

Regulation of the cigarette

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Introduction

The cigarette is a uniquely efficient nicotine delivery device which has so far escaped significant controls on its composition and production throughout the world. This is in stark contrast to most other consumer products. While the reasons for this disparity are interesting, there can be no excuse for continuing to allow the tobacco industry alone to decide what will go into cigarettes, and therefore what is present in both mainstream (inhaled) and sidestream (environmental) smoke.

It must be emphasised that the policies during the 1960s and 1970s which favoured reduction of tar and nicotine levels over time has not produced the benefits expected. Rather, changes in cigarette design (1) have brought about reductions in some carcinogens, but increases in others.

Tar and nicotine

The term 'tar' was coined by the tobacco industry to describe the total particulate matter in cigarette smoke. Tar is made up of over 4000 substances, many of which are carcinogens or toxins. The carcinogens include the polyaromatic hydrocarbons, for which benz[a]pyrene (BAP) is a surrogate; the tobacco specific nitrosamines (TSNAs), for which 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) may be a suitable surrogate; as well as a number of other cancer-causing substances. Important toxins include lead, arsenic and other heavy metals, as well as formaldehyde and ammonia.

Nicotine is the addictive constituent of cigarette smoke, and an important motivating force behind continuing cigarette usage.

Smoking-related deaths and changes in cigarette composition

How have changes in cigarette composition and design influenced trends in mortality from smoking-induced diseases over past decades? Three main lines of evidence will be considered.

First, in the United Kingdom, death rates from lung cancer among men have been falling in over the past two decades. It seems likely that this trend is in some part influenced by the substantial reductions in the tar content of cigarettes sold over the past 50 years (2).

Second, data from the first (CPSI) and second (CPSII) Cancer Prevention Studies of the American Cancer Society, which recruited men from birth cohorts approximately 30 years apart, show a different picture. It was found that mortality from lung cancer in men actually increased over this interval, despite reductions in cigarette tar content. At first glance, the decrease in mortality projected as the result of reductions in tar yield

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in the 1950s and 1960s did not materialise during the 1970s and 1980s. It is possible, however, that this interpretation may be too simple -- the situation is discussed in more detail in reference 3.

Third, it is important to note that the incidence of adenocarcinoma of the lung -- a form of smoking-induced lung cancer that has a different site and pathology from the more common squamous cell lung tumour caused by smoking - has increased over past decades in the United States of America and elsewhere, in both relative and absolute terms (4). It is possible that this increase in adenocarcinoma may be related to an increase in the use of reduced tar cigarettes.

In summary, then, while the precise effects of reduced tar cigarettes are somewhat uncertain, it is clear that this strategy has not been as beneficial as initially expected.

The FTC system of measuring tar and nicotine

The tar and nicotine content of cigarettes is usually measured using the Federal Trade Commission (FTC) system, a machine-based measurement system which gauges the amount of the component in a puff volume of 35 mls of smoke and at a puff interval of one minute. However, this method has several important shortcomings. Because these parameters do not represent the actual smoking patterns of humans, the FTC measurement does not necessarily reflect the dose of tar or nicotine received by the smoker. People may take inhaled more deeply and for longer, take more frequent puffs, or block ventilation holes in the cigarette with their fingers. The result is that the smoker may inhale up to twice the dose of nicotine measured by the FTC system, and up to ten times as much tar [5].

The phenomenon of compensatory smoking has been known since the pioneering work of Russell in the 1970s. He showed that smokers of low nicotine cigarettes inhaled more deeply, and sometimes more often, thereby receiving a higher dose than the packet led them to expect. Moreover, the recent introduction of ventilated filters has reduced machine-measured nicotine yields, but not necessarily the dose received by the smoker.

Recent disclosures of tobacco industry documents have revealed that manipulation of the composition of cigarettes by, for example, addition of ammonia to alter the pH of smoke, has resulted in increased absorption of nicotine into the bloodstream, thereby giving the smoker a bigger 'fix'. Likewise, because tar measurement has taken no account of the qualitative changes in cigarette smoke over time, it is also misleading.

Regulation of tar

Although regulation of such a complex mix of chemicals may at first sight seem difficult, in practice it is not. Analysis of the 40 or so major carcinogens and toxins shows a large variation in levels between brands. As relatively low levels of these components are already present in some brands, it is therefore obvious that the levels of these substances can and should be minimised.

Regulation of nicotine

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Regulation of the actual received dose of nicotine is difficult, as the individual smoker controls the volume and frequency of the puffs they take. However, it is possible to control the nicotine content of the cigarette itself. The main issue is how this can best be measured so that effective controls can be applied. Controlling the nicotine dose available in each cigarette could be achieved by setting a limit on available nicotine by product weight. The smoker should then be informed of two facts. First, the limit of by weight of nicotine in the cigarette and second, that deep inhalation increases the nicotine dose received. This information could be included on the packet label.

Strategies for regulation

It must be recognized that cigarette design is best understood by the tobacco industry, is clouded by commercial secrecy, and that no government has applied the necessary research resources to know enough to tell manufacturers how to make their product. Nevertheless, it is certainly possible to apply the principles learned in reducing vehicle emissions to the cigarette, and to base regulations upon this approach.

The policy issues then become:

- ? Governments must claim power to regulate the content of cigarette smoke -this power already exists in some countries.
- ? Health authorities require suitable advisory systems involving independent scientists and with mandatory access to industry information.

Tar

There is great diversity in the levels of major carcinogens in mainstream smoke yields on the world market. The evidence that cigarettes with lower carcinogen levels can be made and sold is indisputable -cigarettes low in nitrates and nitrosamines are already made and sold.

Initially, major carcinogens such as BAP, NNK, and N-nitrososonicotine (NNN) should be targeted. A sensible starting point might be to establish the market median for each of these major substances and, given twelve months notice, set this as the maximum level permitted. As half of the products on the market will already have reached this median level, this seems practical as an initial target. The process could then be repeated at two-year intervals until significantly lower levels of each component are achieved. Over time this process would allow progressive reduction in carcinogens and other toxins, since the starting point is a level found to exist on the market and already achieved by at least some manufacturers.

Nicotine

The first essential is a new measurement system. However, a measure of nicotine in smoke content cannot accurately reflect what gets into the smoker's bloodstream, as it cannot control for compensatory smoking practices. Therefore, while control of smoke yield can be achieved through measuring the nicotine content of the cigarette itself, the process by which the levels of nicotine permitted in cigarettes is decided must be informed by behavioural analyses.

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Perhaps the ultimate policy decision is whether mass weaning of nicotine-dependent populations should be attempted by reducing the maximum nicotine dose per cigarette through regulation. This decision cannot easily be made in the light of current knowledge.

Nevertheless, the goal of reducing the addictiveness of cigarettes is a proper one and should be considered as a matter of policy. The alternative of accepting the status quo is unsatisfactory.

In facing the decision to control nicotine yields, policymakers must understand that the rise of cigarette smoking was a vast unplanned experiment performed by the tobacco industry, which was initially ignorant of its product's toxicity. Long-term decisions on nicotine policy will require similarly large experiments based on sensibly considered probabilities. The decision to reduce tar and nicotine was sensible when conceived, but has been subverted by industry manipulation. While this mistake should not be made again, it must not be allowed to prevent the development of innovative regulatory policies.

The testing and regulation of new tobacco products should be subject to conditions and control similar to those that govern the testing of new pharmaceuticals. So far the tobacco industry has not produced a successful alternative to the standard cigarette. While they should not be discouraged from doing so, such a product should not enjoy marketing advantages over nicotine replacement therapy (NRT) and other nicotine alternatives, as is currently the case. Rather, clean sources of nicotine should be treated more favourably than over the cigarette, in keeping with their benefit and safety to the user.

References

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