

Tools for Advancing Tobacco Control in the XXIst century:
POLICY RECOMMENDATIONS FOR SMOKING CESSATION AND
TREATMENT OF TOBACCO DEPENDENCE
Tools for public health

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This publication has been produced following the WHO meeting on Global Policy for Smoking Cessation which took place in Moscow on 14 and 15 June 2002. The purpose of the meeting was to develop policy recommendations for smoking cessation and treatment of tobacco dependence, taking into account countries' different national contexts, culture, health-care systems and financing capacity. The meeting was divided into three parts. The first part consisted of country-specific presentations on the status of smoking cessation activities; it highlighted the major barriers and challenges in developing national smoking cessation programmes within national health care systems. The presentations during the second part of the meeting addressed various cessation methods including: communication campaigns; Quit & Win campaigns; quitlines and internet services; smoke-free places; behavioural interventions; nicotine replacement therapy and pharmacotherapies; adherence to smoking cessation therapies; training of health professionals; and future research needs and capacity-building. The last part of the meeting was conducted in the form of a workshop; it focused on translating the Mayo Clinic Recommendations on smoking cessation and treatment of tobacco dependence into feasible activities, taking into account the different levels of political will and availability of resources for tobacco control within countries.

The meeting was organized by Dr Vera da Costa e Silva (who also chaired the meeting), Nejma Macklai, Annemieke Brands and Sonia Huang of the WHO Tobacco Free Initiative (TFI) at Headquarters in Geneva; Dr Haik Nikogosian, Patsy Harrington, and Galina Kaern of the WHO Office for Europe in Copenhagen; and Dr Mikko Viennonnen and Diliara Sunyakova of the WHO Office in Moscow. Funds were generously provided by the Department for International Development Cooperation of the Finnish Ministry for Foreign Affairs (FINNIDA), and the meeting was graciously hosted by the Ministry of Health of the Russian Federation.

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List of Abbreviations

DOH	-	Department of Health
ETS	-	environmental tobacco smoke
FCTC	-	Framework Convention on Tobacco Control
NGO	-	Nongovernmental Organizations
NRT	-	nicotine replacement therapy
OTC	-	over the counter
PHC	-	primary health care
SRNT	-	Society for Research on Nicotine and Tobacco
TFI	-	Tobacco Free Initiative
WHO	-	World Health Organization
WNTD	-	World No-Tobacco Day

Foreword

The current escalation in tobacco use and in tobacco-related death and disease can only be reversed by investment in comprehensive tobacco control.

On 24 May 1999, the World Health Assembly (WHA) paved the way for stemming the global rise and spread of tobacco products. It unanimously backed a resolution calling for a WHO Framework Convention on Tobacco Control (WHO FCTC), a new legal instrument to address tobacco promotion and sponsorship, illicit trade of tobacco products, tobacco taxes and agricultural diversification. It is anticipated that the WHO FCTC will be adopted during the Fifty-sixth World Health Assembly in May 2003. With the Convention as a coordination vehicle, national public health policies, tailored around national needs, can be advanced without obstruction from transnational phenomena such as smuggling, advertising, promotion and sponsorship.

With respect to smoking cessation and treatment of tobacco dependence, the text of the final draft of the WHO FCTC states that the Parties to this Convention, “Recognizing that cigarettes and some other products containing tobacco are highly engineered so as to create and maintain dependence, and that many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic, and that tobacco dependence is separately classified as a disorder in major international classifications of diseases” have agreed to “develop and disseminate appropriate, comprehensive and integrated guidelines based on scientific evidence and best practices, taking into account national circumstances and priorities, and to take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence”.

A crucial phase of the work on the WHO Framework Convention on Tobacco Control (WHO FCTC) will commence after its adoption by the WHO Member States. It is treaty practice that after adoption of a treaty, much of the work surrounding the treaty shifts from the international to the national and sub-regional level. It is also treaty practice to support many Member States to ratify and then later implement the treaty in question. The support may be technical or other. Treaty-related capacity-building activities will need to be integrated into the treaty implementation scheme. Therefore, while one phase of this historic journey is likely to close with the planned adoption of the WHO FCTC in May 2003, a new chapter will begin.



In order to respond to requests for technical assistance on legal, scientific, policy and practical steps after adoption of the WHO FCTC, the WHO Tobacco Free Initiative (TFI) is currently actively involved in developing various guidelines for countries. The purpose of these guidelines is to provide evidence-based background material to countries working towards tobacco-control measures tailored to their local needs.

The TFI believes that tobacco-control efforts are more likely to be sustained when incorporated into existing national, state and district level health structures and linked with existing positions and accountability processes. Government health sectors are expected to play a vital role in increasing awareness among health professionals and contributing to the development of sustainable tobacco-control programmes at the country level. Such a systematic approach will also pave the way for a multisectoral acceptance of tobacco control efforts in countries.

Evidence has shown that cessation is the only intervention with the potential to reduce tobacco-related mortality in the short- and medium-term. An emphasis on prevention of tobacco consumption will, in the short run, only have a limited positive effect on tobacco-related morbidity and mortality, as prevention strategies do not affect existing tobacco consumers. The participants at the WHO meeting on Global Policy for Smoking Cessation, hosted in Moscow by the Ministry of Health of the Russian Federation on 14 and 15 June 2002, emphasized that, along with an individual approach (behavioural and/or pharmacological interventions) to smoking cessation, a supportive environment needs to be created that encourages tobacco consumers in their attempts to quit. Treatment of tobacco dependence needs therefore to be part of a comprehensive tobacco-control policy along with measures such as taxation and price policies, advertising restrictions, dissemination of information and protection of non-smokers through the creation of smoke-free public places.

We encourage countries to implement the evidence-based policy recommendations on smoking cessation and treatment of tobacco dependence, developed by experts from both developing and developed countries, as part of a comprehensive tobacco control strategy. We sincerely hope that the recommended actions will eventually contribute to a reversal of the current escalation in tobacco consumption and tobacco-related death and disease.

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WHO's Noncommunicable Diseases and Mental Health (NMH) Cluster

Executive Summary

At present, over 1,300 million people in the world are current smokers (World Bank, 1999). Four-fifths of them live in low- or middle-income countries. In the twenty-first century, tobacco, if unchecked, will lead to one billion deaths, four-fifths of which will occur in low-income countries. Within 20 years, tobacco dependence could become the world's single largest cause of premature death or years lived with disability (measured in "disability-adjusted life years", DALYs, which is a comparative index of the burden of disease or injury). Current statistics indicate that it will not be possible to reduce tobacco-related deaths over the next 30-50 years, unless adult smokers are encouraged to quit. The statistics underline the importance of the WHO Framework Convention on Tobacco Control (WHO FCTC) which, when ratified, will become the mechanism for worldwide legislative and policy measures to reduce adult smoking rates. Raising tobacco taxes, banning advertising of tobacco products and increasing smoke-free places are all measures that increase pressure to quit smoking.

In view of the addictiveness of tobacco products, many tobacco-users will need support in quitting. Support for smoking cessation or "treatment of tobacco dependence" refers to a range of techniques including motivation, advice and guidance, counselling, telephone and Internet support, and appropriate pharmaceutical aids, all of which aim to encourage and help tobacco users to stop using tobacco and to avoid subsequent relapse. The success of these interventions depends on their synergistic use in a broader context of a comprehensive tobacco-control strategy.

There is overwhelming evidence for the health benefits, effectiveness and cost-effectiveness of quitting smoking and of treatment for tobacco dependence, a disorder recognized by the tenth version of WHO's International Classification of Diseases (WHO, 1992). Treatment for tobacco dependence is safe and efficacious. However, despite the availability of cost-effective treatment for tobacco dependence, the public health sector in many countries, is not investing in smoking cessation services, nor in the development of an infrastructure that will motivate smokers to quit and support them in doing so. Furthermore, in most countries, provision for treatment, training of health-care providers, education and information on the wide use of cessation therapies, as well as financial resources are limited and rarely incorporated into standard health care. Also, smoking cessation is not seen as a public health priority and is not necessarily approached as a key tobacco-control strategy in governmental and institutional workplans. Beside specific interventions for smoking cessation, a



general supportive environment that will stimulate smokers to quit is not usually considered a component of smoking cessation policies.

It is against this background that the meeting, upon which this document is based was convened by the WHO Tobacco Free Initiative as a forum within which to explore and recommend potential avenues for progress in the areas of smoking cessation and treatment of tobacco dependence taking into account countries' different national contexts, culture, health-care systems and financing capacity. These were considered within the overall context of the efforts being made internationally to formulate a global policy on tobacco control for reducing the prevalence of tobacco use and exposure to tobacco smoke. The meeting was hosted by the Ministry of Health of the Russian Federation and took place in Moscow in June 2002. Funds for the meeting were provided by the Department for International Development Cooperation of the Finnish Ministry for Foreign Affairs (FINNIDA).

The meeting gathered 31 participants, including country representatives from Brazil, Canada, Germany, Hong Kong Special Administrative Region of China, the Russian Federation, Seychelles, Thailand, the Philippines, Venezuela and Qatar, with varying experiences in implementing cessation policies. International experts/scientists presented the current best practices for smoking cessation and treatment of tobacco dependence from Canada, Finland, Hong Kong (SAR, China), Spain, the United Kingdom, the United States of America, joined by WHO staff from headquarters and regional offices.

The meeting was intended to contribute to strategy development that supports tobacco users all over the world in their efforts to quit, drawing in Member States, civil society and the scientific community. It focused particularly on the mechanisms suitable for use by both developed and developing countries within a wide range of possible cost-effective interventions.

The meeting emphasized the need for creating a supportive environment that would encourage smokers in their attempts to quit. Raising tobacco taxes, banning advertising of tobacco products, smoke-free-environment policies, education and mass media campaigns to increase smokers' awareness and decrease accessibility of tobacco products, along with community-based smoking cessation programmes were highlighted as pillars of the process for reducing the numbers of smokers. Issues such as possible ways to use the primary health system to address smoking cessation were discussed, as well as the different possible forms of reducing the costs of such interventions.



Common challenges and opportunities for implementing smoking cessation policies and tobacco-control supportive programmes at varying levels of infrastructure and resources for tobacco control were discussed. Key barriers to developing national smoking cessation policies and tobacco-control supportive programmes were identified. These included inadequate training and lack of motivation among health-care providers to undertake and deliver smoking cessation activities; lack of resources and government funding; unavailability and inaccessibility of pharmacotherapy products; the absence of mechanisms for the financing or subsidizing of pharmacotherapy products by insurance companies; lack of coordination between various sectors involved in providing smoking cessation interventions and, more importantly, the lack of integration of smoking cessation interventions into an overall policy on tobacco control.

The Mayo Clinic's recommendations of 1999 (annex I), were used as the basis for discussion and were further elaborated. Prioritization of smoking cessation policies and programmes was highlighted, depending on the levels of the health-care system infrastructure, political will, and human and financial resources in various countries.

A review of the evidence base of effective smoking cessation and treatment of tobacco dependence demonstrates that behavioural and pharmacological therapies for tobacco dependence can contribute substantially to greater health gains. Efficacious and highly cost-effective treatments have been reviewed by a number of authoritative bodies. These reviews advocate that all health-care personnel and clinicians should consistently deliver smoking cessation interventions to their patients.

Evidence-based pharmacotherapy offers a variety of options for individuals. These include several forms of nicotine-replacement therapy (gum, lozenge, patch, nasal spray and oral inhaler) and bupropion. The general efficacy of the evidence-based medicines is similar in providing an approximate doubling of the probability of long-term smoking cessation. Behavioural treatment can be effective in its own right and can also substantially increase the success of pharmacotherapy. A wide variety of behavioural and pharmacological therapies have proved effective. However, no single approach should be emphasized to the exclusion of the others, because the therapies vary widely in their efficacy, acceptability, cost-effectiveness and their cost on an individual and population basis.

Working with individual smokers to change their smoking behaviour is an important goal, but it has a limited impact if the environmental factors that promote and support smoking are not also addressed. Hence, population-based interventions should be viewed as complementary approaches to individual-based behavioural or pharmacological



interventions. Public health approaches such as mass media campaigns, Quit and Win competitions and telephone helplines serve to play an important role in changing societal norms and promoting smoking cessation. Mass media campaigns can increase knowledge about the health effects of smoking and the benefits of stopping. They can also change and reinforce attitudes towards stopping, provide clues to simple action and influence smoking behaviour. Quitlines have an important role to play as part of an overall comprehensive smoking cessation programme. They provide a low-cost, easily accessible, popular and effective service. Quit and Win campaigns have been using innovative communication methods and partnerships, including the involvement of community organizations and health services, to achieve cessation rates of around 20%. The smoke-free workplace is a cost-effective public health approach that encourages the important long-term goal of de-normalizing tobacco use. Taking a public health approach can affect large numbers of individuals at minimal cost.

Human and financial resources are a prerequisite for sustaining smoking cessation and treatment of tobacco dependence interventions at both the population and individual level. Building capacity to educate and train health-care providers to advocate and deliver smoking cessation and treatment of tobacco-dependence strategies will be essential for ensuring success. The role of policy-makers, health professionals, and researchers who seek to reduce tobacco prevalence will be imperative in getting tobacco cessation onto the agenda. And the role of the international community in ensuring accessibility and availability of treatment of tobacco-dependence is also important. The international community can help by providing a forum for sharing and distributing information, writing up guidelines and reviews on best practices, raising funds and establishing partnerships with research and academic institutions in the area of smoking cessation and treatment of tobacco dependence.

Finally, to further expand and make more widely available smoking cessation interventions and treatment of tobacco dependence at the national level, governments need to increase political commitment and financial resources in support for effective population and individual based tobacco cessation interventions. To ensure sustainability of smoking cessation, governments need to incorporate tobacco cessation policies and programmes into other basic health care and this within the context of a comprehensive tobacco control strategy employing a broad range of policies.

Through the experiences and lessons learned from country presentations, expert reviews and discussions on how to assist countries in implementing smoking cessation strategies, the participants of the two-day meeting drew up a series of



recommendations. These are considered to be the priority elements to be undertaken by governments, NGOs, and health-care professionals interested in making public-health gains in the short and medium term:

- A smoking cessation policy should be part of any comprehensive tobacco-control policy if smoking cessation efforts are to be effective and sustainable;
- A supportive environment, which includes a decrease in accessibility of tobacco products, a reduction in social acceptance of tobacco consumption and an increase in information, will improve the likelihood of smokers quitting;
- All tobacco-users should be offered effective treatment for tobacco dependence;
- Member States should develop evidence-based national policy guidelines for the treatment of tobacco dependence;
- Awareness should be increased among health-care professionals, administrators, and policy-makers of both the benefits and cost effectiveness of smoking cessation interventions relative to other health-care interventions;
- Training should be provided to all health-care providers at primary care, community and national level to enable them to deliver smoking cessation interventions effectively;
- New partnerships are needed to increase commitment and the pool of financial and technical support for implementing evidence-based treatment.

A crucial phase of the work on the WHO Framework Convention on Tobacco Control (WHO FCTC) will commence after its adoption by the WHO Member States. Member States should be supported to ratify and later implement the treaty in question. The support may be technical or other. In order to be able to respond to requests for technical assistance on legal, scientific, policy and practical steps after the adoption of the WHO FCTC, the WHO Tobacco Free Initiative (TFI) is currently actively involved in developing various guidelines for countries. The purpose of these guidelines is to provide countries working towards tobacco control measures with evidence-based background material tailored to their specific local needs. The *Policy Recommendations for Smoking Cessation and Treatment of Tobacco Dependence* are part of this activity.

Scientific rationale

In 2003, tobacco use is expected to kill approximately 5 million people worldwide (WHO, 2002). Already, it is responsible for one in ten adult deaths; by 2030 that figure is expected to be one in six, or ten million deaths each year—more than any other cause and more than the projected death tolls from pneumonia, diarrhoeal diseases, tuberculosis, and the complications of childbirth for that year combined. If current trends persist, about 500 million people alive today will eventually be killed by tobacco use, half of them in productive middle-age, losing 20 to 25 years of life.



In view of the addictiveness of tobacco products, many tobacco users will need support for quitting. Although not comparable, population surveys indicate that approximately one-third of smokers attempt to quit each year. They further show that the majority of these smoking cessation attempts are undertaken without help. Only a small percentage of cigarette smokers (1-3%) achieve lasting abstinence (at least 12 months of abstinence from smoking) using willpower alone (Fiore et al., 2000).

Promotion of smoking cessation and the treatment of tobacco dependence can achieve immediate benefits. While much of the worldwide effort is directed at reducing the initiation of tobacco use in children and adolescents, concurrent efforts to treat current smokers as well as reduce initiation would have a much more immediate, as well as long-term effect. According to the World Bank, efforts to deter children from smoking would have no impact on global smoking-related mortality for about three decades, since most of the projected deaths for the next 50 years are those of existing smokers (World Bank, 1999). These projections suggest that, if adult consumption were to decrease by 50% by the year 2020, approximately 180 million tobacco-related deaths could be avoided. In contrast, if the initiation of smoking by young people were to be reduced by 50% by the year 2020, only about 20 million tobacco-related deaths would be avoided. Clearly, public-health policies which focus on increasing cessation among both groups are needed, as well as strategies to decrease initiation.

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Résumé d'orientation

Aujourd'hui, on compte plus de 1,3 milliard de fumeurs dans le monde (Banque mondiale, 1999). Les quatre cinquièmes de ces fumeurs vivent dans des pays à revenu faible ou moyen. Au XXI^e siècle, si rien n'est fait pour enrayer le tabagisme, celui-ci entraînera la mort d'un milliard de personnes, dont les quatre cinquièmes dans des pays à faible revenu. D'ici vingt ans, la dépendance à l'égard du tabac pourrait devenir la principale cause au monde de décès prématurés ou d'années vécues avec une incapacité (mesurées en « années de vie ajustées sur l'incapacité », ou DALY, indicateur comparable de la charge de morbidité ou d'incapacité). Les statistiques actuelles montrent qu'il ne sera pas possible de réduire le nombre de décès liés au tabagisme au cours des 30 à 50 prochaines années sans encourager les adultes à cesser de fumer. Les statistiques soulignent l'importance de la convention-cadre de l'OMS pour la lutte antitabac qui, une fois ratifiée, deviendra le mécanisme permettant de mettre en oeuvre des mesures législatives et politiques à l'échelle mondiale pour réduire les taux de tabagisme chez l'adulte. L'augmentation des taxes sur le tabac, l'interdiction de la publicité en faveur des produits du tabac et la multiplication du nombre de lieux où il est interdit de fumer sont autant de mesures susceptibles d'inciter les gens à cesser de fumer.

Compte tenu du caractère dépendogène des produits du tabac, de nombreux consommateurs auront besoin d'une aide pour arrêter de fumer. Cette aide au sevrage, ou « traitement de la dépendance à l'égard du tabac », fait appel à toute une série de techniques – motivation, avis et recommandations, conseil, soutien téléphonique ou par Internet et produits pharmaceutiques auxiliaires – qui toutes visent à encourager les fumeurs à cesser de fumer et à éviter les rechutes. Le succès de ces interventions dépend de leur utilisation en synergie dans le contexte plus large d'une stratégie globale de lutte antitabac.

Un volume considérable de données atteste des avantages pour la santé, de l'efficacité et de la rentabilité du sevrage tabagique et du traitement de la dépendance à l'égard du tabac, trouble reconnu dans la dixième version de la Classification internationale des Maladies (OMS, 1992). Le traitement de la dépendance à l'égard du tabac est sûr et efficace. Toutefois, malgré l'existence de traitements d'un bon rapport coût/efficacité, le secteur de la santé publique de nombreux pays n'investit pas dans des services de sevrage tabagique, ni dans la mise en place d'une infrastructure susceptible de motiver les fumeurs à cesser de fumer et de les aider à le faire. En outre, dans la plupart des pays, la fourniture d'un traitement, la formation



des soignants, l'éducation et l'information sur les diverses thérapies, ainsi que les ressources financières sont limitées et rarement intégrées dans les soins de santé généraux. D'autre part, le sevrage tabagique n'est pas considéré comme une priorité de santé publique ni nécessairement comme une stratégie essentielle de lutte antitabac dans les plans de travail des pouvoirs publics et des institutions. En dehors des interventions visant spécifiquement à encourager le sevrage, un environnement général propice qui inciterait les fumeurs à cesser de fumer ne constitue généralement pas un élément des politiques de sevrage.

C'est dans ce contexte que la réunion qui fait l'objet du présent document a été convoquée par l'Initiative pour un monde sans tabac (TFI) pour encourager et recommander des mesures possibles pour favoriser les progrès dans les domaines du sevrage tabagique et du traitement de la dépendance à l'égard du tabac en tenant compte du contexte, de la culture, des soins de santé et des capacités de financement qui diffèrent selon les pays – et dans le cadre général des efforts déployés au niveau international pour élaborer une politique mondiale de lutte antitabac, en réduisant la prévalence du tabagisme et l'exposition à la fumée du tabac. La réunion a eu lieu à Moscou, en juin 2002, à l'invitation du Ministère de la Santé de la Fédération de Russie, et a bénéficié d'un financement du Département de la Coopération internationale au Développement du Ministère finlandais des Affaires étrangères (FINNIDA).

La réunion a rassemblé 31 participants, y compris les représentants des pays suivants : Allemagne, Brésil, Canada, Fédération de Russie, Hong Kong, région administrative spéciale de Chine, Philippines, Qatar, Seychelles, Thaïlande et Venezuela, qui ont acquis chacun leur propre expérience de l'exécution de politiques de sevrage. Les experts/scientifiques internationaux ont présenté les meilleures pratiques actuelles en matière de sevrage tabagique et de traitement de la dépendance à l'égard du tabac appliquées dans les pays suivants: Canada, Espagne, Etats-Unis d'Amérique, Finlande, Hong Kong, région administrative spéciale de Chine et Royaume-Uni de Grande-Bretagne et d'Irlande du Nord ; des membres du personnel du Siège et des bureaux régionaux de l'OMS assistaient également à la réunion.

La réunion avait pour but de contribuer à l'élaboration d'une stratégie qui aide les fumeurs partout dans le monde à cesser de fumer, en faisant appel aux Etats Membres, à la société civile et à la communauté scientifique. Elle était axée en particulier sur des mécanismes qui conviennent aussi bien aux pays développés qu'aux pays en développement et offrent un vaste éventail d'interventions possibles et d'un bon rapport coût/efficacité.



La réunion a souligné la nécessité de créer un environnement propice qui encourage les fumeurs à cesser de fumer. L'augmentation des taxes sur le tabac, l'interdiction de la publicité en faveur des produits du tabac, des politiques préconisant l'interdiction de fumer, des campagnes d'éducation et des campagnes dans les médias pour sensibiliser les fumeurs et rendre les produits du tabac moins accessibles, alliées à des programmes communautaires de sevrage tabagique sont considérées comme autant de mesures essentielles pour réduire le nombre de fumeurs. On a également abordé des questions telles que les utilisations possibles du système de soins primaires dans ce domaine ainsi que les différentes possibilités de réduire les coûts de ces interventions.

Les problèmes les plus répandus et les possibilités de mise en oeuvre de politiques de sevrage et de programmes de soutien à la lutte antitabac selon différents niveaux d'infrastructure et de ressources ont été étudiés. Les principaux obstacles à l'élaboration de politiques nationales de sevrage ou de programmes de soutien à la lutte antitabac ont été répertoriés : manque de formation et manque de motivation parmi les dispensateurs de soins, peu enclins à entreprendre des activités pour encourager les gens à cesser de fumer ; manque de ressources et de crédits publics ; absence de produits pharmacothérapeutiques ou manque d'accès à ceux-ci ; absence de mécanismes de financement ou de subventionnement des produits thérapeutiques par les compagnies d'assurance ; manque de coordination entre les divers secteurs impliqués dans les interventions et, plus important encore, manque d'intégration des mesures de sevrage dans une politique d'ensemble de lutte antitabac.

Les recommandations de la clinique Mayo de 1999 (annexe I) ont été utilisées comme base de discussion et ont été complétées. On a insisté sur la fixation de priorités dans les politiques et les programmes de sevrage tabagique, en fonction des infrastructures du système de santé, de la volonté politique et des ressources humaines et financières dont disposent les divers pays.

Un bilan des connaissances concernant les méthodes efficaces de sevrage tabagique et de traitement de la dépendance à l'égard du tabac montre que les thérapies comportementales et pharmacologiques de la dépendance tabagique peuvent contribuer pour beaucoup à améliorer les résultats sur le plan sanitaire. Des traitements efficaces et très rentables ont été passés en revue par un certain nombre d'instances faisant autorité, qui préconisent que l'ensemble du personnel de santé et des cliniciens proposent systématiquement des mesures de sevrage tabagique à leurs patients.

La pharmacothérapie reposant sur des données scientifiques offre tout un éventail d'options. Il s'agit des différentes formes de substitution de la nicotine (gomme à mâcher, pastilles, patches, pulvérisateur nasal ou inhalateur), et du bupropion.



L'efficacité générale des traitements fondés sur des bases scientifiques est comparable, puisqu'ils permettent de doubler en gros la probabilité d'un sevrage tabagique durable. La thérapie comportementale peut être efficace à elle seule et peut également augmenter sensiblement les chances de succès de la pharmacothérapie. Un large éventail de thérapies comportementales et pharmacologiques se sont avérées efficaces. Toutefois, aucune méthode ne devrait être privilégiée à l'exclusion des autres car l'efficacité, l'acceptabilité, le rapport coût/efficacité et le coût des traitements pour un individu ou la population tout entière varient considérablement.

Il est important de travailler avec le fumeur en vue de modifier son comportement tabagique mais cette action n'a qu'un impact limité si l'on ne s'attaque pas en même temps aux facteurs environnementaux qui favorisent et entretiennent l'habitude de fumer. Les interventions fondées sur la population et les méthodes comportementales et pharmacologiques axées sur l'individu doivent donc être considérées comme complémentaires. Les approches de santé publique telles que les campagnes dans les médias, les concours récompensant les personnes qui cessent de fumer ou les numéros de téléphone à appeler pour se faire aider jouent un rôle important en modifiant les normes sociales et en encourageant l'abandon du tabac. Les campagnes d'information peuvent contribuer à mieux faire connaître les méfaits du tabac sur la santé et les bienfaits du sevrage. Elles peuvent modifier et renforcer les comportements à l'égard de l'arrêt du tabac, proposer des solutions simples et infléchir le comportement des fumeurs. Les numéros d'appel ont un rôle important à jouer dans le cadre de programmes complets de sevrage tabagique, car ils offrent un service bon marché, facilement accessible, populaire et efficace. Des concours organisés dans certains pays (« Quit and Win ») récompensent l'abandon du tabac en faisant appel à des méthodes de communication et à des partenariats novateurs, notamment en associant des organismes communautaires et les services de santé, et ont permis d'obtenir des taux d'abandon du tabac d'environ 20 %. L'interdiction de fumer sur le lieu de travail est une mesure de santé publique rentable qui encourage à long terme la dissuasion de la consommation de tabac, laquelle n'est plus considérée comme la norme. L'adoption d'une approche de santé publique peut permettre de toucher un grand nombre de personnes pour un coût minimal.

Les ressources humaines et financières sont une condition préalable au maintien d'interventions en faveur du sevrage tabagique et du traitement de la dépendance à l'égard du tabac aussi bien au niveau de la population qu'au niveau individuel. Le développement des capacités de formation des dispensateurs de soins afin qu'ils soient en mesure de préconiser et d'appliquer les stratégies de sevrage et de traitement de la dépendance tabagique sera indispensable au succès de ces mesures. Le rôle des décideurs, des professionnels de santé et des chercheurs, qui s'efforcent de réduire



la prévalence du tabagisme sera décisif si l'on veut inscrire cette problématique à l'ordre du jour. Le rôle de la communauté internationale en vue d'assurer l'accessibilité et la disponibilité du traitement de la dépendance à l'égard du tabac est également important ; elle peut en effet apporter sa contribution en offrant une tribune à l'échange d'informations et à leur diffusion, en élaborant des principes directeurs et en passant en revue les meilleures pratiques, en mobilisant des fonds et en mettant en place des partenariats avec les établissements universitaires et de recherche.

Enfin, afin d'élargir encore et de rendre plus accessibles les interventions favorisant le sevrage et le traitement de la dépendance à l'égard du tabac au niveau national, les pouvoirs publics doivent renforcer la volonté politique et accroître les ressources financières en faveur des interventions efficaces aussi bien au plan individuel qu'au niveau de la population. Afin d'assurer la pérennité du sevrage, les pouvoirs publics doivent introduire des politiques et des programmes de sevrage dans les soins de santé de base et le faire dans le contexte d'une stratégie complète de lutte antitabac faisant appel à un large éventail de moyens.

Sur la base de l'expérience acquise et des enseignements tirés des exposés de pays, des bilans d'experts et des discussions sur la façon d'aider les pays à mettre en oeuvre les stratégies de sevrage tabagique, les participants à la réunion de deux jours ont établi une série de recommandations. Ces recommandations sont considérées comme les éléments prioritaires à entreprendre par les gouvernements, les ONG et les professionnels de santé qui souhaitent faire progresser la santé publique à court et à moyen terme:

- Une politique de sevrage tabagique doit être inscrite dans la politique globale de lutte antitabac si l'on veut que les efforts pour faire abandonner le tabac soient efficaces et durables;
- Un environnement propice, visant à restreindre l'accessibilité des produits du tabac, faire en sorte que la consommation de tabac soit moins bien acceptée socialement et développer l'information, augmentera les chances pour les fumeurs de cesser de fumer;
- Tous les consommateurs de tabac devraient se voir offrir un traitement efficace de leur dépendance;
- Les Etats Membres devraient élaborer de grandes orientations nationales fondées sur des données factuelles pour le traitement de la dépendance à l'égard du tabac;
- Il faudrait sensibiliser davantage les professionnels de santé, les administrateurs et les responsables de l'élaboration des politiques en les rendant attentifs à la fois aux avantages et à la rentabilité des mesures visant à favoriser le sevrage tabagique par rapport à d'autres interventions sanitaires;



- Une formation devrait être dispensée à tous les agents de santé au niveau des soins primaires, comme au niveau national et communautaire, pour leur permettre de mettre en oeuvre efficacement des interventions favorisant le sevrage tabagique;
- De nouveaux partenariats s'imposent si l'on veut renforcer l'engagement et mettre en commun le soutien financier et technique pour dispenser un traitement reposant sur des bases scientifiques.

L'une des phases décisives de l'élaboration de la convention-cadre de l'OMS pour la lutte antitabac commencera après son adoption par les Etats Membres de l'OMS. Ces derniers doivent être encouragés à ratifier puis à mettre en oeuvre le traité. Cet encouragement peut être d'ordre technique ou autre. Pour pouvoir répondre aux demandes d'assistance technique sur des points juridiques, scientifiques, de politique générale ou pratiques, après l'adoption de la convention-cadre, l'Initiative pour un monde sans tabac (TFI) s'emploie actuellement à mettre au point des principes directeurs à l'intention des pays. L'objet de ces textes est de fournir aux pays qui s'efforcent de définir des mesures de lutte antitabac une documentation générale fondée sur des données factuelles et adaptée à leurs besoins locaux spécifiques. Les recommandations en matière de sevrage tabagique et le traitement de la dépendance à l'égard du tabac s'inscrivent dans le cadre de cette activité.

Bases scientifiques

En 2003, la consommation de tabac fera environ 5 millions de décès dans le monde (OMS, 2002). Déjà, elle est responsable d'un décès d'adulte sur dix; d'ici 2030, ce chiffre passera à 1 sur 6, soit 10 millions de décès par an – plus que toute autre cause et plus que l'ensemble des décès qui seront imputables, selon les projections, à la fois à la pneumonie, aux maladies diarrhéiques, à la tuberculose et aux complications de l'accouchement cette année-là. Si les tendances actuelles persistent, près de 500 millions de personnes vivantes aujourd'hui mourront par suite du tabagisme, dont la moitié dans leurs années productives, perdant 20 à 25 années de vie.

Compte tenu du caractère dépendogène des produits du tabac, de nombreux consommateurs auront besoin d'une aide pour cesser de fumer. Bien que non comparables, les enquêtes menées dans la population indiquent qu'environ un tiers des fumeurs s'efforcent d'arrêter de fumer chaque année. Elles montrent par ailleurs que la majorité de ces tentatives de sevrage sont entreprises sans aide extérieure. Seul un petit pourcentage de fumeurs de cigarettes (1 à 3 %) parvient à s'arrêter durablement de fumer (au moins 12 mois d'abstinence) à la seule force de leur volonté (Fiore et al., 2000).



Promouvoir le sevrage tabagique et le traitement de la dépendance à l'égard du tabac peut produire des résultats immédiats. Si une grande partie des efforts mondiaux visent à éviter que les enfants et les adolescents commencent à fumer, les efforts parallèles visant à traiter les fumeurs auraient un effet beaucoup plus immédiat et durable. Selon la Banque mondiale, les efforts visant à dissuader les enfants de commencer à fumer n'auront aucun impact sur la mortalité mondiale liée au tabac avant 30 ans, car l'essentiel des décès qui surviendront d'après les projections au cours des 50 prochaines années concernent les personnes qui fument déjà (Banque mondiale, 1999). D'après ces projections, si la consommation des adultes diminuait de 50 % d'ici 2020, quelque 180 millions de décès dus au tabac pourraient être évités. En revanche, si l'on parvenait à réduire de 50 % la consommation de tabac chez les jeunes d'ici 2020, on n'éviterait qu'environ 20 millions de décès dus au tabac. Il est évident que des politiques de santé publique axées sur une réduction de la consommation de tabac dans ces deux groupes s'imposent, au même titre que des stratégies visant à dissuader les gens de commencer à fumer.

Références

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Resumen

Actualmente en el mundo hay más de 1300 millones de fumadores (Banco Mundial, 2000), de los cuales cuatro quintos viven en países de ingresos bajos o medianos. Si no se controla, en el siglo XXI el tabaco dará lugar a mil millones de defunciones, cuatro quintos de las cuales se registrarán en países de ingresos bajos. En 20 años la dependencia del tabaco podría convertirse en la principal causa mundial de muerte prematura o de años vividos con discapacidad (medidos en «años de vida ajustados en función de la discapacidad», o AVAD, un índice comparativo de la carga de morbilidad o de lesiones). Las estadísticas actuales indican que no será posible reducir las defunciones relacionadas al tabaco en los próximos 30-50 años a menos que se aliente a los fumadores adultos a abandonar el hábito. Las estadísticas ponen de relieve la importancia del Convenio Marco para el Control del Tabaco de la OMS (CMCT OMS) que, cuando se ratifique, se convertirá en el mecanismo legislativo y normativo mundial destinado a reducir las tasas de tabaquismo en adultos. El aumento de los impuestos al tabaco, la prohibición de la publicidad de los productos de tabaco y los entornos libres de humo de tabaco permiten ejercer presión para que se deje de fumar.

Debido al carácter adictivo de los productos de tabaco, muchos consumidores necesitarán apoyo para renunciar a ellos. El apoyo para el abandono del hábito de fumar, o «tratamiento de la dependencia del tabaco», comprende una variedad de medios (por ejemplo motivación, prestación de asesoramiento y orientación, apoyo psicológico, incluso por teléfono y por Internet, y la utilización de productos farmacéuticos apropiados) destinados a alentar y ayudar a los consumidores de tabaco a abandonarlo y evitar las recaídas. El éxito de estas intervenciones depende de su aplicación sinérgica en un contexto más amplio dentro de una estrategia integral de control del tabaco.

Hay pruebas abrumadoras de los beneficios para la salud y de la eficacia y la costoeficacia del hábito de fumar y del tratamiento contra la dependencia del tabaco, un trastorno reconocido como tal en la décima edición de la Clasificación Internacional de Enfermedades, de la OMS (OMS, 1992). El tratamiento es seguro y eficaz. Sin embargo, a pesar de ello, en muchos países el sector de la salud pública no está invirtiendo en servicios de promoción del abandono del hábito de fumar ni en el desarrollo de una infraestructura que permita motivar y ayudar a los fumadores a abandonar el consumo del tabaco. En la mayoría de los países, las provisiones en materia de tratamiento, capacitación de los dispensadores de asistencia sanitaria,



educación e información a este respecto, así como los recursos financieros para ello, son limitados y rara vez forman parte de la atención de salud ordinaria. En los planes de trabajo gubernamentales e institucionales, el abandono del hábito de fumar no se considera como una prioridad de salud pública ni como parte de una estrategia clave. Aparte de las intervenciones específicas, las políticas tampoco comprenden la promoción de un entorno general propicio al abandono del hábito.

Habida cuenta de estos antecedentes, la iniciativa de la OMS *Liberarse del Tabaco* (TFI) convocó la reunión sobre la cual se basa este documento para que sirviera de foro en el cual explorar y recomendar posibles vías encaminadas a hacer adelantos en las áreas de abandono del hábito de fumar y tratamiento de la dependencia del tabaco teniendo presentes los diferentes contextos nacionales, la cultura, los sistemas de atención de salud y la capacidad financiera de los países, todo ello en el marco general de los esfuerzos desplegados internacionalmente para formular una política mundial de control del tabaco mediante la reducción del consumo y de la exposición al humo de tabaco. La reunión, hospedada por el Ministerio de Salud de la Federación de Rusia, se celebró en Moscú en junio de 2002 con financiación del Departamento de Cooperación Internacional para el Desarrollo del Ministerio de Relaciones Exteriores de Finlandia (FINNIDA).

Entre los 31 participantes figuraban representantes del Brasil, el Canadá, Alemania, la Región Administrativa Especial de Hong Kong (China), la Federación de Rusia, Seychelles, Tailandia, Filipinas, Venezuela y Qatar, que tenían una experiencia variada en materia de políticas de abandono. Varios expertos y científicos internacionales y personal de la sede de la OMS y las oficinas regionales expusieron las mejores prácticas actuales de promoción del abandono del hábito de fumar y del tratamiento de la dependencia del tabaco en el Canadá, Finlandia, la Región Administrativa Especial de Hong Kong (China), España, el Reino Unido y los Estados Unidos de América.

Se había previsto que la reunión contribuyera a la elaboración de estrategias encaminadas a prestar apoyo a los consumidores de tabaco de todo el mundo en sus esfuerzos para abandonar el tabaco, con la participación de los Estados Miembros, la sociedad civil y la comunidad científica. Se prestó especial atención a la selección de los mecanismos más apropiados para los países tanto desarrollados como en desarrollo a partir de una amplia variedad de intervenciones económicas posibles.

Se insistió en la necesidad de crear un entorno propicio que aliente a los fumadores en sus intentos de abandonar el hábito. El aumento de los impuestos al tabaco, la prohibición de la publicidad de los productos de tabaco, las políticas favorables a los entornos sin humo de tabaco, la educación y las campañas difundidas por los medios



de comunicación con el fin de aumentar la conciencia y reducir las posibilidades de acceso de los fumadores a los productos de tabaco, junto con los programas comunitarios de promoción del abandono del hábito de fumar, se destacaron como pilares del proceso de reducción del número de fumadores. Se examinaron temas tales como posibles maneras de utilizar el sistema de atención primaria de salud para fomentar el abandono del hábito de fumar, así como diferentes formas de reducir los costos de esas intervenciones.

Se examinaron retos comunes y posibilidades de aplicación de políticas de promoción del abandono del hábito de fumar y programas favorables al control del tabaco en diversos niveles de la infraestructura con recursos variables para el control del tabaco. Se identificaron los principales obstáculos que dificultan el establecimiento de esas políticas y programas en los países. Entre ellos figuran la capacitación inadecuada y la falta de motivación de los dispensadores de asistencia sanitaria para iniciar y realizar actividades de promoción del abandono del hábito de fumar, la falta de recursos y financiamiento del gobierno, la no disponibilidad y la inaccesibilidad de los productos farmacoterapéuticos, la ausencia de mecanismos de financiación o de subsidio de los productos farmacoterapéuticos por las aseguradoras, la falta de coordinación entre los diversos sectores que trabajan en intervenciones de promoción del abandono del hábito de fumar y, lo que es más importante, la falta de integración de esas intervenciones en una política general sobre control del tabaco.

Las recomendaciones formuladas por la Mayo Clinic en 1999 (anexo I) se utilizaron como base para la discusión y se elaboraron más. Se destacó la asignación de prioridades en materia de políticas y programas de abandono del hábito de fumar según los niveles del sistema de salud, la voluntad política y los recursos humanos y financieros de los diversos países.

Un examen de la base de datos probatorios sobre el abandono del hábito de fumar y el tratamiento eficaz de la dependencia del tabaco muestra que los tratamientos comportamentales y farmacológicos contra la dependencia del tabaco pueden contribuir sustancialmente a aumentar los beneficios de salud. Varios órganos autorizados han examinado tratamientos eficaces y sumamente económicos y recomiendan que todo el personal de salud, inclusive los médicos, promuevan sistemáticamente el abandono del hábito de fumar entre sus pacientes.

La farmacoterapia basada en datos probatorios ofrece una variedad de opciones personales. Éstas comprenden diversas formas de terapia de sustitución de la nicotina (chicles, pastillas, parches, sprays nasales e inhaladores orales) y bupropión.



La eficacia general de estos medicamentos es similar porque duplican aproximadamente la probabilidad de abandono del hábito a largo plazo. El tratamiento comportamental puede ser eficaz por sí mismo y puede mejorar sustancialmente los resultados de la farmacoterapia. Hay una amplia gama de terapias comportamentales y farmacológicas de demostrada eficacia. Sin embargo, no se debe privilegiar ningún método con exclusión de los otros porque los tratamientos varían mucho en eficacia, aceptabilidad, eficiencia y costo según los individuos y las poblaciones.

Es importante tratar de modificar el comportamiento de los fumadores de forma individual, pero ello tiene efectos limitados si se desatienden los factores ambientales que promueven y apoyan el tabaquismo. En consecuencia, las intervenciones basadas en la población deben considerarse como complementarias de las intervenciones comportamentales o farmacológicas a nivel individual. Enfoques de salud pública tales como campañas por los medios de difusión, concursos y líneas telefónicas de ayuda desempeñan una función importante en la modificación de pautas sociales y la promoción del abandono del hábito de fumar. Las campañas por los medios de difusión dan a conocer los efectos del tabaco en la salud y los beneficios que conlleva abandonarlo. También pueden cambiar y reforzar actitudes a favor de que se deje el hábito, dar ejemplos de acciones sencillas e influir en el comportamiento de los fumadores. Las líneas telefónicas de ayuda desempeñan un papel importante como parte de programas integrales generales de abandono del hábito de fumar. Prestan un servicio de bajo costo, fácilmente accesible, popular y eficaz. Los concursos en los que se premia a quienes abandonan el hábito aplican métodos de comunicación innovadores y fórmulas de asociación en las que participan organizaciones comunitarias y servicios de salud, y logran tasas de abandono de alrededor de un 20%. El de los lugares de trabajo sin humo de tabaco es un enfoque de salud pública económico que promueve la importante meta de largo plazo consistente en desnormalizar el consumo de tabaco. La aplicación de criterios de salud pública permite llegar a un gran número de personas a un costo mínimo.

Los recursos humanos y financieros son un requisito previo para mantener las intervenciones encaminadas a promover tanto en la población como a nivel individual el abandono del hábito de fumar y el tratamiento de la dependencia del tabaco. La creación de capacidad para educar y adiestrar a los dispensadores de asistencia sanitaria a fin de que fomenten y apliquen estrategias de promoción del abandono del hábito de fumar y de tratamiento de la dependencia del tabaco será esencial para el éxito. La función de los formuladores de políticas, los profesionales de la salud y los investigadores que procuran reducir la prevalencia del tabaco será imprescindible para que la promoción del abandono del hábito de fumar se incorpore en los programas. La comunidad internacional también desempeñará una función importante



para asegurar la accesibilidad y la disponibilidad del tratamiento de la dependencia del tabaco y ofrecer un foro en el cual se comparta y distribuya la información, se preparen normas y exámenes sobre las mejores prácticas, se recauden fondos y se establezcan lazos de asociación con investigadores e instituciones académicas en la esfera de la promoción del abandono del hábito de fumar.

Por último, a fin de que las intervenciones de promoción del abandono del hábito de fumar y tratamiento de la dependencia del tabaco tengan mayor alcance y sean más accesibles a nivel nacional, los gobiernos deben reforzar el compromiso político y los recursos financieros en apoyo de intervenciones eficaces de promoción del abandono del hábito de fumar a nivel de la población e individual. Para asegurar la sostenibilidad del abandono del hábito de fumar, los gobiernos deben incorporar las políticas y programas de promoción de ese abandono en otros servicios de atención básica de salud y hacerlo en el contexto de una estrategia integral de control del tabaco aplicando una gran diversidad de políticas.

Merced a la experiencia y las enseñanzas extraídas de las ponencias de representantes de países, los exámenes de expertos y los debates sobre la forma de ayudar a los países a poner en práctica las estrategias de promoción del abandono del hábito de fumar, los participantes en la reunión de dos días formularon una serie de recomendaciones cuya aplicación por los gobiernos, las ONG y los profesionales de la asistencia sanitaria interesados en conseguir beneficios de salud pública en el corto y el mediano plazo se considera prioritaria, a saber:

- Una política de promoción del abandono del hábito de fumar debe formar parte de una política más amplia de control del tabaco para que los esfuerzos de abandono del hábito sean eficaces y sostenibles;
- Un entorno propicio, que comprende una reducción de la accesibilidad de los productos de tabaco, una pérdida de aceptación social del consumo del tabaco y un aumento de la información, contribuirá a que sea más probable el abandono por parte de los fumadores;
- Se debe ofrecer a todos los consumidores de tabaco un tratamiento eficaz contra la dependencia del tabaco;
- Los Estados Miembros deben establecer normas nacionales basadas en pruebas para el tratamiento de la dependencia del tabaco;
- Se debe fomentar la concientización de los profesionales de la asistencia sanitaria, los administradores y los formuladores de políticas acerca de los beneficios y de la eficacia en función de los costos de las intervenciones de promoción del abandono del hábito de fumar en relación con otras intervenciones de atención de salud;
- Se debe capacitar a todos los dispensadores de asistencia sanitaria a nivel de la atención primaria, la comunidad y el país para que puedan realizar eficazmente



intervenciones de promoción del abandono del hábito de fumar;

- Se necesitan nuevas alianzas para reforzar el compromiso con el tratamiento basado en pruebas y aumentar el apoyo financiero y técnico.

Después de la adopción del Convenio Marco de la OMS para el Control del Tabaco (CMCT OMS) por los Estados Miembros de la OMS comenzará una fase decisiva del trabajo. Los Estados Miembros deben contar con apoyo técnico o de otra índole a la hora de ratificar y posteriormente aplicar el tratado. Para poder responder a las peticiones de asistencia técnica sobre las medidas legislativas, científicas, de política y prácticas que se habrán de tomar después de la adopción del CMCT OMS, la iniciativa Liberarse del Tabaco de la OMS (TFI) está elaborando directrices destinadas a los países. La finalidad de las mismas es ofrecer a los países que estén preparando medidas de control del tabaco material de apoyo basado en pruebas y adaptado a sus necesidades locales específicas. Las *recomendaciones sobre políticas de promoción del abandono del hábito de fumar y del tratamiento de la dependencia del tabaco* forman parte de esta actividad.

Justificación científica

Se prevé que en 2003, el consumo de tabaco matará a unos 5 millones de personas en todo el mundo (OMS, 2002). El tabaco ya es responsable de una de cada 10 defunciones de adultos; para 2030 se prevé que la cifra será de una de cada seis, o sea 10 millones de defunciones anuales, es decir más que cualquier otra causa y más que las defunciones por neumonía, enfermedades diarreicas, tuberculosis y complicaciones del parto combinadas previstas para ese año. Si las tendencias actuales persisten, unos 500 millones de personas que están vivas hoy con el tiempo morirán por causa del consumo de tabaco, la mitad de ellas en la productiva edad mediana, con lo que habrán perdido 20 a 25 años de vida.

Habida cuenta del carácter adictivo de los productos de tabaco, muchos consumidores de éstos necesitarán apoyo para dejarlos. Aunque no son comparables, las encuestas de población indican que, cada año, aproximadamente un tercio de los fumadores tratan de dejar de fumar y que en la mayor parte de los casos lo hacen sin ayuda. Sólo un pequeño porcentaje de fumadores de cigarrillos (1%-3%) logran una abstinencia duradera (al menos 12 meses de abstinencia del tabaquismo) aplicando solamente la fuerza de voluntad (Fiore et al., 2000).

La promoción del abandono del hábito de fumar y el tratamiento de la dependencia del tabaco pueden dar beneficios inmediatos. Mientras que gran parte de los esfuerzos mundiales están dedicados a reducir el inicio del consumo de tabaco en los niños y



adolescentes, si se hicieran esfuerzos simultáneos para tratar a los fumadores actuales además de reducir la iniciación, los efectos serían mucho más inmediatos y de largo plazo. Según el Banco Mundial, los esfuerzos para disuadir a los niños de que fumen tardarían unos tres decenios en tener repercusiones sobre la mortalidad mundial relacionada con el tabaquismo, ya que la mayor parte de las defunciones proyectadas para los próximos 50 años son las de los fumadores existentes (Banco Mundial, 1999). Estas proyecciones sugieren que, si para el año 2020 disminuyera un 50% el consumo de los adultos, se podrían evitar aproximadamente 180 millones de defunciones relacionadas con el tabaco. Por otra parte, si para esa misma fecha se redujera un 50% el inicio del tabaquismo juvenil, sólo se evitarían unos 20 millones de defunciones relacionadas con el tabaco. Evidentemente, se necesitan políticas de salud pública que hagan hincapié en el abandono por parte de ambos grupos, así como estrategias de reducción del inicio.

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Over the last 30 years understanding concerning effective tobacco-control strategies has shifted, from focusing solely on changing the behaviour of individual smokers towards a broader and more comprehensive approach that targets the environment and promotes change in social norms. Education of smokers on the risks they face and clinic-based smoking cessation programmes have been supplemented by efforts to change community norms, increase the cost of cigarettes, restrict places where smoking is permitted, and provide mass-media campaigns to promote cessation. These efforts have shifted overall prevalence in the United States from 47% in 1965 to approximately 22% in 1999 (National Cancer Institute, 2000). According to the tobacco-use survey conducted in 1999 by the Bureau of the Census in the United States at the request of the National Cancer Institute, currently almost 50% of all those who have ever smoked are former smokers (Bureau of the Census for the National Cancer Institute, 2001).

At the heart of these efforts has been the important long-term goal of de-normalizing tobacco use. Promoting change in social norms is essential to successful smoking cessation, since the social environment provides the context for smoking cessation and encourages smokers in their attempts to quit.

Policies for community interventions to promote cessation by changing social norms are a good investment. For example, there is evidence that smoke-free workplaces have multiple effects: from 1986 to 1999, the number of smoke-free workplaces increased by 50% in the United States, while second-hand smoke exposure, as measured by the median (50th percentile) serum cotinine levels, decreased by 75% among the population aged three years and older (Health and Nutrition Examination Survey). In addition, smoke-free workplaces make it easier for workers to reduce or stop smoking (Fichtenberg et al., 2002).

The tobacco industry's own data anticipate that, if smoking were banned in all workplaces, there would be a 74% increase in quitting rates and a substantial loss in industry revenues. These are important reasons for the industry's opposition to legislation that seeks to expand smoke-free coverage (Heronimus, 1992).

Furthermore, the public-health approach to tobacco control can affect large numbers of individuals at minimal cost. The smoke-free workplace is a cost-effective approach, and increasing the cost of cigarettes through increased taxation is another.

In addition to price and tax measures to reduce the demand for tobacco, non-price tobacco-control measures to reduce the demand for tobacco will further enhance a



supportive environment. Such measures include: protection from exposure to tobacco smoke; regulation of the contents of tobacco products; regulation of the packaging and labelling of tobacco products; education, communication, training and public awareness; regulation of tobacco advertising, promotion and sponsorship; and measures relating to the reduction of the supply of tobacco. Tobacco supply can be reduced by addressing illicit trade in tobacco products; prohibiting the sale of tobacco products to and by minors; and providing support for economically viable alternative activities for tobacco workers, growers and individual sellers.

Evidence from countries of all income levels shows that price increases on cigarettes are highly effective in reducing demand. Higher taxes induce some smokers to quit, and prevent other individuals from starting. They also reduce the number of ex-smokers who return to cigarettes and reduce consumption among continuing smokers. On average, a price rise of 10% on a pack of cigarettes would be expected to reduce demand for cigarettes by about 4% in high-income countries and by about 8% in low-and middle-income countries, where lower incomes tend to make people more responsive to price changes. As children and adolescents are more responsive to price rises than older adults, this intervention would have a significant impact on them (World Bank, 1999).

The mass media provides an important means of changing social norms and ultimately promoting smoking cessation. Evidence suggests that media campaigns are most effective in inducing smoking cessation when the social structure has actively changed the environment for the smoker. The synergistic combination of media campaigns and social change effectively stimulates positive attitudinal and behavioural changes with respect to smoking cessation (National Cancer Institute, 2000). According to the World Bank (1999), “information shocks”, such as the publication of research studies with significant new information on the health effects of smoking, reduce demand. Their effect appears to be greatest when a population has relatively little general awareness of the health risks. Comprehensive bans on advertising and promotion can reduce demand by around 7%, according to econometric studies in high-income countries (World Bank, 1999).

Investment in these strategies is paying off. In Canada, a recent study has demonstrated that restrictive municipal laws limiting public smoking are positively related to the increased numbers of non-smokers and decreased numbers of cigarettes consumed by continuing smokers (Stephens, et al., 2001). New data from the National Cancer Institute’s American Stop Smoking Intervention Study, one of the largest tobacco-control studies ever undertaken by the United States government, also show that restrictive state-level clean indoor-air policies and increased taxation decrease the prevalence of smoking and achieve lower consumption levels (Stillman F. et al., forthcoming).



Effectiveness and reach of community interventions

	Effectiveness (%)	Population reach (%)
Local World No Tobacco Day (WNTD)	0.15	90
Broader community-wide interventions with:		
High effectiveness	0.5	100
Medium effectiveness	0.1	100
Low effectiveness	0.05	100
Quit and Win competition with:		
Average cost and participation	8	1.26
Low cost and participation	6	0.27
High cost and participation	10	3.11

Source: Parrott et al, 1998. *Thorax* 1998; 53 (Supplement 5, Part 2): S11-S16

In January 2002, the Canadian Cancer Society released a study – Evaluation of New Warnings on Cigarette Packages – that indicates that the precedent-setting health warning on cigarette packages introduced in 2001 is effective at discouraging smoking. The national study conducted between 19th September and 10th October 2001, surveyed 2,031 Canadian adults aged 18 and over, including 633 smokers. The results indicate that for a significant proportion of smokers, the warnings increased the motivation to quit, raised the level of concern about the health effects of smoking, and improved awareness of the health effects of smoking. The Canadian success with health warnings is inspiring international action.

Brazil tobacco-product packs have a picture-based warning as of 31 January 2002 and a European Community Directive gives its member countries the option of using pictures. An opinion survey of a population of 2,216 respondents of 18 years of age and older, conducted in April 2002 in 126 Brazilian municipalities three months after the implementation of the new warnings showed that 73% of smokers supported the measures and that 54% of them changed their opinion regarding health consequences of smoking after the new health warnings were enforced. An estimated 67% of smokers responded that they wanted to quit after seeing the new health warnings. The new health warnings had a greater impact on those with low incomes and lower levels of education (Costa e Silva, 2002).



Building Supporting Environments

Smoking Cessation as a Key Policy of the National Tobacco Control Programme in **BRAZIL**

- Promoting smoking cessation and increasing the availability and accessibility of cessation-related resources has been one of the four key strategies of the comprehensive national tobacco-control programme in Brazil for the past 13 years.
- An effective network of State and Municipal Health Offices has ensured execution of the action plan throughout the country. Management of the programme is shared by the Ministry of Health with all 26 states, the Federal District and with more than 3,500 municipalities.
- A legislation that bans tobacco advertising promotion and sponsorship and creates smoke free places builds a supportive environment for smokers to quit.
- Reference centres have been established that act as specialized smoking cessation centres. Training is provided to health professionals who can then deliver brief smoking cessation interventions in routine work as well as deliver behavioural interventions and pharmacotherapy. The delivery of smoking cessation therapies has been well integrated with other strategic health programmes.
- Information supporting cessation is also being provided through strong visual health warnings and national hotline numbers on cigarette packages encouraging smokers to seek cessation support.

In the Netherlands, from 1 May 2002, manufacturers of tobacco products have been obliged to print new health warnings on the packaging of tobacco products. A survey among a population of 8,836 respondents of 15 years of age and older, among whom 2,812 (31.8%) were smokers, has shown that the new warning labels printed on the packaging of tobacco products have made smoking less appealing, particularly to the group of smokers who intend to stop smoking. As a result, many of the people in this group are now more motivated to stop smoking and some of them are already smoking less. This group makes up more than a third of all smokers. Projected to the total Dutch population, this adds up to a total of more than 1,375,000 smokers in the Netherlands (Willemsen, 2002).

Tobacco-control efforts, especially efforts to change the social norms concerning smoking, have faced constant challenges. To date, evaluation of tobacco-control efforts only have assessed the effect of the public-health investment and have not taken into account the countervailing forces that have sought to undermine or devalue this investment. The thousands of millions of US dollars spent each year by the tobacco industry in the United States alone, is testimony to the enormous effort to increase demand for smoking. This has implications for the efforts to promote cessation (Stillman F. et al., 1999).

Another intervention would be to help those who wish to quit by making it easier for them to obtain nicotine-replacement therapy (NRT) and other cessation interventions.



NRT markedly increases the effectiveness of cessation efforts and also reduces an individual's withdrawal costs. Yet in many countries, NRT is difficult to obtain (World Bank, 1999).

Therefore, the supportive environment for smokers and tobacco users must further be reinforced by increased availability and accessibility to low-cost health system services which will support the quit attempts. To this extent the various components of the health system, including primary care and secondary care, must be adjusted in order to be able to deliver smoking cessation and treatment of tobacco dependence interventions in a more permanent manner. These services should, in addition to brief advice, be able to provide long-term follow-up treatment if required. It is important to include smoking cessation and treatment of tobacco dependence in (public or private) insurance coverage.

According to the World Bank (1999), the combined effect of all these demand-reducing measures is not known, since smokers in most countries with tobacco-control policies are exposed to a mixture of them and none can be studied strictly in isolation. However, there is evidence that the implementation of one intervention supports the success of others, underscoring the importance of implementing tobacco control as a package.

In summary, policy efforts take time, but they have caused a major change in social norms. This has had a major positive effect on smoking behaviour in the United States and other countries where tobacco control efforts have been successful. These changes have occurred despite the tobacco industry's continued massive investment in the undermining of public policy and maintenance of smoking. Comprehensive tobacco-control efforts must be continued, while at the same time expanding support for population and individual-based cessation efforts.

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Matrix I

A broad policy framework for a comprehensive strategy on smoking cessation and treatment of tobacco dependence

The matrix below demonstrates a broad framework for addressing smoking cessation and treatment of tobacco dependence in which governments could progressively choose minimal, expanded and core recommendations, as they strengthen and build their resources and capacities to sustain a comprehensive strategy for smoking cessation. This broader framework includes a mix of three main strategies: *a public health approach* that seeks to change the social climate and promoting a supportive environment; *a health systems approach* that focuses on promoting and integrating clinical best practices (behavioural and pharmacological, which help tobacco-dependent consumers increase their chance of quitting successfully) into a sustainable health care system; and a *surveillance, research and information approach* that promotes the exchange of information and knowledge so as to increase awareness of the need to change social norms. Elements that would be included in such a mix are: increasing taxes on cigarettes, banning advertising and promotion of tobacco products, increasing public health information, creating smoke-free places, and encouraging smoking cessation (using both behavioural therapy and pharmacotherapy approaches).

**Matrix I****Promoting a supportive environment - the public health approach**

	MINIMAL	EXPANDED	CORE
Tax	Constant real prices of all tobacco products (i.e. nominal prices to grow in line with overall inflation).	Positive growth in real prices of all tobacco products (i.e. annual increase in nominal prices to exceed overall inflation).	5% annual increase in real prices of all tobacco products.
Clean indoor air	100% smoke-free hospitals	None	100% of all public places and workplaces, with enforcement
Advertising, promotion, sponsorship	Partial ban on direct advertising	Total ban on direct advertising	Total ban on direct and indirect advertising, promotion and sponsorship
Public health education programmes-awareness	Hold nationwide activities for WNTD and media events	Frequent media campaigns (paper, radio, TV)	Sustained and systematic media campaigns
Structural capacity of programmes	Designated focal person (shared)	Full-time focal person	+ National Committee on Tobacco Control
Advocacy	Gathering information	Dissemination of information	Actively promoting locally relevant programmes
Quitlines	None	Lines available in selected places	Lines available nationwide
Warning and health messages	Minimal	Messages from MOH or other relevant authority	Rotating messages, half-surface size, pictorial, including a cessation message
Product regulation	Minimal disclosure of ingredients	None	Comprehensive list of ingredients (+control)



Matrix I

Promoting clinical best practices - the health-systems approach

	MINIMAL	EXPANDED	CORE
Establish clinical treatment as priority	General statement in written government policy	None	Strong statement in written government policy
Define role of constituents regarding clinical treatment	Information exchange	Coordinated	Institutionalized, shared resources
Make funding available for non-pharmacological treatment	No funding available (smokers pay for treatment)	Partial funding by government	Total funding by government and or private sector
Make funding available for pharmacological treatment	No funding available (smokers pay for treatment)	Partial funding by government	Shared funding by government private insurance to ensure total coverage for treatment
WHO Essential Drugs List	No cessation drugs	Selected NRT	NRT + drugs of demonstrate effectiveness
Assess tobacco use and offer treatment	Patients at risk should be assessed for tobacco use	None	All patients should be assessed for tobacco use during routine care using stages-of-change model
Availability of pharmacological treatment	None	+ selected NRT	++ other pharmacotherapy
Extent of coverage of pharmacological treatment	Available only at specialized centers for specified populations, e.g. secondary prevention of CVD (tertiary care)	Secondary care	All primary health care facilities.
Availability of behavioural treatment	Self-help, opportunistic brief advice	Targeted stage-based (motivated) intervention	Intensive, behavioural counselling (specialist)
Use of Practice Guidelines for clinical treatment	Establish and make available minimum guidelines which are culturally relevant	None	Establish and make available comprehensive guidelines that are consistent with other accepted standards.
Pre-graduate training of health-care professionals	Minimal curriculum in professional schools	None	Extensive curriculum in professional schools and continuing education programmes
Post-graduate training for cessation	None	In-service training	Certified programmes

Matrix 1

Promote surveillance, research and information-exchange

	MINIMAL	EXPANDED	CORE
Monitor sales of NRT	Annual tracking of prices and regulatory and advertising status of all dosage forms of NRT.	Annual sales/use of all dosage forms of NRT.	Annual sales/use by population segment (e.g. age, gender, income, education) of all dosage forms of NRT.
Prevalence and consumption	Conduct surveys on prevalence of tobacco use and consumption among youth	Among health professionals and other high-risk groups	Among adult populations by gender, education and economic status
Knowledge attitudes and practices	Conduct opinion polls to assess level of awareness among different segments of the population of the health risks associated with tobacco use	Conduct surveys on assessing behaviours and attitudes towards tobacco - control measures and understand how social health risks associated norms are formed	Conduct surveys on assessing smokers' reasons and intentions to quit
Process	Conduct surveys and evidence-based research	Monitor patterns and programmes	Evaluate programmes and policies

With the aim of strengthening and building the capacity of countries to implement effective smoking cessation policies, representatives from countries with varying levels of infrastructure and resources for tobacco control, met to share and exchange experiences and know-how on how to put in place effective policies and strategies for tobacco cessation. In particular, they provided an overview of their countries' experiences in implementing cessation policies and best practices, discussed the challenges and opportunities for developing national smoking cessation policies and programmes and provided practical recommendations for a comprehensive policy on cessation.

Selected country experiences

Selected country experiences and examples of successful strategies can be found in relevant chapters throughout this book. These are based on the presentations made by the participants from the different countries. Interested readers can obtain further information about these experiences from the respective participants whose contact details are listed in annex II of this book.

Common challenges

The various country experiences presented during the Moscow meeting revealed many common challenges and opportunities in implementing policies and programmes on smoking cessation and treatment of tobacco dependence:

- Smoking cessation and treatment of tobacco control have so far been treated as isolated activities, rather than as part of a national policy to be addressed in the context of an overall policy on tobacco control;
- Lack of motivation of health-care providers and professionals to address smoking cessation and treatment of tobacco control as a means of prevention;
- Misinformation on the part of health-care providers concerning interventions on effective smoking cessation and treatment of tobacco dependence (therefore there is a need both for better information flow to providers on best practices and for better interpretation of that information);
- Inadequate training of health-care providers to deliver effective interventions on smoking cessation and treatment of tobacco dependence in all health-care settings;
- Lack of support for routine assessment of tobacco dependence by health-care providers in health services;



- Lack of resources and government funding for the implementation of effective interventions on smoking cessation and treatment of tobacco dependence;
- Lack of availability and accessibility of pharmacotherapy products in most countries (i.e due to high costs of NRT and pharmacotherapy products);
- Lack of financial coverage or subsidization of pharmacotherapy products by insurance companies;
- Lack of coordination between various sectors involved in providing interventions for smoking cessation and treatment of tobacco dependence.

Despite the numerous barriers identified as impediments to implementing and delivering effective interventions for smoking cessation and treatment of tobacco dependence, many countries have been successful in implementing strategies aimed at improving the rate of cessation of tobacco use. Such strategies include, for example, the development of nationwide campaigns to increase awareness among populations of the benefits of smoking cessation; implementation of smoke-free policies in health units, public places and workplaces; training of health-care providers; dissemination of evidence-based information and best practices on smoking cessation methods; increasing the accessibility and availability of NRT products; promotion of partnerships with governments and NGOs to support evaluation, research, training and resource development; and the creation and organization of national multisectoral committees for tobacco control.

In summary, in order to further expand and make more widely available various interventions for smoking cessation and treatment of tobacco dependence, country experts recognized the following areas for improvement in their countries (not exclusive):

- Increase political commitment and financial resources in support of effective population- and individual-based smoking cessation interventions, and ensure efficient resources for health units to monitor and evaluate the implementation of treatment for tobacco dependence;
- Introduce tobacco control law and improve law enforcement, as the case may be;
- Reinforce and sustain activities relating to smoking cessation and treatment of tobacco dependence within the context of a comprehensive tobacco-control strategy, employing a broad range of policies;
- Set up a national committee and a tobacco control office with a structure and a budget;
- Integrate tobacco-cessation interventions into other basic health care programmes;
- Have health care centres registered and working as reference centres for smoking cessation and treatment of tobacco dependence;
- Convince health professionals and patients to treat nicotine addiction as a chronic



illness in order to enhance their responsiveness and responsibility for undertaking appropriate measures, which will increase the likelihood of cessation;

- Develop and enhance advocacy through the media to create a tobacco-free society, and to encourage social and family support to motivate tobacco users to quit;
- Develop models and promote transfer of technology for health professionals in every health-care setting, especially in primary health care units;
- Have local and national leaders serve as role models in society;
- Support enforcement of smoke-free legislation in all public places and workplaces;
- Further develop alternative means to increase cessation;
- Reach specific population groups, including light and moderate smokers, providing them with information on the “how to’s” of successful quitting and where to receive assistance.

The following sections will review the available behavioural and pharmacological therapies for smoking cessation.

Rationale

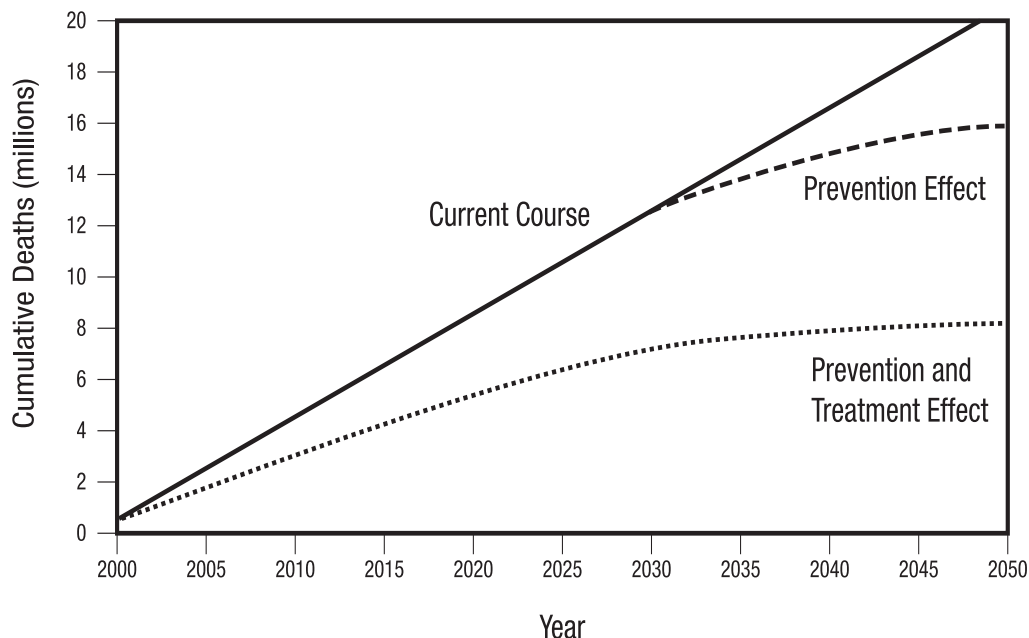
Behavioural and pharmacotherapy for tobacco dependence and withdrawal can contribute substantially to improved health by enabling cessation of tobacco use. Even among persons who might ultimately achieve tobacco abstinence without therapy, the benefits can be profound if treatments help people to achieve tobacco abstinence earlier, because the risk of disease is strongly related to the duration of tobacco use. Several concepts are discussed that can contribute to understanding the place of therapy in tobacco-disease-control efforts.

The first concept to understand when contemplating the provision of treatment for a disease in general is the nature of the disease and factors that can impede the efficacy and utilization of a treatment. In the case of tobacco dependence there are at least three important considerations. The first is that tobacco dependence is a powerful biological and social process that strongly impedes achieving and sustaining cessation. The second is that tobacco dependence is often accompanied by unrealistic fears about treatment as well as the assumption that treatment really is not needed. This is typical across addictions and is sometimes referred to as the “denial” or “rationalization” factor because of the tendency of addicted persons to deny that they are truly addicted and need help, and because they may assume that treatment is riskier than the disease. Third is that this disease is promoted to an unprecedented extent by the tobacco industry, which engages all manner of economic, social, political and regulatory pressures to enable it to establish and sustain tobacco dependence.

Treatment can make it possible, but rarely makes it easy, to achieve cessation from tobacco. Whereas tobacco products are designed and marketed for maximum appeal, treatment medications for addiction are designed with greatest consideration to safety and efficacy, including attention to reduce overuse or addictive use of the products. This means that treatment is, by design, less appealing than tobacco, and whereas the main problem with tobacco is enabling and sustaining cessation, a major problem with most treatment is to foster compliance and adequate use to achieve



Projected Tobacco-Caused Mortality Patterns



Projections of smoking-related mortality based on present trends (**current course**), compared with projections of effective prevention (**prevention effect**) and effects of combined prevention and treatment (**prevention and treatment effect**).

(Source: Henningfield and Slade, 1998)

and sustain tobacco abstinence. Furthermore, whereas the tobacco industry ensures that tobacco products are readily available, attractive, and highly affordable, pharmacotherapy is frequently out of reach, available often only by prescription or from limited points of sale, and is often more expensive on a daily basis and point of sale basis because it is generally distributed in packages that include behavioural treatment guidance and sufficient units to discourage simple occasional use as a temporary substitute for tobacco. Behavioural therapy similarly is often not readily available, is human-resource intensive, and has been found to appeal only to sub-populations of tobacco-users.

Evidence-based pharmacotherapy offers a variety of options for individuals that are important to match with the wide variations in individual preferences. These include several forms of nicotine-replacement therapy (gum, lozenge, patch, nasal spray and oral inhaler) and bupropion. The general efficacy of the evidence-based medicines is similar in providing an approximate doubling of the probability of long-term smoking cessation. Behavioural treatment can be effective in its own



right and can also substantially increase the success of pharmacotherapy.

Efficacious and highly cost-effective treatments have been reviewed in many countries and institutions and they advocate that all health-care personnel and clinicians should consistently deliver smoking cessation interventions to their patients. Behavioural treatment ranges from brief opportunistic interventions by health professionals to encourage and support cessation, to highly structured programmes to address withdrawal, cope with cravings, and avoid relapse to tobacco use.

Major challenges for the twenty-first century include making treatments culturally relevant and appropriately tailored to individuals and populations, and making treatment as readily accessible as are the tobacco products themselves.

Treatment should ideally be offered as one component of comprehensive tobacco-control efforts that include increased taxes on tobacco, restrictions on public smoking, education emphasizing the dangers of tobacco and benefits of cessation, and restrictions on tobacco-product marketing; these are critical for cessation efforts, treatment utilization and the maintenance of tobacco abstinence.

Behavioural interventions

The efficacy of behavioural therapies for the treatment of tobacco dependence has been comprehensively reviewed in the United States' *Clinical Practice Guideline: Treating Tobacco Use and Dependence* (Fiore et al., 2000), reports from the US Surgeon General (United States Department of Health and Human Services, 2000) and the Royal College of Physicians; United Kingdom (Royal College of Physicians, 2000) and in the online treatment resource, [treattobacco.net](http://www.treattobacco.net) (see <http://www.treattobacco.net>). A variety of behavioural therapies have been shown to be efficacious for many smokers. Behavioural therapy ranges in complexity from simple advice offered by a physician or other health-care provider to much more extensive

You CAN quit smoking!
Without gaining weight

Many people are afraid to quit smoking because they worry about gaining weight. But you can quit without a lot of weight gain.

Remember: each smoke must be replaced by something — be prepared for the cravings.

You need to find ways to stay away from tobacco while staying away from fattening foods.

Being more physically active can help.

It will be easier to be active as your lungs recover their health.

For more information on tobacco, its health effects and ways to overcome a tobacco addiction, talk to a doctor, nurse or pharmacist or visit www.infotobacco.com

Health Canada 8

Example of a tip with smoking cessation messages used on cigarette packages in Canada



therapy offered by counsellors or specialized smoking cessation clinics. Clearly, as the level of complexity of the therapy increases, the cost to the smoker or third-party provider increases, and the availability of the therapy, particularly among developing countries, decreases.

Physician advice

Simple advice from a physician has been shown to increase abstinence rates significantly (by 30%) compared to no advice (Fiore et al., 2000). Although there have been no systematic studies of advice by other clinicians, it is plausible that a similar increase in abstinence rates would be observed (Fiore et al., 2000). United States guidelines recommend the “Five A’s approach”: ask about tobacco use; advise all users to quit; assess willingness to make a quit attempt; assist the patient to quit; and, arrange follow-up contact (Fiore et al., 2000). Whereas the absolute effect of brief advice is relatively small, this intervention can have considerable global impact because of the large number of people who visit their physicians (<http://www.treatobacco.net>). Physicians are in a unique position because of their ability to advise patients who would like to quit, as well as smokers who do not intend to quit (Jackson et al., 2001). For smokers who do not intend to quit smoking, physicians should inform and sensitize patients about tobacco use and cessation, especially by personalizing the benefits. For smokers who are insecure about their ability to quit, physicians may use motivational strategies, such as discussing barriers to cessation and their solutions. The benefits of such interventions can be enhanced by critical points, such as helping the patient to select a specific day to quit and personalizing the potential benefit. For smokers ready to quit, the physician can offer strong support, help set a quitting date, prescribe pharmaceutical therapies for nicotine dependence, such as replacement therapy and/or bupropion (with instructions for use), and suggest behavioural strategies to prevent relapse.

Self-help materials

Generic self-help materials are no better than brief advice from a health professional, but are more effective than no intervention, and they have the advantage of being able to reach large numbers of people at relatively low per-person cost; thus they can be cost-effective, even though not as efficacious as medication (Stead and Lancaster, 2000). For example, a Cochrane review meta-analysis found that self-help materials with no face-to-face contact had a small benefit (OR=1.2) over no self-help materials (Stead and Lancaster, 2000). Materials intended to encourage smokers to attempt to quit and to help them in their efforts are increasingly becoming widely available in



developed countries, and need to be available in regions where they are presently difficult to obtain. In choosing particular materials to provide or recommend, it is important to take account of the accessibility of the material (<http://www.treatobacco.net>). It is especially important that the materials are appropriate in language, literacy level and cultural approach. For example, in some cultures it is important to tie the benefit and rationale for cessation to the family. Printed materials are most common and may range from a brief guide and tips sheet to a structured manual with exercises to guide quit attempts. Resources may include audiocassettes, videos or computer programs, as well as those widely available on websites. The increasing accessibility of the Internet should increase opportunities for individually tailored self-help therapies.

Approaches that are more recent have concentrated on making self-help materials appropriate to the needs of individuals (Stead and Lancaster, 2000). In eight trials included in a Cochrane review meta-analysis, individually tailored materials were more effective than generic materials (OR=1.4). Individually tailored materials are based upon the individual response of smokers at baseline, and can then provide smokers with interactive feedback about their stage of change, decisional balance considerations regarding the pros and cons of quitting smoking, temptations that might develop in the most important smoking situations and techniques for coping with specific situations (Prochaska et al., 1993).

Telephone contact is an economical way of adding personal contact to self-help materials. Six trials examined by the Cochrane review, included the benefit of proactive calls from a counsellor.

Behavioural and psychological interventions

Behavioural support, with multiple sessions of individual or group counselling, assists smoking cessation. Both individual and group therapy have been shown to improve quit rates beyond those seen with self-help materials alone (Stead and Lancaster, 2000). There appears to be no difference between individual and group therapy in terms of quit rates; therefore, either therapy may be of benefit (Stead and Lancaster, 2000). Groups are theoretically more cost effective, but their usefulness may be limited by difficulties in recruiting and retaining participants (Stead and Lancaster, 2000).

Three types of counselling and behavioural therapies have been shown to produce higher abstinence rates: 1) providing smokers with problem-solving/skills training (e.g. avoiding situations where other people are smoking, identifying triggers to



smoking); 2) providing social support as part of treatment; and 3) helping smokers to obtain social support outside of treatment (Fiore et al., 2000). Another type of behavioural therapy shown to be associated with positive outcomes is aversive smoking (Hajek and Stead, 2000). Aversive smoking involves guided smoking, where the patient smokes intensively, often to the point of discomfort, nausea and/or vomiting. Aversion therapy pairs the pleasurable stimulus of smoking a cigarette with some unpleasant stimulus. The objective is to extinguish the urge to smoke. Such therapy can be effective but requires more extensive staff support than other behavioural therapies and it appears not to be widely acceptable.

A main tenet of therapy with person-to-person contact is “more is better.” Whereas minimal contact (i.e. less than three minutes), as with physician contact, can increase abstinence rates by 30% over no contact, more intensive counselling (more than 10 minutes) can more than double abstinence rates (Fiore et al., 2000) compared to no contact. A dose-response curve also has been observed for both total amount of contact time and the number of person-to-person treatment sessions (Fiore et al., 2000).

Mass media communication campaigns

The impact of mass media has been extensively studied in Australia, Canada, Finland and the United States. Mass media campaigns can increase knowledge about the health effects of smoking and the benefits of stopping. They can also change and reinforce attitudes towards stopping, provide cues to simple action and influence smoking behaviour.

Telephone Quitlines/Internet-based services

Quitlines are a low-cost and easily accessible smoking cessation service. They provide confidential and anonymous support to smokers wanting to quit. Quitlines can be available for extended hours, including evenings and weekends, and will often be on a freephone or low-call rate.

Telephone help lines use two main approaches: reactive, in which smokers can simply telephone the line, and proactive, in which counsellors ring callers back and give ongoing telephone support. The effectiveness and cost-effectiveness of proactive telephone counselling for smoking cessation is now widely recognized (US Department of Health and Human Services, 2000a). The effectiveness of reactive telephone counselling is harder to demonstrate because of the difficulties in undertaking randomized controlled trials with a reactive service. However, there is an increasing understanding that other evaluation methods may be more appropriate for reactive



services, although reactive telephone counselling can also be an effective and cost-effective intervention (Owen, 2000; WHO Europe).

Quitlines are a popular and easily accessible intervention that can reach large numbers of smokers. The study of the United Kingdom's Quitline concluded that for a single intervention to reach 4.2% of the total population of adult smokers in England was a major achievement (Owen, 2000). Quitlines can also reach groups who have difficulty accessing mainstream smoking cessation services. The United Kingdom's Asian Quitline receives 20 000 calls per year and is reaching 10% of SouthAsian tobacco users in the country (South Asia Social Researcher's Forum, 2001). For the vast majority of callers, the line is their first contact with any form of smoking cessation service. Sweden's *Sluta Rota Lingen* has had a similarly positive experience in attracting ethnic minority smokers.



Quitlines are increasingly developing a range of quality smoking cessation counselling services using the Internet, which are integrated with the telephone helplines. A number of quitlines in European countries such as Denmark, Germany, the Netherlands and Sweden are developing innovative services building on their mainstream service.

There are now many “quit smoking” sites currently available on the Internet to offer smokers help and support. Two of the better known sites are www.quitnet.org (run in association with Boston University Department of Public Health) and www.stop-tabac.ch (set up by the University of Geneva). Other more generic sites may also include smoking cessation pages e.g. www.netdoctor.com. Research into the use and effectiveness of these sites is just beginning (Etter, et al., 20001; Takahashi, et al., 1999; Yuasa, et al., 2000; West, et al., 2001). In the United Kingdom smoking is concentrated particularly amongst unskilled manual workers and it is this group which has least access to the Internet (27% compared to 70% of professionals). However, with the advent of newer and faster technology it is likely that the problem of lack of access will soon be overcome. As a means of delivering health care



information and support the Internet has the potential to reach a wide range of smokers and tobacco-users.

Quitlines have an important role to play as part of an overall comprehensive smoking cessation programme. They provide a low-cost, easily accessible, popular and effective service. Quitlines are increasingly incorporating online counselling as part of a flexible range of services for smokers. The Internet offers the potential to reach large numbers of smokers at low cost and the challenge is to develop a range of innovative and effective web-based services which smokers will want to use.

Quit and Win competitions

Quit and Win is a cost-effective, evidence-based smoking cessation method for population-wide public health use that also more broadly supports national tobacco-control work. The Quit and Win campaigns use innovative communication methods, partnerships, community organization and health service involvement to bring about cessation rates of around 20%. Conservative evaluation methods of one-year follow-up evaluation of the participants have shown that 10%-30% of the participants have stayed completely smoke-free during the whole year following the Quit and Win campaign.

Quit and Win is a rapidly growing smoking cessation campaign that contains a positive message for smokers. The participants stop using tobacco for at least the

International Co-ordinating Centre: FINLAND

Five successful international Quit & Win campaigns have been organized as collaborative efforts between the National Public Health Institute, Finland and WHO.

These campaigns have been held every other year from 1994 (when 13 countries participated) to 2002 with 77 countries and approximately 700,000 participating smokers.

Around 100 countries (through governments or nongovernmental partners) have expressed interest in participating in 2004, when one million smokers are expected to take part.

This internationally applicable, incentive-based intervention has achieved highly successful abstention rates in countries.



contest period of four weeks and, if they succeed, they are eligible to win prizes. The Quit and Win organizers in the countries provide the financial means and the prizes for their local campaigns and follow an internationally standardized protocol. Prior to the contest all participants have been using tobacco daily for at least one year and have to be 18 years of age or older. The International Quit and Win Coordinating Centre is situated at the National Public Health Institute in Finland and the campaigns are carried out in close collaboration with WHO.

Smoke-free places

The smoke-free workplace is a cost-effective public-health approach that encourage the important long-term goal of de-normalizing tobacco use. Furthermore, taking a public-health approach can affect large numbers of individuals at minimal cost (National Cancer Institute, 1991; US Department of Health and Human Resources, 2000c). Working with individual smokers to change their smoking behaviour is an important goal, but has limited impact if the environmental factors that promote and support smoking are not also addressed. The creation of smoke-free places, especially smoke-free work sites, is thus an essential component of any successful strategy to promote smoking cessation.

The United States has over 20 years' experience with changing public policy to promote smoke-free places. The creation of public and private policies to restrict smoking has been found to be an extremely effective approach to promoting cessation (US Department of Health and Human Services, 2000c). Numerous studies have documented the effects of these restrictions on employee smoking behaviour. Studies have been conducted in health-care settings, government agencies, insurance companies, telecommunications companies, and among other random samples of the workforce. These studies found reductions in average daily consumption of cigarettes and lower overall prevalence rates. The percentage of smokers contemplating quitting was also higher in smoke-free work sites, and such sites also seemed to promote long-term quitting (Emont et al., 1993; Stillman et al., 1990; Borland et al., 1991; Wakefield et al., 1992).

The tobacco industry's own internal documents have revealed that smoking restrictions were considered to be a major threat to their profitability since they found that, "Smokers facing workplace restrictions have a 84% higher quit rate than average" and it was expected that a "10% decline in consumption" could be expected if smoking was banned in all workplaces (Heronimus, 1992).



Legislation to restrict smoking in public places is also an effective strategy to support cessation, since an additional benefit of this regulation is a reduction in smoking among the general public. Clean indoor air laws are associated with lower smoking prevalence and higher proportions of quitters. States that impose more tobacco-control smoking restrictions along with higher taxes have the lowest consumption rates (Gilpin et al., 2000; Stephens et al., 2001). Just passing a law or establishing a restrictive policy does not accomplish these reductions. The policy has to be implemented with care, along with the provision of supportive services for cessation and enforcement procedures should be established.

Pharmacologic interventions: tobacco dependence and withdrawal

Many people are able to successfully quit smoking on their own and with behavioural self-help guidance (World Bank, 1999; Fiore et al., 2000). However, most smokers are nicotine-dependent and could benefit from interventions to address the physiological aspects, specifically the disorders of tobacco dependence and tobacco withdrawal, which are recognized by the ICD-10 – International Classification of Diseases (World Health Organization, 1992).

The development of pharmacotherapies to treat nicotine dependence has focused on the alleviation of tobacco-withdrawal symptoms. For example, as noted in the next section, nicotine-replacement medications reduce withdrawal symptoms by partially replacing the nicotine normally achieved by smoking. Antidepressants such as bupropion and nortriptyline may be efficacious for smoking cessation because of their reduction of the cessation-induced depression that is related to nicotine withdrawal. Clinical trials to promote cessation by pharmacologically reducing other withdrawal symptoms such as anxiety have also been attempted (Henningfield, Fant and Gopalan, 1998).

Efficacy across products

There are currently two categories of medication that are available for smoking cessation: nicotine replacement medications and non-nicotine medications. Among the non-nicotine medications, one, bupropion, has been specifically approved for smoking cessation whilst others discussed in this review are considered effective even though they have never been specifically approved by regulatory authorities as smoking cessation treatment products. Bupropion and the various nicotine replacement therapy (NRT) products have been most widely studied, and this research supports the conclusion that all are effective under a broad range of conditions, and all may



be concluded to approximately double the rate of abstinence compared to placebo (Royal College of Physicians, 2000; US Department of Health and Human Services, 2000; Fiore et al., 2000; www.treatobacco.net). Comparing efficacy across products is problematic because there has been very little direct within-study comparison of the products and because success rates vary so widely across products. However, it can be concluded that the products are effective with guidance provided in their labelling, but that improved outcomes can be achieved with more intensive behavioural support (Royal College of Physicians, 2000; US Department of Health and Human Services, 2000; Fiore et al., 2000; see also www.treatobacco.net). There is no validated system for matching cigarette smokers to the treatment form that will produce the most successful outcomes; however, people do vary in the form that is most acceptable (e.g., gum versus patch) and persons who have tried to quit smoking and failed with one product might find another product more effective. Therefore, it is important to make available as many of the products as possible. The following sections will review those medications within each category that have been clinically proven to be effective.

Nicotine replacement medications

The most direct way to help people manage the symptoms of nicotine dependence and withdrawal is therapeutic use of nicotine medication (Fiore et al., 2000; Henningfield, 1995; Henningfield, 1995; American Psychiatric Association, 1996). Nicotine medications make it easier to abstain from tobacco by replacing, at least partially, the nicotine formerly obtained from tobacco and thereby providing nicotine-mediated neuropharmacologic effects such as increased expression and reduced turnover of nicotine receptors in the brain and other parts of the body, alteration of brain EEG and regional cerebral glucose metabolism, and activation of dopaminergic reinforcement systems in the brain (US Department of Health and Human Services, 1988).

There appear to be at least three major mechanisms by which smoking cessation efforts are enhanced (Henningfield, 1995; Benowitz, 1993). First, medications may reduce either general withdrawal symptoms or at least prominent ones, thus enabling people to function while they learn to live without tobacco-use. Second, medications may also reduce the reinforcing effects of tobacco-delivered nicotine. Finally, nicotine medications may provide some effects for which the patient previously relied on cigarettes, such as sustaining desirable mood and attention states and making it easier to handle stressful or boring situations. For most people who use replacement medications, discontinuation from the medication occurs within a few months following smoking cessation. Some people need to use the medications longer in order to avoid



resumption of cigarette smoking, but it is not clear how to determine, prior to cessation, which people will need longer-term use and how long they will need to use the medication.

Current forms of nicotine replacement therapy

Transdermal patch

There are currently four patch formulations on the market that vary widely in their design, pharmacokinetics, and duration of wear (i.e., 24- and 16-hour wear). The diversity in patch systems has been described in reviews (Benowitz, 1995; Gorsline J, 1993), and the differences in pharmacokinetics has been illustrated in a head-to-head clinical trial (Fant et al., 2000). Because it is not possible to predict which smokers would find which particular patch characteristics most desirable or effective, it is useful to ensure access to several if not all types. For example, some smokers may require a patch that delivers higher and faster levels of nicotine whereas others may prefer a patch that delivers lower levels of nicotine more gradually.

All of the patch types are available in a range of dosages, which permits higher-dependent smokers to use the strongest patches and lower-dependent smokers to use a lower dose according to the guidance provided for each brand. The range of dosages for each brand also means that users can gradually decrease their nicotine intake over a period of several weeks or longer to enable a gradual adjustment of their bodies to lower nicotine levels and ultimately to a nicotine-free state.

The main advantage of the nicotine patch over acute NRT formulations is that compliance is based on whether or not the patient places the patch on the body in the morning, rather than on the patients' actively using a product throughout the day. For this reason, compliance with patch therapy tends to be higher than for other NRT products (Hajek et al., 1999). The nicotine patch delivers nicotine more slowly than acute NRT formulations, although nicotine plasma concentrations can get higher during the day with patch use than with acute NRT use, especially if the patient does not use the acute NRT product as many times during the day as recommended (Benowitz, 1993; Henningfield, 1995).

The most frequently reported side effects occurring with nicotine patch use are local skin reactions, with up to 50% of patients experiencing this effect (Fiore et al., 2000). Moving the site of patch application daily as instructed can reduce the incidence of skin reactions to the patch. Sleep disturbances have also been commonly reported with 24-hour patches, and a dose effect has been noted, with 21-mg patches producing



higher rates of sleep disturbance than 14- or 7-mg patches (Transdermal Nicotine Study Group, 1991). Physicians may recommend that persons who have sleep disturbances either use a lower dose patch or remove the patch after 16 hours and do not wear it while sleeping.

Acute dosing

Gum

The first NRT that was made available to consumers was transmucosally-delivered nicotine polacrilex (“nicotine gum”). This was initially approved for prescription marketing in several European countries, Canada and the United States in the early 1980s and many other countries later in the 1980s. By the 1990s, many countries had approved availability of the gum without prescription either from pharmacies or in many countries as an over-the-counter or general sales product. Mint and orange flavours of nicotine gum have been introduced in an effort to increase compliance with use instructions among patients who found the original (“peppery”) flavour to be unpalatable. Hundreds of basic and clinical research studies have been done documenting the safety and efficacy of the product for smoking cessation and for treating withdrawal symptoms, including craving (Royal College of Physicians, 2000; US Department of Health and Human Services, 2000; Fiore et al., 2000).

Nicotine gum is not chewed like ordinary confectionary gum, but is intermittently chewed and held in the mouth over about 30 minutes, as needed, to release its nicotine. It is available in both 2-mg and 4-mg dosage forms, each of which typically deliver approximately 50% of their nicotine over a 15-30 minute period of oral use (Benowitz et al., 1987). Thus, when gum is chewed on a fixed schedule of 10 pieces per day, a smoker receives about 10 mg or 20 mg of nicotine per day using the 2-mg or 4-mg gum formulations, respectively. The average systemic intake of nicotine from cigarettes is about 30mg per day (Townsend, 2002). Thus, most gum chewers do not match the nicotine levels achieved daily through the smoking of a cigarette. Furthermore, because of the relatively slow absorption of nicotine from gum compared to smoke inhalation, individual doses do not produce the extremely high arterial levels of nicotine produced by smoke inhalation (Henningfield, 1995). Smokers who use fewer pieces of gum achieve much lower concentrations of nicotine, which may reduce the efficacy of the treatment.

Due to the importance of replacing nicotine in adequate quantities, success with nicotine gum treatment depends in part on how many pieces of gum the smoker chews per day (Russell et al., 1983). Smokers that are more dependent have been



shown to improve their chances of achieving abstinence with the 4-mg than the 2-mg gum (Tonnesen et al., 1988). After a few weeks or months, the number of doses per day is reduced gradually until it is no longer required. This tapering phase is several weeks in duration for many users but should be continued as long as needed to permit gradual adaptation of the body to reduced nicotine and to avoid relapse to smoking.

Lozenge

The nicotine lozenge is the most recent NRT to receive approval for smoking cessation in the US, and is available in many European countries as well. The lozenge is available in 2-mg and 4-mg formulations. Instructions for use and dosing are similar to nicotine gum, but the lozenge is not chewed; it dissolves in the mouth over approximately 30 minutes with some variation across individuals. As with nicotine gum, nicotine from the lozenge is absorbed slowly through the buccal mucosa and delivered into systemic circulation. The lozenge provides an alternative to the gum for persons who need intermittent and controllable nicotine dosing, but who do not find gum chewing acceptable.

The amount of nicotine absorbed per lozenge appears to be somewhat higher than that delivered by gum. Single dose studies demonstrated 8-10% higher C_{max} values and 25-27% higher $AUC_{0-\infty}$ values from lozenges compared to gums at both 2-mg and 4-mg dose levels, which is probably due to the residual nicotine retained in the gum (Choi et al., 2003).

Sublingual tablet

A small nicotine tablet has been developed, and is currently being marketed in many European countries. The product is designed to be held under the tongue where the nicotine in the tablet is absorbed sublingually. Like the lozenge, the tablet has the advantage of not requiring chewing. The levels of nicotine obtained by use of the 2-mg lozenge and 2-mg nicotine gum are similar (Molander and Lunell, 2001).

In a randomized, double-blind, placebo-controlled trial of 2-mg sublingual tablets, success rates for complete abstinence for active versus placebo were 50% vs. 29% at 6 weeks, 42% vs. 23% at 3 months, 33% vs. 18% at 6 months and 23% (Wallstrom et al., 2000). This doubling of quit rates is comparable to the doubling seen with other forms of NRT. In this trial, adverse events were mild and tolerable, the most common being irritation and soreness in the mouth and throat.



Oral inhaler

The nicotine vapour inhaler, which consists of a mouthpiece and a plastic cartridge containing nicotine, was first marketed in the United States in 1998 as a prescription smoking cessation medication. The vapour inhaler was designed to satisfy behavioural aspects of smoking, namely, the hand-to-mouth ritual, while delivering nicotine to reduce physiological withdrawal symptoms produced by tobacco withdrawal. It is important to note that although termed an “inhaler” the majority of nicotine is delivered into the oral cavity (36%) and in the oesophagus and stomach (36%) (Lunell et al., 1996). Very little nicotine is delivered to the lung (4%). Because absorption is primarily through the oral mucosa, the rate of absorption is similar to that of nicotine gum.

Each inhaler cartridge contains 10 mg nicotine, of which up to 4 mg can be delivered and 2 mg can be absorbed (Molander et al., 1996) following frequent “puffing”. Patients may self-titrate with the inhaler to the level of nicotine they require. However, as with nicotine gum, success is largely dependent on the number of doses taken per day. In clinical trials, most smokers who successfully abstained from smoking used between 6 and 16 cartridges per day.

Nasal spray

Nicotine nasal spray was designed to deliver doses of nicotine to the smoker more rapidly than was possible with use of the gum or patch. The device currently available to consumers is a multi-dose bottle with a pump mechanism fitted to a nozzle that delivers 0.5 mg of nicotine per 50-uL squirt. Each dose consists of two squirts, one to each nostril (Fiore et al., 2000).

Nicotine from the nasal spray is absorbed into the blood rapidly relative to that delivered by gum or patch. Whereas the rate of plasma nicotine absorption with the spray approaches that of cigarettes and oral snuff, the magnitude of the increase in plasma nicotine concentrations is lower. According to labelling, the dose of nasal spray should be individualized for each patient based on the patient’s level of nicotine dependence and the occurrence of symptoms of nicotine excess. Patients should be started with one or two doses per hour, which may be increased up to the maximum of 40 doses per day. One dose of nasal spray per hour (1-mg nicotine) for 10 hours produces average plasma concentrations of 8 ng/ml.



Improving delivery

High-dose patches

The use of higher-dose patches would be predicted to better mimic the doses of nicotine achieved during tobacco use, particularly among heavy and more dependent users. Jorenby et al. (1995) conducted a randomized, double-blind clinical trial among 504 smokers who received 22 mg or 44 mg patches under different counselling conditions (Jorenby et al., 1995). Among those receiving minimal contact, the 44-mg dose produced greater abstinence at four weeks than did the 22-mg dose (68% versus 45%; $P < 0.01$). Hughes et al. (1999) conducted a randomized, double-blind trial in which 1039 smokers received 0, 21, 35, and 42 mg/day for six weeks followed by tapering over the next 10 weeks (Hughes et al., 1999). Continuous abstinence rates for the 0, 21, 35, and 42 mg doses at the end of treatment (12 weeks) were 16%, 24%, 30%, and 39%; however, there were no statistically significant differences between active treatments. Fredrickson et al. (1995) conducted an open-label study among 40 smokers to determine the safety and tolerability of a 44-mg/day dose for smoking cessation (Fredrickson et al., 1995). Subjects received 44 mg/day for four weeks followed by four weeks of 22 mg/day. Biochemically confirmed point prevalence smoking cessation rates were 65% and 55% at weeks four and eight of patch therapy. Taken together, these results suggest that there is some evidence to indicate that higher-dosage nicotine patches may improve treatment outcomes for highly dependent individuals.

Combined patch + acute forms

A strategy for further improving the efficacy of NRT is to combine one medication that allows for passive nicotine delivery (e.g. transdermal patch) with another medication that permits ad libitum nicotine delivery (e.g. gum, nasal spray, inhaler). The rationale for combining NRT medications is that smokers may need both a slow delivery system to achieve a constant concentration of nicotine to relieve cravings and tobacco-withdrawal symptoms, as well as a faster acting preparation that can be administered on demand for immediate relief of breakthrough cravings and withdrawal symptoms (Sweeney et al., 2001). This speed of onset of effects may be particularly important in the morning, when the withdrawal symptoms and craving are at a peak for many smokers. The patch provides nicotine in a steady-state and passive form while gum can be manipulated to accommodate the users' needs. Thus combining use of the nicotine patch, which may prevent the appearance of severe withdrawal, with the gum, which can provide relief in trigger-to-smoke contexts, may provide an excellent treatment option over either therapy alone.



Clinical trials suggest incremental efficacy of patch plus gum compared to either product alone (Kornitzer et al., 1995; Puska et al., 1995). Less research is available on combinations of the patch and other acute NRT formulations. However, one study that compared the efficacy of the nicotine inhaler plus nicotine patch versus nicotine inhaler plus placebo patch for smoking cessation found a significantly higher abstinence rate at one year among those who used the combination (Bohadana et al., 2000). No studies have examined the patch in combination with lozenge, nasal spray, or inhaler, though it could be predicted that similar incremental efficacy would be observed with the combination.

Despite the possibility of increased efficacy, present NRT labelling warns against combination use. Without removal of such warnings, these strategies will be largely limited to smoking cessation specialists and clinics. The complexity of obtaining approval for combination medications, combined with the difficulty of marketing combination products, has slowed attempts by manufacturers to gain regulatory approval for combination therapies (Sweeney, Fant, Fagerstrom, McGovern, and Henningfield, 2001).

Nicotine safety and toxicity

Although nicotine can be toxic at very high dosages, relative to those typically delivered by use of tobacco or nicotine-replacement medications, its toxicological effects in tobacco use are generally considered modest compared to the many carcinogens and other toxins present in tobacco products and the many more produced when tobacco products are burned (Benowitz, 1998; Hoffmann and Hoffmann, 1997). For example, nicotine is not a carcinogen and nicotine replacement is not a risk

Improving availability of Nicotine Replacement Therapies **Selected experiences**

BRAZIL - Brazil has been providing free support for smoking cessation services (pharmacological products and cognitive behavioural therapies) since 2002.

CANADA - A number of provinces and territories, including Ontario, Quebec and the Yukon cover nicotine-replacement therapies in Canada, nicotine replacement therapies are not taxable when prescribed by a physician. When purchased over the counter, taxes range from 7% to 15% but many provinces no longer impose a provincial sales tax.

HONG KONG (SAR, CHINA) - NRT is being provided through four outpatient facilities of the department of health.



factor for cancer. Nonetheless, nicotine delivered by tobacco products and medications is not benign. It can produce a variety of potential adverse effects depending upon the dose and pattern of administration. For example, cigarette smoking during pregnancy produces a high risk of problems that are attributed to the high levels of nicotine exposure and the additional substances available in the smoke such as carbon monoxide (Dempsey and Benowitz, 2001). At doses delivered by nicotine-replacement medications, the risk of adverse effects from nicotine during pregnancy appears substantially lower than by smoking. However, because the possibility of risks cannot be ruled out, it is generally recommended that a doctor be consulted concerning use of the medications during pregnancy (Oncken, 1996; Windsor et al., 2000). Similarly, nicotine is a presumed risk factor for coronary artery disease leading to labelling on nicotine medications advising persons with histories of heart disease to consult with a doctor before using the products (Benowitz and Gourlay, 1997).

The future

True pulmonary inhaler

As previously noted, the nicotine “inhaler” does not deliver nicotine to the lung, but rather deposits nicotine into the mouth and throat where it is absorbed through the buccal mucosa, making its delivery of nicotine more comparable to nicotine gum or lozenge than to a cigarette. Specifically, cigarettes deliver nicotine to the lung where absorption is rapid and almost complete. A true pulmonary inhaler, unlike the currently available nicotine inhaler, would deliver nicotine to the lung in a manner more comparable to cigarette smoking. This would be predicted to deliver a dose of nicotine sufficient to reduce background cravings and withdrawal symptoms, and would allow for rapid relief of acute cravings and morning craving. Because the delivery of nicotine directly to the lung would effectively mimic the effects of cigarette smoking on a physiologic level, the smoker could eliminate the need for tobacco, and subsequently taper the nicotine level over time to alleviate dependence upon nicotine altogether.

Although there are substantial technological challenges to producing an effective and acceptable lung inhaler, the greatest barrier to development may be the potential for abuse and the regulatory implications. Specifically, if the medication meets criteria for a controlled substance, its marketing could be severely restricted along the lines of morphine-like analgesics. The mechanisms of the regulatory framework are the United States Government’s Controlled Substance Act, and the World Health Organization’s Convention on Psychotropic Substances (McClain and Sapeinza,



1989). The provisions of the Controlled Substance Act were raised with respect to the nasal nicotine formulation for smoking cessation in 1994 when the FDA and other federal agencies considered whether the formulation should be regulated as a controlled substance such as morphine (US Food and Drug Administration, 1995; US Food and Drug Administration, 1996). In the final analysis, it was concluded that even though the nasal formulation met accepted criteria for a controlled substance, its abuse liability was substantially less than that of the ubiquitously available tobacco products and that prescription level of control would be adequate. Whether regulatory authorities would come to such a conclusion with a lung inhaler, if the lung inhaler were of substantially increased abuse liability is uncertain. Such uncertainties can be expected to limit commercial development of such a product because of the uncertain market for a tobacco-cessation product that is regulated as a controlled substance. This issue may require resolution if it is considered important to encourage development of NRT products that deliver nicotine to the lung or by other means that increase its abuse liability.

Non-nicotine medications and substances for treating tobacco dependence

In principle, a substance might be efficacious in treating dependence (i.e. aiding smoking cessation) without being efficacious in alleviating composite withdrawal scores and vice versa. Furthermore, a substance might be effective in treating a specific symptom of withdrawal without providing adequate relief of other withdrawal symptoms to justify its being considered efficacious for treatment of nicotine withdrawal. Whereas the ideal smoking cessation medication would be consistently effective in reducing all signs and symptoms of nicotine dependence and withdrawal, there is, in fact, wide variation in the degree to which various substances produce beneficial smoking cessation-related effects. Furthermore, substances with even narrowly limited benefits might be useful in helping people to reduce or quit smoking; however, it is important for health professionals and consumers alike to understand the benefits and limitations of substances used to treat nicotine dependence and withdrawal and to underline the degree to which various products are interchangeable.

A wide range of non-nicotine substances has been marketed for people who need help in reducing or quitting smoking and managing symptoms associated with withdrawal (Henningfield, Fant, and Gopalan, 1998). Currently, only bupropion has received regulatory approval for the treatment of tobacco dependence. However, clonidine and nortriptyline are also listed as “second-line medications” in the United States’ *Clinical Practice Guideline: Treating Tobacco Use and Dependence* (Fiore et al., 2000). Below is a brief summary of the evidence on these medications.



Adherence to long-term quitting therapies a study in Hong Kong (SAR, China)

The Hong Kong Smoking Cessation Health Centre provides smoking cessation services with trained counsellors and nicotine-replacement therapy. The services provided are free including a one week supply of NRT.

Of the 989 clients who were successfully followed up at three months, 90% (895 out of 989) were prescribed NRT.

A study was conducted on their adherence to cessation therapy, adherence being defined as self-reported use of NRT for at least four weeks.

Adherence to NRT therapy was seen to be a major factor associated with success in quitting and a significant predictor for quitting. The quit rate in the adherent group was 43% and significantly greater than the 29% in the non-adherent group.

Based on step-wise logistic regression analysis, predictors of adherence were seen to be age, sex, educational status, quitting for one day or more in the last attempt, experience of using NRT in the past, and perception of quitting as difficult. Those who were male, older, with more education and past experience of quitting or NRT use were more likely to adhere.

Overall prevalence of adherence was seen to be low, at 25% for three weeks of self-reported use and 19% for four weeks of use.

Bupropion hydrochloride

Negative mood is one of the symptoms of tobacco withdrawal, which may account for failures to quit smoking and relapse after cessation. For this reason, several antidepressants have been tested as smoking cessation aids. Bupropion Hydrochloride (Zyban[®], GlaxoSmithKline) is a sustained-release formulation of the antidepressant medication. This is the first non-nicotine medication that has received approval by the United States Food and Drug Administration (FDA) for a smoking cessation indication, and is listed as a first-line therapy in the United States' *Clinical Practice Guideline: Treating Tobacco Use and Dependence* (Fiore et al., 2000). It takes about five days or longer to achieve steady state plasma levels of the drug, thus it is suggested that a smoker begin use of the drug about one week before the quit date (Hurt et al., 1997). In a meta-analysis of two placebo trials of bupropion, the estimated odds ratio of efficacy relative to placebo was 2.1 (95% confidence interval 1.5-3.0) (Fiore et al., 2000).



There is also some evidence that a combination of bupropion and nicotine patch can increase efficacy over either product alone (Jorenby et al., 1999). However, there is currently no indication for combination use, and complexities in obtaining regulatory approval and difficulties in marketing make it unlikely that such an indication will be sought by manufacturers.

Clonidine

Clonidine has been shown to diminish symptoms of both opiate and alcohol withdrawal symptoms (Gossop, 1988), and may be useful for diminishing some tobacco withdrawal symptoms as well. Although not approved by regulatory authorities for smoking cessation, the United States' *Clinical Practice Guideline: Treating Tobacco Use and Dependence* (Fiore et al., 2000) has given clonidine an "A" level of evidence indicating that there is a consistent pattern of positive findings in multiple well-designed clinical trials. In a meta-analysis of five trials in which clonidine doses varied from 0.1mg to 0.75 mg/day, the estimated odds ratio of efficacy relative to placebo was 2.1 (95% confidence interval 1.4-3.2) (Fiore et al., 2000). These results suggest that clonidine may be efficacious in the treatment of tobacco dependence, but the conditions under which it is most appropriately used are not well defined.

Nortriptyline

Nortriptyline is a tricyclic antidepressant that has been tested as a potential pharmacotherapy for smoking cessation. The United States' *Clinical Practice Guideline: Treating Tobacco Use and Dependence* (Fiore et al., 2000) has given nortriptyline a "B" level of evidence indicating that there is some evidence supporting efficacy. In a meta-analysis of two trials, the estimated odds ratio of efficacy relative to placebo was 3.2 (95% confidence interval 1.8-5.7) (Fiore et al., 2000). These results suggest that nortriptyline may be efficacious in the treatment of tobacco dependence; however, because of the paucity of data, the medication should be considered a second-line therapy.

Conclusion

There is a wide range of treatment options that have been proved effective, including behavioural and pharmacological therapies. There is no single approach that should be emphasized to the exclusion of others because the therapies vary widely in their efficacy, their acceptability, their cost-effectiveness, and their cost on an individual



and population basis. For example, pharmacotherapies tend to require less human resource time to deliver and are more effective than many behavioural therapies, but can cost more in material resources. However, for some populations (e.g. pregnant women, and persons with heart disease), for whom there is an especially great benefit of cessation, the costs may be more readily justified. Minimal interventions by health professionals offer not only an important and cost-effective approach, such interventions can help to change the culture from one in which the health professionals are models for smoking to one in which they are models of non-smoking. Furthermore, public health approaches such as mass media campaigns, Quit and Win competitions and telephone help lines serve to play an important role in changing societal norms and promoting smoking cessation. Working with individual smokers to change their smoking behaviour is an important goal but has limited impact if the environmental factors that promote and support smoking are not also addressed. Hence, population-based interventions should be thought of as complementary approaches to individual-based behavioural or pharmacological interventions.

On the basis of the variety of proven methods and variety of needs within and across countries, it would appear that the ideal goal would be to work towards maximizing the options and occasions for smoking cessation interventions, both population- and individual-based, within and across countries.

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