

Social and economic aspects of reduction of tobacco smoking by use of alternative nicotine delivery systems (ANDS)

Summary report of a roundtable organised by:

The UN Focal Point on Tobacco or Health

in collaboration with

**the International Council on Alcohol and Addictions (ICAA) and
the European Medical Association Smoking or Health (EMASH)**

Geneva, Palais des Nations, 22–24 September 1997



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European

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Smoking or

Health

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Edited by
Lars Ramström
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Note

This document is a summary report of the *Roundtable on Social and Economic Aspects of Reduction of Tobacco Smoking by Use of Alternative Nicotine Delivery Systems (ANDS)*, held at Palais des Nations, Geneva, 22–24 September 1997.

The roundtable was convened by the UN Focal Point on Tobacco or Health under the auspices of the United Nations Conference on Trade and Development (UNCTAD) in collaboration with the International Council on Alcohol and Addictions (ICAA) and the European Medical Association Smoking or Health (EMASH).

In his opening statement, the chairman of the roundtable, Mr Raúl Uranga, UN Focal Point on Tobacco or Health, welcomed the participants and observers to the roundtable and emphasised the importance of this first meeting of a group of experts to evaluate the scientific evidence supporting alternative nicotine delivery systems as an effective means to help over 1 billion tobacco-dependent consumers to stop smoking or at least substantially reduce the risks associated with tobacco consumption. He hoped that the work of the meeting would advance the understanding of and propose solutions to the greatest preventable health problem confronting humanity today and in the foreseeable future.

A number of papers were presented to give an overview of the current scientific development in the areas concerned. Discussion on the scientific presentations led to a number of conclusions and recommendations with regard to future public health strategies.

The organising bodies

The UN Focal Point on Tobacco or Health was established by the Secretary-General of the United Nations in accordance with Resolution 1993/79 of the United Nations Economic and Social Council (ECOSOC), when it considered, in July of 1993, and for the first time, the seriousness of the global tobacco pandemic. On that occasion, the Council stressed that the serious health consequences of tobacco use cannot be tackled effectively without appropriate strategies for demand reduction, and therefore urged governments to intensify their commitment and efforts designed to reduce tobacco consumption and the demand for tobacco products, including the implementation of comprehensive multisectoral plans at the country level. In addition, the Resolution requested the Secretary-General to seek the full collaboration of the UN System Organisations, and other international organisations, as appropriate, to contribute to the successful implementation of effective comprehensive strategies through multisectoral collaboration among international agencies. To coordinate the implementation of this Resolution, the Council requested the Secretary-General to establish a UN Focal Point on Tobacco or Health, which the Secretary-General did by locating it at the United Nations Conference on Trade and Development. The UN Focal Point on Tobacco or Health has been in operation since December 1993 and has carried out all the tasks assigned to it by the first, as well as the subsequent ECOSOC resolutions on Tobacco or Health.

The International Council on Alcohol and Addictions (ICAA) is an umbrella organisation for all those concerned with reducing and preventing the harmful effects of the use of alcohol, drugs and tobacco. It provides a neutral, objective platform for both professional and lay people. As an international non-governmental organisation, ICAA is in consultative status (Category II) with ECOSOC, in official relations with the World Health Organization, and has close ties with other international and regional bodies such as the International Labour Organization (ILO), the United Nations Educational, Scientific, and Cultural Organization (UNESCO), the Economic and Social Commission for Asia and the Pacific (ESCAP) and the Council of Europe. ICAA runs scientific conferences in terms of annual institutes and triennial congresses. These are structured, to a large extent, in relation to the various sections that are established for special fields, e.g. tobacco dependence.

The European Medical Association Smoking or Health (EMASH) is a voluntary, non-profit organisation open to physicians and other health professionals who are interested in:

- i) smoking and health issues in general;
- ii) promoting no smoking among health professionals;

- iii) promoting the concept of smoke-free healthcare premises;
- iv) helping smokers to stop smoking, including use of nicotine replacement therapy, if appropriate.

EMASH is in working relations with the World Health Organization (WHO), the European Union and UNCTAD. It runs annual seminars in various countries and has produced concise 'Guidelines on Smoking Cessation for Physicians and Other Health Professionals'.

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Introduction

The scope of the roundtable: to meet the need for the largest possible reduction in tobacco smoking

Dr Lars Ramström, Director, Institute for Tobacco Studies, Stockholm, Sweden

It is important to define the goals of tobacco control; the World Health Organization (WHO) definition is ‘reduction of smoking-related morbidity and mortality’. Nearly 200 million existing smokers may die prematurely of tobacco-related disease (TRD) before the year 2025; these smokers cannot be assisted by prevention-of-onset programmes, but if smoking cessation is adopted on a large scale an estimated 30–70% of those deaths (i.e. 60–140 million) could be delayed.

It should be noted that although per capita cigarette consumption is decreasing in developed countries, the mortality from TRD continues to increase in most of these countries. This probably reflects the fact that those smokers who continue to smoke in developed countries are highly nicotine-dependent and also have the highest risk of developing TRD. Consequently, the number of people quitting does not adequately predict the outcome in terms of mortality reduction. The type of smokers who quit is also important; if a heavy smoker quits, the loss of many life-years can be avoided, whereas the corresponding gain is much less with a light smoker. In general, heavy smokers are those with the strongest nicotine dependence, i.e. those who have the greatest difficulty in stopping.

According to their nicotine-dependence levels, smokers may be divided into four categories, i.e. those who are able to:

- quit without nicotine replacement (low nicotine dependence)
- quit with temporary nicotine replacement (moderately dependent)
- quit only with continued nicotine replacement (highly dependent)
- only reduce smoking (but not quit) with continued nicotine replacement (very highly dependent).

The first two categories are taken care of in existing smoking cessation programmes, whereas the second two categories are often ‘forgotten’ or consciously neglected. This is unacceptable not only from the humanitarian point of view but also from the public health and economic points of view. These highly dependent, heavy smokers are the ones whose quitting will have the greatest positive impact in terms of reducing mortality from TRD and related economic losses to society. Even a partial gain, arising from a change where these smokers reduce their cigarette consumption, can have more impact than light smokers quitting completely.

The scope of the current meeting is to review how the emerging variety of alternative nicotine delivery systems (ANDS) can help to expand tobacco control policies in such a way as to reduce smoking-related disease and death to the greatest extent, with special reference to highly dependent smokers.

Summaries of presentations on experiences of and prospects for alternative nicotine delivery systems (ANDS)

Nicotine dependence issues

Nicotine dependence as a barrier to reduction of smoking-related mortality

Dr John Hughes, Professor of Psychiatry, University of Vermont, Burlington, USA

The fact that tobacco use can induce pharmacological dependence on nicotine is now accepted by the WHO, the American Psychiatric Association (APA), the US Food and Drug Administration (FDA) and other bodies. However, there are important differences between nicotine and other drugs of dependence.

First, nicotine does not cause intoxication. This may actually increase the dependence potential of nicotine because there are no social or cognitive limits on intake, allowing continuous intake throughout the day.

Second, although traditional drugs of dependence produce profound acute effects, the effects of nicotine are subtle. However, unlike other drugs, nicotine produces a multiplicity of effects that may aid anxiety, aggression, concentration, hunger and mood.

Third, traditional drugs of dependence are only taken a few times daily, and the dose may vary because of drug purity, whereas nicotine from cigarettes is taken many times daily and the same dose is delivered each time.

Fourth, cigarettes are much easier to obtain than traditional drugs of dependence. The ready availability and low cost of cigarettes increases the dependence potential of nicotine.

Fifth, and perhaps most importantly, inhalation of smoke from cigarettes also leads to extremely rapid absorption, which is optimal for inducing and maintaining dependence.

The best evidence that nicotine dependence acts as a barrier to smoking cessation comes from clinical studies showing that highly nicotine-dependent smokers (those who score highly on the WHO criteria or Fagerström Test for Nicotine Dependence (FTND)) are much less likely to quit. Nicotine dependence in a population may vary; as low-dependent smokers can quit more easily, so the remaining smokers may be more nicotine-dependent. If this is the case, then more traditional drug-abuse strategies, e.g. intensive treatment, pharmacotherapy, etc., may need to be applied, rather than focusing efforts on prevention and education. However, this scenario may not be true. In the USA, with increasing anti-smoking legislation many smokers have reduced their number of cigarettes smoked per day, so nicotine dependence may be decreasing. In addition, nicotine dependence also varies across countries. Serial tracking of nicotine dependence in populations is required; simply monitoring the number of cigarettes smoked per day is not adequate.

Turning to the long-term use of nicotine replacement, the major causative factors for TRD are the carcinogens, carbon monoxide (CO) and other toxins contained in tobacco smoke, rather than nicotine *per se*. In common with heroin, for example, it is the contaminated delivery system that kills nicotine users. Both increasing evidence of the safety of nicotine and the necessity for some smokers to use nicotine replacement therapy (NRT) long term to stop smoking are leading to extended use of nicotine replacement products, particularly as the dependence potential of existing nicotine replacement preparations is very low.

Another possibility for treating nicotine dependence is the concomitant use of nicotine replacement and tobacco to decrease tobacco consumption; recent data suggest that smokers can reduce cigarette consumption and maintain that reduction with the aid of NRT. One study by Fagerström et al. showed that smoking reduction did not undermine cessation; in contrast, smoking reduction served as a preliminary step towards cessation.

In conclusion:

- nicotine dependence does occur and occurs often
- the essence of nicotine dependence is in its lack of intoxication, multiplicity of pharmacological effects, rapid onset of action, frequent administration and easy access
- nicotine dependence can be a barrier to cessation and this varies across countries and time-points
- long-term use of nicotine replacement appears to be safe and may be necessary for some highly dependent smokers
- the use of nicotine replacement to achieve smoking reduction may be an acceptable alternative to cessation, but further study is required.

The physiology of nicotine dependence

Dr Jack Henningfield, Associate Professor, Johns Hopkins University School of Medicine, Baltimore, and Vice-President, Health Policy and Research, Pinney Associates, Bethesda, Maryland, USA

According to the US FDA, nicotine in cigarettes is a drug, and tobacco products are nicotine delivery devices. The primary objective of the FDA with respect to smoking is to reduce the death and disease caused by tobacco products. The main cause of death with some addictive drugs, e.g. heroin, is exposure to the toxins of the drug delivery system rather than the drug itself; this also applies to nicotine. In effect, TRDs are side-effects of nicotine addiction. The risk of premature death in addicted cigarette smokers is 50% greater than in non-smokers, and the level of risk is related to the amount and type of toxin intake.

The recent (1997) National Cancer Institute monograph (No. 8) supports a model developed by David Burns which demonstrated that excess mortality is directly related to the number of cigarettes smoked each day, with risk increasing rapidly with each year beyond approximately 45 years of age. The model predicts that reduced risk of premature death could be achieved by reducing smoking, with greater benefits occurring as a function of greater reduction and earlier age at onset of smoking reduction. This raises the concept that smoking reduction should be considered by those smokers who are unable or unwilling to completely abstain from tobacco. Of course, the greatest benefits occur with complete abstinence, which should remain the ideal goal. Some health benefits of quitting are immediate, e.g. women who quit on becoming pregnant have no greater risk than never-smokers. Similarly, the beneficial effects of quitting with respect to heart disease may also be rapid. Most smokers start when they are young; as an earlier age at onset leads to a worse prognosis for health risk, prevention efforts must be expanded. However, these must be accompanied by youth-targeted cessation efforts for those who have made the early transition from casual use to addiction.

Individuals do not start smoking primarily for pharmacological reasons, but their inability to reduce or stop smoking when they desire to do so is highly determined by the action of nicotine on the structure and function of the nervous system, such as increasing numbers of nicotine receptors in the brain. These changes may persist for long periods in many people and may even be irreversible in certain individuals. Thus, it is possible that some smokers will require prolonged, or even lifelong, NRT.

Nicotine affects the peripheral cholinergic nervous system and activates several subpopulations of nicotine receptors in the brain. It is a potent psychoactive drug, and too high an initial dose results in adverse effects. However, the body's initial toxic reaction soon gives way to physical and behavioural dependence. Importantly, similar levels of nicotine dependence have been found in young smokers and adults. To date, the primary focus has been on preventing young people from smoking, but it is now realised that many young smokers also need treatment.

Cigarette smoking is a flexible-dosage system, and different types of product are available. In the USA, most smokers smoke low-tar/low-nicotine cigarettes, but this has not reduced the incidence of TRD because these cigarettes are designed to readily allow smokers to obtain much higher levels of tobacco smoke constituents than those suggested by their machine-derived tar and nicotine ratings.

The addictive nature of nicotine results from its effect on the body. The addictive action of nicotine occurs in the brain, where nicotine binds to many different types of receptors; with continued nicotine use the brain develops excess receptors (up-regulation). The effects of nicotine are determined by the dose, speed of delivery to the nervous system, level of the individual's

tolerance and other features of the nicotine delivery system. Thus, nicotine delivery systems vary widely in their addictiveness and toxic effects. Cigarettes, which rapidly deliver nicotine in high doses, constitute the most addictive and toxic nicotine delivery system. Pure nicotine delivered more slowly, e.g. by gum or transdermal patch, has an extremely low toxic and addictive potential. Physiological dependence also develops, i.e. the body needs nicotine to function normally. This has been recognised among pilots who smoke, and in order to prevent clinical symptoms (impaired mental ability) developing during long flights nicotine replacement has been recommended for US pilots who cannot/will not quit. Dependent smokers deprived of nicotine show brain dysfunction.

The half-life of nicotine is short (approximately 2 hours), and it takes 4–8 hours to develop clinically significant withdrawal symptoms, so upon waking in the morning the body *needs* nicotine replenishment to enable optimal functioning. Regarding the time-course of nicotine withdrawal, symptoms peak within 1–2 days and gradually decline over 4–5 weeks. Low-dose NRT can reduce these withdrawal symptoms.

The dose level of nicotine is a determinant of the drug's effects, and nicotine delivery systems are not equal. The speed of nicotine delivery determines its effects, and rapid peak plasma nicotine levels cause pleasure. Cigarettes and smokeless tobacco products are sophisticated dosage systems that employ dose-control techniques utilised by pharmaceutical companies. Among tobacco products, cigarettes are the most toxic and most addictive, while cigars and moist forms of snuff are also toxic and addictive although *possibly* less so than cigarettes; Swedish moist snuff is less toxic (but still addictive). Similarly, among NRT products the nasal spray permits more rapid delivery and relatively higher doses of nicotine compared to transdermal patches, which deliver nicotine more gradually.

In summary:

- nicotine is psychoactive, euphoric and reinforcing, produces tolerance, results in physiological dependence and has useful effects (weight control, mood control, relief of tobacco withdrawal symptoms)
- existing attempts to control tobacco focus on prevention, but we now need to consider treatment and prevention efforts in concert for youths and adults
- because the nature and amount of tobacco product delivery is a determinant of the risk of death and disease, reduction of tobacco exposure should be considered for smokers who are unable or unwilling to completely abstain
- supplemental and possibly extended nicotine intake via medicines such as gum and patches may be necessary for some individuals in order to sustain tobacco abstinence or reduced tobacco toxin exposure.

Safety and toxicity of nicotine

Dr Neal Benowitz, Professor of Medicine, University of California, San Francisco, USA

Current figures estimate 0.25 billion premature deaths among existing smokers (i.e. assuming no one else starts smoking) in developed countries. Alternative nicotine delivery approaches involve the use of nicotine in less hazardous forms than cigarette smoking. The risk of nicotine *per se* is an important consideration in the benefit/risk analysis of nicotine-based approaches to harm reduction. There is a widely held misconception that nicotine is implicated in TRD. To date, there is still no definitive evidence that nicotine directly contributes to human disease, but several areas of concern remain.

The primary areas of concern for nicotine toxicity are cardiovascular (CV) disease and reproductive disorders. There is *no* evidence that nicotine causes cancer or lung disease. Although nicotine could theoretically cause or aggravate peptic ulcer disease, the evidence for this in humans is slim.

The action of nicotine most likely to be involved in CV disease or reproductive disturbances is activation of the sympathetic nervous system, resulting in a small increase in heart rate and blood pressure and constriction of some blood vessels. Such effects could aggravate existing coronary heart disease. However, most of the harm observed in smoking-related CV disease appears to result from the other components of tobacco smoke, including CO, oxidant gases, glycoproteins and polycyclic aromatic hydrocarbons. CO binds with haemoglobin in the blood, reducing oxygen availability to the myocardium. Cigarette smoking also increases the risk of thrombosis through the actions of oxidant gases and other combustion products, but not nicotine.

Several clinical studies of the use of nicotine gum or patches, even in smokers with known heart disease, have shown no evidence of harm. In addition, no harm is seen even when smokers continue to smoke while concomitantly using nicotine replacement medications. If nicotine replacement can assist a patient with CV disease to quit or even smoke fewer cigarettes, the benefits of nicotine therapy far outweigh any risks.

The main reproductive disturbances of concern are low birth weight and fetal neurotoxicity. Although nicotine could contribute to low birth weight by constricting uterine blood vessels, other components of cigarette smoke, e.g. CO, are probably more important causative agents. Animal studies suggest that fetal exposure to nicotine can impair brain development, which could contribute to childhood behaviour problems and sudden infant death syndrome. However, if the alternative is cigarette smoking, which delivers nicotine with many other toxins, then nicotine replacement use should be encouraged during pregnancy, i.e. pregnant women are better off using NRT than smoking.

In summary, current medical evidence suggests that the risks of nicotine medications in healthy adults are minimal (if any). Even in patients with CV disease, or in pregnant women, the risks of nicotine are far less than those of continued cigarette smoking. The benefits of nicotine therapy to aid smoking cessation, or even in lieu of tobacco use, far outweigh the risks of continued smoking or the use of nicotine itself.

Alternative nicotine delivery systems (ANDS)

Nicotine replacement therapy medications

Dr Karl Olov Fagerström, Helsingborg Hospital, Sweden

The idea for NRT emerged from an observation that some smokers used smokeless tobacco to prevent or relieve withdrawal symptoms when not allowed to smoke in submarines. NRT was developed in Sweden in the early 1970s. At that time there was substantial resistance to nicotine-containing gum, as smoking was not perceived to be as harmful as we now know it to be, and nicotine was considered to be toxic. This contrasts with the situation today, when experts are requesting more effective nicotine replacement products in order to reduce smoking-related harm.

The speed of nicotine delivery is critical to the development of subjective effects. Self-administration of NRT results in plasma nicotine levels that are approximately 30% of those observed with cigarette smoking. Five nicotine replacement preparations are currently available.

Gum: offers flexible dosing, comes in two strengths (2 mg for low-dependent and 4 mg for highly dependent smokers), has some behavioural component (oral gratification) and is good for preventing relapse. The 2 mg and 4 mg gums release approximately 1 and 2 mg, respectively, of nicotine, some of which is swallowed (and is not therefore bioavailable). After a single dose, the time to maximum concentration (T_{\max}) is approximately 30 min.

Patch: is convenient to use (discreet), has no behavioural component and provides a guaranteed dose, but can only prevent withdrawal symptoms (cannot be used to treat craving). Patches come in several strengths, and two types are available: day + night (24 hours) and daytime only (16 hours). Although patches deliver nicotine gradually throughout the day, with the T_{\max} 4–9 hours after application, nicotine delivery is not constant throughout the day.

Nasal spray: is fast acting (peak effect at 7–10 min), offers rapid craving relief, is flexible and is effective in highly dependent smokers. One dose delivers 1 mg of nicotine, of which 60% (0.6 mg) is bioavailable. Although the spray is faster acting than the gum, it is much slower than cigarette smoking.

Oral inhaler: offers behavioural replacement and sensory effects (nicotine in the throat), is flexible and is good for preventing relapse. ‘Inhaler’ is a misnomer as nicotine is not inhaled into the lungs; rather, the vaporised nicotine is absorbed through the buccal mucosa. However, as one puff releases 13 μg of nicotine (whereas one cigarette yields approximately 100 μg), smokers have to work hard to obtain adequate nicotine.

Sublingual tablet: is flexible. Each tablet contains 2 mg of nicotine; highly dependent smokers are recommended to use 2 tablets simultaneously. The pharmacokinetic parameters of the tablet resemble that of the 2 mg gum.

Compared with cigarettes, there is little abuse potential with any of the above nicotine replacement preparations. These preparations cannot compete with cigarettes in terms of speed of delivery/ euphoric effects.

One drawback of nicotine replacement preparations is limited accessibility; prescriptions may be needed in some countries. In addition, acceptability varies between preparations, e.g. chewing may not be socially acceptable, the nasal spray may be embarrassing, etc. More effective nicotine replacement preparations are needed to improve acceptability and efficacy.

Regarding efficacy, nicotine replacement medications double quit rates compared with placebo. The largest European cessation study (CEASE) showed NRT to be effective in low-dependent smokers. However, for highly dependent smokers a combination of two NRT preparations may be required. One study showed active gum plus active patch to be significantly more effective than one active plus one placebo preparation.

With respect to the selection of a nicotine replacement preparation, there is no 'best' preparation, as different products suit different smokers. Smokers should be allowed to self-select their optimal preparation. Highly dependent smokers need high-dose preparations (e.g. 4 mg gum), and some may require a combination of nicotine replacement preparations.

Finally, the duration of treatment varies. Some low-dependent smokers do not need the full 3 months' treatment; others may require >3 months' treatment for cessation, whereas some may only be able to reduce smoking (but not quit) while using NRT. Clinical trials only assess efficacy and safety, and studies are required in order to evaluate the optimal duration of use.

Smokeless tobacco

Dr Freddi Lewin, Karolinska Institute, Huddinge University Hospital, Sweden

‘Smokeless tobacco’ is a term used to describe a variety of products containing tobacco as the principal constituent, used without combustion. Smokeless tobacco use is an old habit that continues to be widespread in some parts of the world. Some of these products, e.g. Indian smokeless tobacco, which contributes to the high incidence of oral cancer, are very toxic. If smokeless tobacco is to gain acceptance as a replacement for cigarette smoking, products need to be much less harmful than cigarettes. This limits the possibilities to only a few preparations. The product must have been in use for a long period, and its production technique and content must be well controlled. Any such product must also be priced competitively and be socially acceptable.

The most widely used form of smokeless tobacco in the USA and Europe (primarily Sweden) is moist oral snuff, which consists of finely ground or cut tobacco leaves. However, Swedish snuff is manufactured in a way that results in low levels of tobacco-specific nitrosamines. Although Swedish snuff does contain some tobacco-specific nitrosamines, there is little evidence that it is carcinogenic. Sweden has the highest per capita consumption of moist oral snuff in the world, and approximately 10% of the population use moist snuff. Around 10% of users are women, and the habit is spread across all socio-economic groups. As the product is placed on the gum, inside the upper lip, potential cancer concerns focus on cancers of the oral cavity, pharynx and oesophagus.

Two recent case-referent studies in Sweden that analysed overall snuff use, years since stopping, age at initiation, duration of use and total consumption showed no evidence for any increased risk of cancer of the upper aero-digestive tract. In comparison, the overall risks were 5.0 for ever-smokers and 8.0 for current smokers.

In summary, the lack of health risks observed with Swedish snuff suggest that it could offer an alternative to cigarette smoking. In addition, it is very cheap compared to cigarettes. However, existing snuff preparations may not be an acceptable substitute for all smokers worldwide because of problems with acceptance (e.g. the strong smell associated with moist snuff) and lack of social tradition (i.e. snuff is not widely used by women, or by other nationals who live in Sweden).

Innovative nicotine delivery systems

Dr John Slade, Professor of Clinical Medicine, University of Medicine and Dentistry of New Jersey, The Robert Wood Johnson Medical School and St Peter's Medical Center, New Brunswick, New Jersey, USA

The patent literature and the test marketing of several novel nicotine delivery systems by RJ Reynolds (USA) shows that some sectors of the tobacco industry have invested heavily in developing products that might have less disastrous health consequences than existing products (cigarettes) for individual consumers who are already addicted to nicotine and who cannot or will not quit smoking.

Eclipse[®], from RJ Reynolds, is an example of these novel devices. The dose of nicotine delivered using Eclipse is similar to that achieved with most cigarettes, whereas the dose of most toxins is far lower with Eclipse than with most conventional cigarettes. The key exceptions are acrolein and CO, which are more abundant in the Eclipse aerosol than in typical cigarette smoke. The yields of major classes of carcinogens from Eclipse are similar to those obtained from 'ultra-low' tar cigarettes.

Recent patent applications show the range of possible paths that production innovation may follow. Of particular interest, in light of the high CO yields with Eclipse-like devices, are patents from Philip Morris (USA) for metal-based heating elements, especially an iron carbide heating element which, it is claimed, evolves virtually no CO.

Finally, the likelihood remains that ordinary cigarettes can be produced in ways which are less toxic. For instance, a tobacco-curing process has been developed that results in a usable leaf which does not contain any tobacco-specific nitrosamines. Such a raw material may be applied in a variety of nicotine delivery devices.

These novel devices and refinements of existing tobacco products should not be introduced into the market without an appropriate regulatory structure. Past experience with filters and low-tar cigarettes shows the pitfalls of the unregulated introduction of novel devices. Regulation should involve an ongoing process of monitoring and should have the goal of reversing the current state of affairs, in which the most poisonous products have the least regulatory supervision while the least toxic products have the strictest regulation.

Potential effects of widespread use of alternative nicotine delivery systems (ANDS)

Public health aspects

Professor Michael Kunze, Director, Institute of Social Medicine, University of Vienna, Austria

ANDS are designed to provide nicotine without the harmful substances contained in cigarette smoke. Several different nicotine replacement preparations already exist.

As high nicotine dependence correlates with a high risk of pulmonary and CV disease and lung cancer, and as highly dependent smokers cannot quit, conventional smoking control measures (prevention and cessation) have a limited impact on the incidence of these TRDs. There is also an inverse relationship between self-help and nicotine dependence in cessation programmes. Additional smoking control measures, with two possible endpoints, cessation (the ultimate goal) and risk (or harm) reduction, are required. Regarding cessation, management of high nicotine dependence requires accurate diagnosis and intensive treatment. Risk reduction may be achieved via either modification of tobacco products or reduced cigarette consumption; the latter may be feasible using nicotine replacement medications.

An important consideration is the well-established dose–response relationship between health risks and exposure to toxins in tobacco smoke. Reduced smoking (smoking fewer cigarettes) is an intermediate stage towards the ultimate goal of decreasing tobacco-related mortality and morbidity. In addition, the use of nicotine replacement to reduce smoking does not appear to undermine motivation to quit; in fact, it increases motivation to stop smoking.

Nicotine is the substance that maintains tobacco consumption. A recent study demonstrated that nicotine dependence among patients with lung cancer was higher than that in the general smoking population. This opens a new approach to cancer control; in effect, treatment of nicotine dependence represents preventative oncology. These findings also support the strategy of smoking reduction in highly dependent smokers who cannot quit.

These benefits of smoking reduction have been calculated using population data, and the results lead to the estimation that significant numbers of premature deaths could be prevented with only modest reductions in smoking.

Regarding the practical management of smoking reduction, baseline smoking parameters must be ascertained, and smokers should be fully informed about smoking reduction and the end goals should be discussed. Clear guidelines need to be developed.

Harm reduction has been controversial with other drug dependencies and it is possible that the widespread use of ANDS will also be subject to discussion by the health community and society. However, prevention of smoking is not enough. Smoking reduction must be considered as one strategy among others, with the entire package focusing on reduction of tobacco-related morbidity and mortality (as opposed to smoking prevalence alone).

Effects on demand for nicotine/raw tobacco

Dr Lars Ramström, Director, Institute for Tobacco Studies, Stockholm, Sweden

Any large-scale reduction in tobacco smoking would undoubtedly benefit public health, but a radically decreased demand for tobacco leaves would have a negative impact on tobacco farmers. Thus, consideration has been given to the development of programmes to assist these farmers, e.g. crop substitution. In the USA, this kind of support has recently been considered by the Advisory Committee on Tobacco Policy and Public Health (the Koop–Kessler Committee).

If tobacco smoking is reduced by widespread use of ANDS, a new factor will emerge: ANDS require continued supply of tobacco leaves from which to get the pure nicotine needed for the preparation of the various nicotine replacement products.

Besides the tobacco industry, tobacco leaves are used by a smaller industry dealing with the extraction of nicotine from *Nicotiana* plants, with growing demand from pharmaceutical companies. The extraction industry uses plant material with the highest possible nicotine yield, e.g. *Nicotiana rustica*, in contrast with cigarette producers, who use tobacco varieties with low nicotine concentrations.

Use of tobacco leaf to prepare ANDS will compensate, to some extent, for the decreased demand for tobacco leaves from tobacco companies that would result from any large-scale use of ANDS to reduce cigarette smoking.

Therefore, policies that actively stimulate use of nicotine replacement preparations may have a greater chance of being accepted not only by those whose primary concern is health, but also by those who have major concerns for the tobacco farmers.

Conditions for large-scale use of alternative nicotine delivery systems (ANDS)

The need for changes to the regulatory environment for nicotine

Mr David Sweanor, Senior Legal Counsel to the Smoking and Health Action Foundation and the Non-Smokers' Rights Association, Ottawa, Ontario, Canada

The current pandemic of tobacco-caused diseases can, to a large extent, be ascribed to the economic rewards garnered by those selling tobacco products and the lack of a regulatory environment that can effectively counter such economics. Far from controlling the tobacco epidemic, regulatory regimes have turned the tobacco industry into what is effectively a 'nicotine maintenance monopoly' by keeping other, less hazardous, forms of nicotine delivery off the market.

At present, the most hazardous forms of nicotine delivery (tobacco products) are the least regulated, whereas the least hazardous forms (pharmaceutical products) are the most regulated. Innovation has been stifled and consumers have effectively been denied access to better products. Through the creation of this nicotine maintenance monopoly, legislation has enriched tobacco companies, giving both the incentive and the resources to oppose public health measures.

Several factors are now converging that could radically alter the nicotine market. These include scientific advances in the study of addiction, technological innovations in nicotine delivery, economic incentives for new products and consumer demands for changes. The key issue for health organisations is how best to utilise the changing nicotine environment through the development of laws that will promote the maximum possible reduction in the harm currently associated with nicotine use. Part of the answer could be to require all nicotine products to be controlled by the same law, with marketing restraints directly linked to the harm potential of individual products. This could create a legal environment that would realign economic incentives in favour of ever-greater reductions in overall harm.

The need for new practices in counselling and treatment

Dr Roberto Masironi, President, European Medical Association Smoking or Health, Meyrin, Switzerland

After 40 years of systematic research and action against the tobacco epidemic, the results to date are modest. Classical approaches, including education, legislation, restrictions on smoking, price increases, etc., have not been very effective in significantly reducing the prevalence of smoking. Moreover, prevention does not address the problem of existing smokers, so we must therefore act now to assist these smokers.

Smoking cessation can best be achieved with professional support. It is also recognised that health professionals should be involved in prevention and, especially, treatment programmes.

Tobacco use can no longer be considered a personal habit; according to the WHO 10th International Classification of Disease, tobacco is a psychoactive substance that can be classed along with opiates and alcohol. Thus, smokers do need medical attention and should be treated accordingly.

Many physicians do not treat smokers on the assumption that it is not their duty, they do not have time to counsel patients, they do not know how to advise smokers, or that they do not know which cessation methods are effective. In addition, many doctors set a bad example by continuing to smoke.

According to the WHO, in developed countries most of the population visit a physician at least annually, presenting the ideal opportunity to dispense effective anti-smoking counselling. Indeed, a 1993 EMASH survey of general practitioners (GPs) in Western Europe found that most doctors considered reducing smoking to have the greatest positive impact on improving public health. However, 70% of GPs thought smokers were behaviourally dependent, whereas only 30% believed in pharmacological dependence.

To overcome the lack of knowledge and misconceptions, EMASH has produced concise (4-page) factual guidelines on smoking cessation for GPs that have been widely translated. According to these guidelines, during routine patient visits GPs should:

- assess patients' smoking habits
- advise patients
- treat highly nicotine-dependent patients
- follow up at 3, 6 and 12 months.

Conclusions and recommendations

Background

According to the WHO, more than 1 billion people currently smoke tobacco products and the prevalence is continuing to increase in many countries. It is estimated that 500 million of these smokers will develop debilitating disease and die as a direct result of their smoking if they are unable to substantially reduce their exposure to tobacco smoke. The goal of the roundtable was to recommend actions to reduce the death and disease caused by tobacco. Although tobacco prevention efforts are critical to long-range public health efforts, in the immediate term it is important, and possible, to reduce death and disease among existing smokers through cessation efforts.

All present forms of tobacco consumption are associated with adverse health effects and should be strongly discouraged. However, it is now evident that the risk of death and disease is related to not only the amount but also the nature of tobacco exposure; for example, daily cigarette smoking is far more dangerous than occasional use of Swedish snuff.

The foregoing observations lead to the conclusion that existing smokers would benefit from support in their efforts to achieve smoking cessation. Furthermore, it is increasingly recognised that for any health problem, whether it be drug dependence or malaria, it is important for prevention and treatment efforts to occur in a simultaneous and coordinated fashion. Thus, to attain a substantial reduction in tobacco-caused death and disease in existing smokers and in future generations, it is important to adopt a triadic approach of coordinated (i) tobacco-use prevention, (ii) smoking cessation, and (iii) reduction of exposure to tobacco toxins in people who are unable or unwilling to completely abstain from tobacco.

The roundtable reached the following conclusions and recommendations.

Scientific findings and conclusions

Scientific research has yielded important implications for tobacco control, including the following.

1. Tobacco products may be considered vehicles for the delivery of nicotine to the bloodstream, which quickly carries nicotine to the brain and other organs. Nicotine produces many physiological and behavioural effects, including alteration of brain chemistry and function, that lead to dependence. The resulting nicotine dependence and withdrawal severely limit the ability of many individuals to abstain from, or even reduce, their tobacco use. Alternative forms of nicotine delivery to replace that provided by tobacco have been shown to enable abstinence, and recent research has focused on their ability to sustain reduced smoking. The duration of need for such nicotine replacement appears to range from a few weeks to the very long term.
2. Most of the major disease-producing constituents of tobacco smoke are found among the combustion products (CO, irritant gases, tar substances, etc.).
3. The main hazard of nicotine is that nicotine dependence maintains tobacco use. Nicotine *per se* does not substantively contribute to most of the medical complications of tobacco use. Nicotine-delivering medications are safe in short-term use when used as an adjunct to smoking cessation, but any long-term use policy should contain surveillance plans to assess long-term safety more fully. The abuse potential of nicotine-delivering medications is minimal because of the slow absorption of nicotine relative to that from smoking. Long-term nicotine use is not of demonstrated harm, with the possible exception of use during pregnancy.
4. Scientific research indicates that nicotine is not a carcinogen.

5. Nicotine may contribute to the cardiovascular risks associated with *smoking*, although other cardiovascular toxins appear to be of greater importance.
6. The effects of nicotine are much greater when delivered rapidly, as when smoking, compared to the slower rate of delivery from medicines for nicotine replacement therapy.
7. Existing nicotine regulation aggravates the tobacco epidemic. It favours the most deadly nicotine delivery devices (cigarettes) and places the greatest constraints in the way of the least harmful products (pharmaceutical nicotine products). This has given a huge marketing advantage to the deadliest products, thereby expanding the tobacco epidemic.
8. A variety of nicotine replacement administration forms will be required to fit individual smokers' preference and degree of nicotine dependence. These will include products that differ in dose and speed of delivery.
9. With decreasing prevalence of smoking in many countries, the remaining smokers appear to be the more dependent smokers, many of whom require formal treatment.

Recommendations

1. The main goal of tobacco policy should be to reduce death and disease caused by tobacco.
2. Prevention of onset of smoking in this and future generations of adolescents is an important policy component in the reduction of tobacco-related deaths but will not affect death rates until the 2020s because of the delay between smoking onset and disease development.
3. Cessation of smoking will be the most important policy component in the reduction of smoking-related deaths over the next 30 years, since virtually all of these deaths will occur among people who already smoke.
4. To reduce morbidity and mortality caused by tobacco, a comprehensive nicotine regulatory approach that gives the greatest relative advantage to the least harmful products is needed. As a general principle, less hazardous nicotine delivery devices should be as, or more, easily available (and affordable) as cigarettes. As an interim measure, countries should consider allowing proven nicotine-delivering medicines to be more widely available through the reduction and simplification of the regulations governing the use of these products.
5. Long-term use of nicotine-delivering medicines should be allowed in order to sustain tobacco abstinence or encourage reduced exposure to harm associated with smoking. The regulatory evaluation of these products must consider possible unintended side-effects (e.g. use as a starter product for nicotine addiction, undermining cessation, etc.). At the same time, such unintended consequences should be examined in relation to the overall impact of these products in reducing morbidity and mortality.
6. Whereas total cessation remains the ultimate goal of tobacco control policy, reduction of exposure to tobacco toxins should be added to the existing treatment approaches. Treatment should be easily accessible for highly dependent smokers who cannot quit by themselves. New treatments and strategies are needed to help those smokers not reached by current approaches.
7. Tobacco products are generally less expensive and easier to obtain than nicotine-delivering medicines; this situation needs to be reversed. Lower-income populations should not be deprived of existing effective nicotine medicines.
8. Health professionals should not only be encouraged to stop smoking but should also be educated on the risks associated with tobacco use and encouraged to play an active role in the control of smoking-related diseases by ensuring that counselling and pharmacological therapy are available to all smokers.
9. In order to assist smokers who are so heavily dependent that they cannot possibly stop smoking, every effort should be made to reduce the toxicity of existing tobacco products.

10. Countries should recognise that tobacco control constitutes one of the most cost-effective strategies for the use of public health resources.
11. Research is needed to support, assess and provide guidance to any new tobacco control efforts; this should therefore form an integral part of tobacco control policies.
12. In all countries, standards governing the toxicity and marketing of tobacco products should be implemented. Over time, the adverse health impact of these products should be reduced through a combination of lower toxicity and reduced promotion and availability.
13. The WHO is requested to consider the above recommendations in future policy-development activities, including the drafting of a framework convention on tobacco control.
14. The UN Focal Point on Tobacco or Health should continue to play its coordinating role in promoting the above recommendations with governments and relevant UN agencies.

Appendices

Roundtable agenda

1. Opening

Statement by the UN Focal Point on Tobacco or Health *Raúl Uranga*

The scope of the roundtable: introductory remarks *Lars Ramström*

2. Experiences of and prospects for alternative nicotine delivery systems (ANDS)

Discussion of background papers covering various aspects related to different ANDS products with respect to social and economic aspects of their use

Nicotine dependence issues

Nicotine dependence as a barrier for reduction of smoking-related mortality *John Hughes*

The physiology of nicotine dependence *Jack Henningfield*

Safety/toxicity of nicotine *Neal Benowitz*

Discussant *John Slade*

Alternative nicotine delivery systems (ANDS)

Nicotine replacement therapy (NRT) medications *Karl Olov Fagerström*

Smokeless tobacco *Freddi Lewin*

Innovative nicotine delivery systems *John Slade*

Discussant *John Hughes*

Potential effects of widespread use of ANDS

Public health aspects *Michael Kunze*

Effects on demands for nicotine/raw tobacco *Lars Ramström*

Discussant *Jack Henningfield*

Conditions for large-scale use of ANDS

The need for changes to the regulatory environment for ANDS *David Sweanor*

The need for new practices in counselling and treatment *Roberto Masironi*

Discussant *Michael Kunze*

Special needs in developing countries *(Open discussion)*

3. Conclusions, recommendations and policy implications on action that may be taken

Adoption of a summary report

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