming the alternative is not absolutely 'safe', or to claim that the pursuit of a less hazardous alternative implies that the alternative is "virtually harmless" (Gray & Henningfield, 2006).

As more alternatives to conventional cigarettes are considered it is clear that there is a wide range of possibilities on the continuum of risk. The variation of risk among interchangeable products creates a strong basis for regulatory intervention aimed at shaping the market. It should also be the basis for accurate communications to consumers. The fact that alternative products can meet the needs of some significant number of those who would likely otherwise smoke cigarettes also raises key issues about just what sort of products might be available, what sort of information consumers can be given about relative risks and what sort of policy environment could achieve maximum public health benefits through the greatest transition of smokers to less toxic alternatives.

The critical issue in looking at consumer safety, and one that makes tobacco/nicotine an ideal area for harm reduction interventions, is that smokers are capable of moving down the risk continuum when offered alternative products and accurate information on relative risks. A pragmatic goal would be to move current smokers as far down the continuum of risk as possible, without depriving consumers of all choice. The consumer who rejects (or cannot achieve) abstinence but will use a product that reduces risk by 90% should not be prevented from making that preferred choice. Indeed, it is exactly the forced choice between smoking and abstinence that reinforces the current dominance of cigarettes.

Fitting harm reduction into existing public health interventions on tobacco

Comparing tobacco control interventions with efforts that have historically been directed at reducing the toll associated with other potentially dangerous consumer products reveals how tobacco and the harms of smoking it, are positioned in the consumer culture. With products such as food, pharmaceuticals, automobiles, electrical goods, toys, sports equipment and caffeine products, reform movements embraced risk reduction. Though this often came after a fight between pragmatists and 'absolutists' (Young, 1989), the transition was not nearly as drawn out or heated as is currently the case on tobacco/nicotine. More than 40 years after the U.S. Surgeon General's Report on the Health Consequences of Smoking opened the protracted public-health campaign to stamp out smoking-related disease, no public-health approach to tobacco has emerged that can fully counteract smoking-promoted morbidity and mortality. While many tobacco-control interventions have reduced smoking rates and prevented millions of deaths, that success is limited: Even today, policy makers refuse to deal directly with the nature of nicotine itself by giving viable alternative delivery systems to smokers. The result is that millions of tobacco users, unable to quit, are not encouraged – or simply not told – that they might be safer by moving down the "risk continuum" to an alternative nicotine-delivery system.

Current debates within tobacco control circles more closely resemble those found on issues such as alcohol, illicit drugs and sexual practices rather than the dangers of consumer items. In regard to substance use and sex, the pragmatism that marks the typical harm-reduction approach to product safety collides with moralistic approaches to human behaviour. The conflicts over drug use, especially in the context of deadly viral infections potentially spread through drug delivery systems (i.e., needle and syringe), are well known. In many countries, battles still rage over what to tell people – especially adolescents – about sex and in particular whether to encourage them to use condoms or simply to abstain from sex outside of marriage. While tobacco use has not yet elicited the same emotional intensity as have concerns about addiction and teen sex, the failure to establish a rational and evidence-based public-health approach to tobacco use can be traced to similar sorts of pragmatism–moralism debates.

And the situation with tobacco might be even more complicated than the debate over illicit drug use. One of the challenges facing tobacco control efforts is that the advocates pushing for social change include both public health pragmatists who are genuinely concerned about reducing tobacco-associated illness and death caused by smoking and moral absolutists whose concern is with the bad habit of substance (nicotine) use. They find common ground on elimination of smoking and doing battle with the tobacco companies. But, as seen in the history of the Pure Food movement in the United States in the 1800s it might be impossible to get absolutists to endorse risk reduction interventions. Those with an abstinence-only view on nicotine (or tobacco) might never change their view regardless of the science, as their views are possibly not actually based on scientific principles any more than the Christian Right's opposition to condoms is primarily based on science.

Can advocates of change in existing policies work together without undermining each other? If so, how? We see two ways in which efforts to reduce tobacco harms are unusual, even in the context of public-health approaches to use of other substances such as heroin or alcohol.

For one, the nature of the marketplace and the increasingly rapid dissemination of information of interest to consumers will undoubtedly see an acceleration of market changes that

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will likely marginalize those tobacco control advocates who adhere to an abstinence-only orientation (Meier & Shelley, 2006). That still leaves those who simply do not yet recognize that risk reduction is, along with prevention, cessation and protection of third parties, one of the four pillars of public health interventions.

The other is that, thus far, tobacco harm reduction has not been backed by the liberal public health establishment. In other contexts, the liberationist and social-justice sentiments of the public-health profession worked in favour of promoting harm-reduction interventions for sex-related harms (condoms) and drug-injection-related harms (syringe exchange), rather than insist that people cease engaging in activities that are potentially risky but impossible to eradicate. To a pragmatist – that is, to the public-health professional – the reason for a behaviour is less important than the fact that the behaviour is going to continue. The public-health profession supported the harm-reduction stance on sex and illicit-drug use even before the safety of those interventions had been established. With tobacco, by contrast, the public-health profession has yet to support tobacco HR despite the strong, consistent, and increasingly extensive evidence that many alternative nicotine delivery systems would be safer than smoking.

An understanding of the public-health profession's position is important, because its voice would sound loud in the policy debate were it to renounce its support of cessation-only approaches. We see two ingredients to the public-health establishment's reluctance to embrace the concept of a continuum of risk and advocate non-cessation approaches for nicotine users.

First, the public-health establishment, at least in the U.S. where much of the policy fight is centred, is inclined to be distrustful of big business in general and Big Tobacco in particular. Two of the foundations of public health, occupational hygiene and worker safety, were built on direct opposition to industry; another, environmental monitoring and maintenance, has depended on advocacy to overcome industry standards that tolerated pollution. And the collusion of private business with government regulators that has produced serious public-health disasters – the Triangle fire in New York, the Bhopal disaster in India, mad cow disease in the U.K. – increases the profession's antipathy.

Second, the tobacco industry has played into the hands of its critics by its attempts to suppress information on the harms of smoking and cover up evidence of its own awareness, from early on, that it was making an intrinsically hazardous product.

The paradoxical, and lamentable, outcome of the public-health profession's anti-industry stance is that government and non-profit public-health agencies will generally not fund the research that would define the continuum of risk for nicotine delivery devices, and thereby allow for rational and evidence-based decision making on behalf of the public's health. Instead, in the U.S. (whose research budget dwarfs other countries'), virtually the only substantive research on alternative delivery systems now being carried out is funded by industry: research on smokeless tobacco products is financed by the tobacco companies, and research on nicotine replacement is financed by the pharmaceutical industry. To public-health advocates whose idée fixe is that industry is singularly self-interested, venal, and treacherous, these funding streams serve to discredit the researchers who are doing what would, otherwise, be the essential work of determining how best to serve the public's health. The consequent situation is this tautology: the only nicotine- or tobacco-related research that is recognized as valid is research funded by the government or non-profits; the government and non-profits will fund only research on smoking cessation; only smoking cessation is a valid public-health intervention.

Using policy levers to reduce the risk of tobacco/nicotine use

The potential for tobacco harm reduction interventions is clarified by examining how risk reduction strategies have been applied elsewhere. The long battles to establish regulations pertaining to the manufacturing of food products or to replace 'snake oil' with science-based pharmaceutical products offer examples of how advances in science and a proliferation of alternative products can combine with changing corporate vested interests and political pressure to fundamentally 'morph' a market. The fundamental change with respect to pure foods and pharmaceuticals did not come with legislation per se (e.g., the U.S.'s Food and Drug Act of 1906), but from two broader cultural phenomena: the growth and professionalization of the craft of medicine, and changes in the social contract that demanded more public responsibility from private manufacturers (with concomitantly expanded compliance by the courts). In America, the medical trade advocated for greater regulation of products having to do with health so that it might dominate the market in health-risk avoidance. The movement for purer foods developed in tandem with awareness of nutritional public health, positioning food regulation across both the medical and consumer arenas. Thus, the role of both the health-care industry and the public-health agencies was essential to the development of policies that reduced food- and prescription-drug-associated harms.

The example of food and pharmaceuticals might be promising for nicotine regulation, since nicotine remains a legal drug and tobacco is a consumer product with recognized appeal. But it also highlights the importance of swaying the medical and public-health professions to embrace harm reduction for nicotine users. And, the need to implement tobacco regulation in ways that will cohere with evidence-based public-health strategies.

There are many regulatory strategies that could be reasonably expected to reduce the present levels of tobacco related morbidity and mortality. A key step would be measures that would put the most hazardous products at the greatest market-

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place disadvantage. As Sweden has long done in dealing with cigarettes versus snus and many other countries have done in dealing with leaded versus unleaded petrol, differential taxation could dramatically change the market. Combustion-based products could be taxed so as to be, for example, at least twice as expensive as non-combustion alternatives. Cigarettes could also be subjected to more rigorous marketing restrictions and package health labelling. In addition, manufacturing standards could require reductions in known toxins without allowing these changes to be used in promotional efforts by the companies in question. Such efforts would simultaneously promote prevention, cessation, and protection of third parties as well as achieving viable harm reduction for continuing nicotine users.

Conclusion

We can reduce tobacco related death and disease far more rapidly than we can reasonably expect to reduce nicotine use by focusing on the fact that people smoke for the nicotine but die from the smoke. Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy. It is more than a pragmatic response to a market that is, anyway, already in the process of undergoing significant changes. It has the potential to lead to one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century.

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