Considerations and Rationale for a National Action Plan to Help Canadian Tobacco Users

Paul W. McDonald, Ph.D.

A National Action Plan for Smokers

Part 1 of 2

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Paul W. McDonald, Ph.D.
University of Waterloo

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Address correspondence to: *Paul McDonald, Ph.D., Associate Professor, Department of Health Studies and Gerontology, University of Waterloo, Waterloo, Ontario, Canada, N2L 3G1. Telephone: (519) 888-4567 ext 5839 Email: pwmcdona@healthy.uwaterloo.ca*

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Preface

This paper is part of a larger initiative. The process began in 1997 when the Canadian Council on Tobacco Control, on behalf of the National Strategy to Reduce Tobacco Use in Canada, commissioned a survey of representatives from various national and provincial organizations concerned with smoking cessation. Survey results were synthesized into a paper entitled, " *A Coordinated Systems Approach to Smoking Cessation: A Working Model*". This document was used as the basis for discussion at a workshop held in Ottawa on November 22 and 23, 1997. The 30 plus participants identified and prioritized a series of actions required to improve support for Canada's tobacco users. The first priority was to "Develop and communicate a national plan (including priorities, resources needed, who to do what, a monitoring and review process) to ensure that Canadians have access to support for smoking cessation programs which are delivered through a strong, coordinated, evidence-based strategy." A follow-up workshop hosted by the Tobacco Control Programme at Health Canada on April 29 and 30, 2002 reiterated the need for such a document. This discussion paper is the result.

The purpose of this paper is to provide an overview of the scope of the problem, consider who uses tobacco in Canada, outline current interventions, and identify gaps and opportunities for a national strategy to help current smokers. A companion paper recommends a series of goals, objectives, evidence-based actions for a national strategy, estimates of how much it would cost to implement it, and who should take primary responsibility for the various actions.

It is important to recognize that this is a discussion paper. While it offers specific ideas and directions, it is also meant to stimulate dialogue and exchange. This paper is intended to challenge common assumptions and traditional perspectives and offer alternative views. I hope readers will offer compelling rebuttals and suggest their own new, bold ideas.

Paul W. McDonald
May 15, 2003

Note:
Due to the nature of this Special Report, it has not undergone the usual review process of the Ontario Tobacco Research Unit.

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Introduction

This is the first of two papers designed to provoke discussion on the creation of a national strategy to help current tobacco users. It begins with sections designed to show why a national strategy is warranted. This is followed by a brief profile of current tobacco users in Canada and a critical overview of current interventions available to help them. The paper ends with a discussion of why it is so difficult to quit and why best practices for the creation of a population-based strategy must go beyond the recommendations suggested by clinical practice guidelines for nicotine dependence. The second paper in this two part series offers suggestions for what a comprehensive population strategy might look like, how much it might cost and how we can pay for it.

Rationale for a National Action Plan

Tobacco use is the leading cause of preventable and premature morbidity and mortality in Canada. The most recent estimates suggest tobacco is responsible for between 35,000 and 45,000 deaths each year (16.5% to 21% of all deaths), including 16 per cent of all potential years of life lost. It is also annually responsible for more than 200,000 hospitalizations and three million hospital days (Ellison, Morrison, de Groh and Villeneuve, 1999; Single, Rehm, Robson and Truong, 2000; Single, Robson, Xie, and Rehm,1996).

Although the prevalence of tobacco use has dropped significantly over the past 15 years (Gilmore, 2002), more than 5.4 million Canadians currently smoke (Health Canada, 2001). Unless they quit using tobacco, up to half of these people may be expected to die prematurely and suffer excessively from a host of chronic diseases as a result of their tobacco use (Doll, Peto, Wheatley et al, 1994).

Not all the news is bad. Those who quit smoking dramatically reduce their future risk of developing a host of diseases and conditions. Risk reduction occurs regardless of how long a person has smoked or whether tobacco related disease is already present (US Department of Health and Human Services, 1990). However, the sooner an individual quits smoking, the greater the reduction in excess risk and the faster the benefits accrue (Taylor, Hasselblad, Henley et al., 2002; U.S. Department of Health and Human Services, 1990). It is also encouraging that more than 40 years of research have produced a wide range of effective treatments to increase the odds that *individual* tobacco users will become and remain abstinent (e.g., Fiore, Bailey, Cohen et al, 2000).

It has been suggested that increasing the utilization and effectiveness of interventions for current smokers has the potential to cut the projected number of tobacco related deaths over the next 50 years by 60 per cent (Henningfield, 2000). In contrast, even if prevention campaigns were 100 per cent effective they only have the potential to reduce smoking related deaths in the same time period by 20 per cent. Peto, Darby, Deo et al. projected that if the smoking initiation rate was cut by 50 per cent by the year 2020, there would be virtually no impact on deaths from smoking in the next quarter century, and only a five per cent reduction in deaths in the second quarter of the next century. However, if the number of smokers were cut by 50 per cent by 2020 by increasing

the cessation rate, the number of projected deaths attributable to smoking would fall by one third in the first quarter of the next century, and by two thirds in the second quarter century.

In summary, while tobacco control efforts aimed at the prevention of new smokers and the protection of persons from environmental tobacco smoke are important, neither of these strategies has anywhere near the same potential to improve population health as efforts aimed at helping current tobacco users to quit or reduce their tobacco use.

The Economic Case for Intervention

Tobacco use results in more than a humanitarian cost. It is also very bad for Canada's economy. Estimates from the early 1990s suggested that smoking costs $9.5 billion each year ($336.00 for each person in Canada), including $2.68 billion on health care costs and $6.82 billion in lost productivity from sick days and other factors (Single, Robson, Xie and Rehm, 1996). However, the economic costs of tobacco use can be dramatically reduced by helping current tobacco users to stop using tobacco. Each one per cent reduction in smoking prevalence in Canada could save between $65 and $97 million in health care costs (Stephens, Kaiserman, McCall and Sutherland-Brown 2000).

By extrapolating data from Oster and his colleagues (1984), Coleman (2000) estimated that over the course of his or her lifetime, *each* light smoker costs the economy an extra $32,280; while the excess costs for moderate and heavy smokers are $47,121 and $77,697 respectively. However, these costs can be significantly reduced if a smoker quits smoking. The precise savings depend on how much a person smokes and when they quit smoking. For example, the excess costs would be reduced by $25,842 for a light smoker who quits between 40 and 44 years of age. The commensurate "savings" for each moderate and heavy smokers who quit at the same age would be $45,118 and $79,300 respectively.

Helping tobacco users to quit and remain abstinent is among the most cost effective health care interventions known. Tengs and his colleagues (1995) estimated that brief physician advice to quit smoking aimed at men aged 45 to 49 would produce cost $1,100 per life year saved. This is comparable to other preventive procedures covered by health insurance in Canada such as screening for cancer of the breast, breast, cervix, and colon. By comparison, procedures such as coronary bypass surgery and coronary angioplasty typically cost $28,000 per life year saved. This raises the question why most Canadians have access to life saving medical procedures such as coronary bypass surgery (and have it paid for through health insurance plans), but cannot be guaranteed timely access to life saving interventions to quit using tobacco. It is particularly troublesome in light of how much money is spent on smoking cessation interventions compared to the amount of money raised through tobacco taxes and duties.

The array of providers and settings makes it difficult to determine the precise amount of money dedicated to the treatment of current smokers in Canada. However, even if we assume that half of the estimated $140 million in public sector funds spent on tobacco control in Canada in 2001 - 02 (exclusive of physician fees) were directed toward treatment, it is less than one third of the

level recommended by the Centers for Disease Control and Prevention Best Practice Guideline for Comprehensive Tobacco Control (1999).

In 2000-01, the federal government collected $2.16 billion from tobacco excise duties and taxes while the provinces and territories collected an additional $2.20 billion in tobacco taxes (National Clearinghouse on Tobacco or Health, 2003). The vast majority of these revenues were collected directly or indirectly from current Canadian tobacco users. Moreover, if we conservatively assume that 2.75 per cent of all cigarettes sold in Canada (for either the domestic or export markets) are consumed by children under age 18, then the federal and provincial governments generate almost as much tax revenue from the illegal sales of tobacco products to children (approximately $120 million/yr) than they invest in tobacco cessation, prevention and protection.

Profile of Tobacco Users in Canada

Approximately 5.4 million Canadians age 15 and over are established users of one or more types of tobacco products. The term "established user" means that the person has moved beyond experimentation and has begun to use one or more tobacco products on a continuous basis (although this may not be on a daily basis). The number of established tobacco users under age 15 is difficult to estimate. The most recent large-scale national survey of youth smoking was the 1994 Youth Smoking Survey. It revealed that seven per cent of 10 to 14 year olds reported being a daily smoker and another 2 per cent reported themselves as an occasional smoker. Less than one per cent of this age group reported that they had quit smoking. If we assume that a similar proportion of today's 10 to 14 year olds smoke, then this would indicate there are an additional 190,000 smokers under age 15.

Types of Tobacco Consumed

The vast majority of tobacco use involves smoking cigarettes. 420,000 Canadians or 6.6 percent of tobacco users, exclusively consume a product other than cigarettes (Health Canada, 1999). Approximately three per cent of Canadians smoke cigars or cigarillos, while another one per cent use pipe tobacco. Less than one per cent use smokeless tobacco. While the use of pipe tobacco has declined since 1994, smokeless tobacco use has remained steady and cigar use has risen slightly (Health Canada, 1999). Nearly 90 per cent of non-cigarette tobacco products are consumed by males.

Occasional Smoking

The proportion of smokers who do not smoke on a daily basis has risen steadily over the past 20 years from 13 per cent of current smokers in 1985 to 17 per cent in 2001 (Gilmore, 2002).

Increases in occasional smoking have occurred across all age groups, with the greatest rise among 20 to 44 year olds (e.g., from 18 per cent in 1985 to 25 per cent in 2001)(Gilmore, 2002).

Tobacco Consumption

Current *daily* smokers report consuming an average of 16.2 cigarettes per day (Health Canada, 2001). The average daily consumption of cigarettes has apparently fallen steadily over the past 15 years. However, these data should be interpreted with some caution since they are based on self reports. It is possible that changes in social norms around smoking may increase pressure to under report one's smoking. While data from domestic tobacco sales also shows a reduction, it does not account for the entire decline suggested by self reported consumption.

Assuming self reports are reasonably reliable, nearly one third of daily tobacco users smoke 10 or fewer cigarettes per day. This has significantly increased since 1994. In contrast, the proportion of daily smokes who consume more than 10 cigarettes per day has declined significantly since 1994. At present, less than six per cent of daily smokers report smoking more than 25 cigarettes per day, which is about half of what it was in 1994/95. The increase in light smoking was particularly pronounced for men and those between 20 and 24 years of age. Decreases in heavy smoking (i.e., more than 25 cigarettes per day) were largest for men, and those 45 to 64 years old.

Populations of Special Concern

Not all groups in Canada are equally likely to smoke. Smokers are over-represented in some sub-populations. It is important to note that many smokers belong to more than one of the groups discussed here. For example, a disproportionately large proportion of youth are Aboriginal. Youth are more likely to be poor than older adults. Substance abusers and those with mental health challenges are more likely to be poor. Women who are pregnant are more likely to have lower incomes and be young adults.

Youth. The highest prevalence rates occur among 20 to 24 year olds. Although 15 to 24 year olds make up less than 17 per cent of the adult population (i.e., age 15+), they make up nearly 21 per cent of Canadian smokers (Health Canada, 2002).

Persons with mental illness and substance abuse problems. The prevalence of smoking in people with certain types of mental illness is also very high. It has been estimated that 65 per cent of persons with mood disorders and 62 to 83 per cent of persons with schizophrenia smoke (Patkar, Gopalakrishnan Lundy et al., 2002; de Leon, Diaz Roger et al., 2002; Hays, Schroeder, Offord et al, 1999). Individuals with other alcohol and drug problems are also thought to have increased prevalence rates of tobacco use, although precise estimates are difficult to find. Estimates on the prevalence of mood, alcohol and illicit drug disorders vary widely. A conservative estimate would be that five to 10 per cent of Canadians suffer from one of the aforementioned conditions at any point in time. Therefore, is it probable that at least 15 per cent of Canadian smokers suffer from one or more of these complicating factors.

Aboriginals. The precise health burden of tobacco use among aboriginals is difficult to assess since the most recent prevalence data come from a 1991 survey. This work suggested 46 per cent Aboriginals over age 14 smoked daily while another 11 per cent were occasional users. This is approximately double the rate among non-aboriginal populations. The Canadian 2001 census indicates there were 799,010 Aboriginals in Canada (2.8 % of the entire Canadian population), including Metis and Inuit. Therefore, an estimated 8.4 per cent of all smokers in Canada are Aboriginal. Clearly, a disproportionately large proportion of the health burden of tobacco will be borne by our Aboriginal peoples.

Low socio-economic status. Tobacco use is significantly higher among persons with low incomes and/or education. According to the 2001 CTUMS, 31.7 per cent of persons in the lowest income groups and 26.1 per cent of those with medium low incomes were smokers compared to rates of 20.7, 18.0 and 22.3 per cent in medium, medium high and high income groups respectively (Health Canada, 2001). Those with low incomes may be more prone to high levels of stress, and low self efficacy, both of which reduce the odds of quitting tobacco use (Statistics Canada, 1999).

Pregnancy and smoking. Approximately 27 per cent of Canadian women between the ages of 20 and 44 report that they have been pregnant in the last five years. Of these, 12 per cent report that they smoked regularly during their most recent pregnancy (Health Canada, 2002). This is down from 19 per cent in 1995 (Health Canada, 1995 Survey on Smoking). Fourteen per cent of pregnant women also reported that their spouse smoked regularly at home during their most recent pregnancy (Health Canada, 2002).

Current Progress in Quitting Behaviour

According to the 2001 CTUMS, 53 per cent of current smokers aged 15+ expressed an intention to quit smoking in the next 6 months while another 17 per cent intended to quit in the next 30 days. This is a significant increase from the 1994 Survey on Smoking in Canada when 34 per cent intended to quit within six months and another 11 per cent within the next 30 days.

In 2001, 38 per cent of daily smokers aged 15 and over reported making one to three quit attempts in the previous year. Another 12 per cent reported making four or more attempts to quit. Fifty-one per cent reported that they did not make any attempt to quit in the previous year. Quit attempts varied by age. Two thirds of 15 to 19 year old daily smokers, 58 per cent of 20 to 44 year old daily smokers, 37 per cent of 45 to 64 year old daily smokers and 45 per cent of those 65 and over reported making at least one quit attempt in the previous year. The average age when smokers succeeded in quitting is 48 for males and 45.5 for females.

The most common methods reported by former smokers to quit were cold turkey or their own will power (82%), followed by nicotine patches (8%), nicotine gum (4%) and Zyban (3%). However, since these data are from former smokers (some of who quit many years ago) it is not possible to determine what methods are currently most popular.

Former smokers age 25 and over reported that concern for their future health (30%), concern for their present health (20%), change in lifestyle (16%), increased cost (8%), pregnancy (7%), concern for the health of one or more family members (7%) and doctors advice (3%) were the most common reasons why they quit. However, once again, since many of these respondents quit several years ago it is difficult to determine how current smokers or recent quitters might respond.

Critical Appraisal of Current Interventions in Canada

Current Public Policy Initiatives

Despite significant momentum and action in tobacco control policy (e.g., no smoking restrictions, warning labels, fire safe cigarettes, increased tobacco taxes), few of these initiatives have a primary aim of helping Canadians to quit or reduce their tobacco use. Rather, most tobacco related policies have tobacco prevention and/or protection as their primary aim. The effects on current smokers are largely regarded as a secondary benefit. With the exception of tax policies, there has been little or no serious discussion about policy as an instrument to aid current smokers.

Current Communication Campaigns

There is a growing body of evidence from the United States, Australia, England and elsewhere that mass communication campaigns can be used to motivate smokers to quit and increase the likelihood they will seek out a formal treatment aid (Schar and Gutierrez, 2001; Sparks and Green, 2000). Communication campaigns are also effective instruments for influencing social norms and building support for investment in social capital, which influence the ability to quit using tobacco (Wallack, 2000). However, in Canada the vast majority of tobacco campaigns financed by public and/or non-profit sources have been directed at reducing exposure to environmental tobacco smoke, tobacco use prevention and, more recently, denormalizing tobacco industry practices. Notwithstanding the 2003 national ad campaign sponsored by Health Canada featuring "Bob" and "Martin", the impact of communication on current smokers is largely regarded as a secondary or indirect outcome.

Twenty per cent of current smokers in Canada can not recall even a single quit aid. Among those who can name a quit aid, more than 25 per cent identified one or more treatments that systematic scientific reviews regard as ineffective (Hammond, Fong, McDonald and Borland, submitted). The only constituency who devotes considerable resources to the promotion of tobacco quit aids is pharmaceutical companies. It should be of little surprise that when asked to identify quit aids, current tobacco users were six times more likely to identify nicotine replacement products (NRT) and four times more likely to identify buproprion than *any* behaviour oriented treatment (Hammond, Fong, McDonald and Borland, submitted). This situation is worrisome given recent evidence that, in the past, the manufacturers of nicotine replacement products have altered their messages and marketing approach in response to

pressure from the tobacco industry (Shamasunder and Bero, 2002) and emerging evidence that NRT may not be effective for some types of smokers (e.g., Pierce and Gilpin, 2002). Moreover, the majority of smokers hold negative attitudes towards the use and utility of pharmacotherapies (Etter and Perneger, 2001). Hence, if this is the only quit aid that tobacco users are aware of, many are unlikely to seek out or use any type of assistance.

Current Uses of Community Organization

There have been few attempts to rigorously evaluate the value of community development, organization and mobilization as strategies for tobacco cessation, although these approaches have been shown to be effective in other areas of tobacco control and health promotion (e.g., Minkler and Wallerstein, 2002; Skinner, 2002). During the COMMIT trial the intervention city of Brantford Ontario established a smokers' network that managed to engage more than 10 per cent of all smokers in the region (Roy Cameron, personal communication). These approaches may hold particular promise for aiding certain important sub-populations such as aboriginals, low income Canadians, and other disadvantaged groups.

Current Treatments

The focus of current interventions for tobacco users involves the provision of cessation programs or treatments. Unfortunately, duplication of purpose and coverage is frequent. An inventory of tobacco cessation programs produced for Health Canada lists dozens of self help booklets, websites, and group programs aimed at similar sub-populations of tobacco users (Health Canada, 2000). Few existing treatment/services make it clear what their primary audience is and/or why a given program is in the best position to provide a service.

Accessibility. Many treatments are not accessible to current smokers. There are relatively few clinics or regulated health professionals that specialize in intensive treatments for smokers wanting to quit. An informal canvas of traditional service providers also finds that group and peer-based programs are not as widely available as in the past. Changes in the health care system make it difficult for some smokers to access family physicians and other health care providers. Many of the health care professionals capable of providing brief counseling are reluctant to do so. Even self help programs offered though booklets and websites may not be as accessible as is commonly believed. For example, most interventions are written at a grade 10 reading level or above, despite evidence that a significant proportion of smokers cannot comprehend material beyond a grade 8 level (Meade and Byrd, 1989). Few programs appear to have been developed or even adapted to suit the mosaic of cultures, language, traditions and special medical conditions that are indicative of Canadian tobacco users.

Coordination and Referral. There are few systematic attempts to refer smokers across programs or services. The lack of a systematic referral network (along with lack of awareness among smokers) may explain, in part, why so few smokers who attempt to quit use any formal quit aid. According to the 2001 CTUMS only 18 per cent of former smokers used a formal quit aid. This is largely unchanged from 1994 when 89 per cent of former smokers reported they

quit "cold turkey", presumably without the use of a quit aid. Not only are insufficient numbers of smokers using quit aids, but many appear to be using inappropriate, inefficient or ineffective treatments. For example, nicotine replacement therapy costs about $1,000 per quitter, but is no more effective for some types of smokers (e.g., light smokers; cf Pierce and Gilpin, 2002) than self help treatments that typically cost one tenth of this amount. Recent reviews of the literature suggest that treatments such hypnosis, laser therapy and acupuncture offer no active treatment benefits (beyond a placebo effect). Despite this, up to 20 per cent of the smokers who use a quit aid seek them out (Health Canada, 2002; Hammond, Fong, McDonald et al, submitted). While there has been some cooperation between service providers, there are no standard or consistent protocols for deciding what types of smokers should be referred to what type of treatments.

Evidentiary Foundation. Smokers regard information on the effectiveness of interventions as being an important consideration when deciding how to quit smoking (Owen and Davies, 1990). Few current treatment programs or services in Canada have been adequately evaluated using accepted scientific standards and practices. There are significant evidence gaps associated with products that are putatively well tested.

While most programs have not been adequately evaluated or developed on the basis of sound theory and/or evidence, there are some important (and relatively recent) exceptions. For example, there is a large body of literature showing that brief clinical interventions delivered by health care professionals such as physicians, dentists, pharmacists and nurses can increase the odds a given tobacco user will quit (Fiore, Bailey, Cohen et al, 2000; USDHHS, 1994). Some provinces (notably BC, Quebec, Ontario and Nova Scotia) have established programs to train health care professionals and evaluate their impact. Significant *clinical* research has suggested nicotine replacement therapy can be highly effective with some types of smokers (Fiore, Bailey, Cohen et al, 2000). There is a significant body of evidence demonstrating that cessation counseling delivered by trained specialists over the telephone is effective (Fiore, Bailey, Cohen et al, 2000; Zhu, Anderson, Tedeschi et al, 2002). Telephone counseling can also enhance the effectiveness of other treatments such as nicotine replacement (e.g., Reid, Pipe and Dafoe, unpublished). By the end of 2003 residents in all provinces (but not the territories) will have access to toll free telephone helplines for smokers that for the most part, either have been or will be rigorously evaluated (McDonald, Filsinger and Walker, 2002). The Canadian Cancer Society widely distributes an effective self-help book through its offices and website (McDonald, Jessup, Brown et al, 2002; Smith Cameron, Payne et al, submitted). Health Canada has recently developed a modestly interactive website for adults (On the Road to Quitting), and youth (Quit 4 Life – revised), that appears to hold promise.

There is clearly much to be done to help current tobacco users. Recent advances have laid the foundation for future action. It is no longer a question of whether we can be successful. Rather, the central question is whether we are making as much progress as we could through better planning, coordination, and the allocation of new resources to proven actions.

Factors Associated with Quitting

Stopping or reducing tobacco use *can* be extremely difficult. For example, longitudinal data suggests that only about five per cent of smokers who attempt to quit and remain smoke free over the long term (e.g., NPHS, 1997). A review of the literature indicates three broad and inter-related categories of factors contribute to this: biology, intra personal factors other than biology, and the socio-physical-economic environment.

The Role of Nicotine Dependency

It is now widely accepted that nicotine *can be* highly addictive. Indeed, some have gone so far as to say that nicotine may be among the most addictive substances known. This is largely based on data suggesting that rates of "tobacco dependence" in the general population are higher than other addictive substances such as alcohol, marijuana or cocaine (Kandel, Chen, Warner et al., 1997) and that relapse rates for the three substances are similar. This, along with data showing that the odds of successfully quitting smoking is related to measures of nicotine dependence (Fiore, Bailey, Cohen et al, 2000), may explain why so many believe the biology of nicotine is the primary reason it is so difficult for tobacco users to quit or reduce their tobacco use. There are several problems with the logic used to reach such a conclusion.

First, the majority of people who experiment with smoking do not become regular users (Driezen, Brown, Cameron and McDonald, submitted). Second, given the legal and social consequences associated with illicit drug use compared to tobacco, illicit drug use is more likely to be under reported. Third, the level of dependence does not *consistently* predict future abstinence (Etter, Houezec and Perneger, 2003) or smoking behaviour (Shiffman et al, 2002). This may be because the factors thought to be indicative of nicotine dependence such as withdrawal and cravings are highly influenced by environmental cues and cognitive factors such expectancy and self efficacy (Juliano and Brandon, 2002; Perkins, 2003; Pickworth, 2003). Perhaps most significant, not all persons who use tobacco or have difficulty in quitting may be classified as nicotine dependent. Indeed, a *sizable majority* of tobacco users do not meet the definition of nicotine dependency. According to the Diagnostic and Statistical Manual of the American Psychiatric Association (DSM-IV; APA 1994) to be classified as dependent, and individual must manifest at least three of the following seven symptoms in the previous year: (1) tolerance; (2) withdrawal; (3) using larger amounts or longer than intended; (4) unsuccessful efforts to cut down; (5) much time spent obtaining the substance; (6) negative social, occupational consequences; and (7) persistent physical or psychological problems. In a population survey of more than 22,000 American adults between 1991 and 1993, Kandel and Chen (2000) found only 27 per cent of males and 30 per cent of females who smoke met the criteria for nicotine dependence. Dependence was lowest among 12 to 17 year olds (28.2%) and rose to 31.5 per cent of 35 to 49 year olds. Nicotine dependency varies by cigarette consumption. However, only 45 per cent of even the heaviest smokers (54+ cigs/day) meet the criteria for nicotine dependency (Kandel and Chen, 2000). While the majority of smokers may not be nicotine dependent in the formal diagnostic sense, it is probable that a significant proportion are, never-the-less, affected by nicotine.

The Heaviness of Smoking Index uses two of the most valid items from Fagerström Scale of Nicotine Dependence (daily cigarette consumption; time to first cigarette after waking) as a proxy measure of nicotine dependence (Heatherton, Kozlowski, Frecker and Fagerström, 1991). As shown in Figure 1, only 12 per cent of *daily* smokers (10% of all current smokers) may be classified as heavily dependent. It is likely that, for this group of smokers, nicotine dependence plays a substantial role in their attempts to quit. Benowitz, Shiffman and others have suggested that less than daily smokers and light daily smokers (e.g., those who smoke less than 5 cigarettes per day) fall below the threshold for the development of nicotine dependency (cf Benowitz 1998; Benowitz and Henningfield, 1994). Pierce and Gilpin (2002) recently reported that nicotine replacement products had no effect on light and medium smokers (e.g., <15 cigs/day). Hence, nicotine probably plays no *substantive* role among the 31 per cent of light daily smokers (26% of all current smokers) plus the 17 per cent of current smokers who do not consume tobacco on a daily basis. On the other hand, while it may not be the most compelling reason, nicotine probably plays at least some role in the remaining 57 per cent of daily smokers (48% of all current smokers). In sum, nicotine probably plays a role in far fewer tobacco users than is commonly believed.

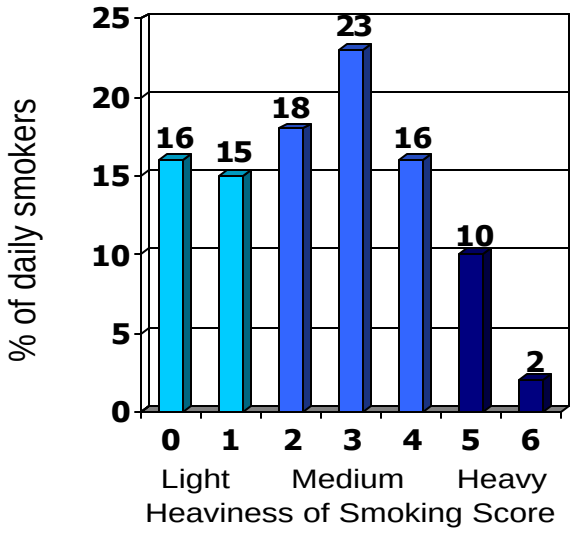

Figure 1. Distribution of heaviness of smoking scores among *daily* smokers in Canada in 2001. Data is from the 2001 Canadian tobacco Use Monitoring Survey.

The Selection Hypothesis Revisited

Characteristics of the "average" smoker in Canada appear to be changing in a way that has implications for treatment. For example, if we assume (as most "experts" currently do) that nicotine dependence is related to the odds of quitting, it has been argued that light smokers will quit first. Hence the residual smokers should be increasingly more nicotine dependent and resistant to quitting (cf Fagerström, Kunze, Schoberberger et al, 1996). However, this may not be the case. For example, as noted previously, an unprecedented proportion of Canadian

smokers (including moderate and heavy smokers) report an immediate intention to quit. Unprecedented numbers also report making a quit attempt in the previous year. Recent trends in daily consumption are also consistent with the notion that many heavy smokers may be reducing their consumption without actually quitting. Nearly 25 per cent of smokers who attempt to quit without success appear to reduce their tobacco consumption by a quarter or more (this means that even those who engage in compensatory behaviour likely reduce their overall intake of toxins). Another 17% reduce their consumption by 5 to 24 per cent. Moreover, most of those who reduce their smoking appear to be able to maintain these reductions for periods of 2 years or more (Hughes, Cummings and Hyland, 1999). This, combined with a greater proportion of young smokers (who tend to have lower consumption levels), have meant that the average self reported daily consumption of cigarettes has fallen significantly in the past 15 years. Finally, the proportion of smokers who do not smoke on a daily basis has risen steadily over the past 20 years from 13 per cent of current smokers in 1985 to 17 per cent of current smokers in 2001 (Gilmore, 2002). In sum, the hypothesis that smokers in the future will be more nicotine dependent and more difficult to treat does not appear to be true.

The Importance of Non-biological Factors

Clinical practice guidelines stress the importance of offering pharmacotherapy to help quitters deal with the biological concomitants of abstinence. Pharmacotherapy is also the most common quit aid (Health Canada, 2002). Therefore, the importance of dealing with intrapersonal factors (particularly cognitions and affect) and the environment appears to be under appreciated by both health care professionals and tobacco users who attempt to quit. Evidence of the profound effect that the environment (social, physical and economic) and cognitive/affective factors play in facilitating or inhibiting quitting or reducing tobacco use include the following.

- Quit ratios (the ratio of current smokers to former smokers) and self-reported daily consumption vary enormously by province. For example, the quit ratio in a province like British Columbia with progressive tax policies and social norms is 60 per cent higher than the quit ratio in Manitoba, a province that has been slower to adopt tobacco reduction policies (Health Canada, 2001). Large differences in quit ratios and consumption persist after adjusting for sex, age and nicotine dependency (McDonald, unpublished data). This is consistent with the notion that the social (e.g., norms), physical (e.g. smoke free spaces) and economic environments (e.g., tobacco taxes) have profound effects on a tobacco users' ability to quit or reduce their smoking.

- Even after adjusting for differences in nicotine dependency, quit rates and ratios vary significantly by social variables such as education and income (Heath Canada, 2001; Statistics Canada, 1999). Once again, this suggests social and economic factors are an important determinant of a person's ability to quit or reduce their tobacco use.

- A tobacco user's social environment and the social support they receive have a profound effect on a tobacco user's ability to quit. For example, having a supportive spouse or partner at home can more than double the odds of quitting, even after adjusting for differences in motivation and tobacco consumption (e.g., Osler and Prescott, 1998).

Smokers using smoking cessation treatments who designate a support person are significantly more likely to quit smoking relative to those without a designated support person (e.g., Carlson, Goodey, Bennet et al, 2002). One's social environment can not only facilitate quitting, but it can also inhibit it. For example, compared to smokers who received no support, those who received positive support were more likely to remain abstinent after a quit attempt while those who resided in a negative social situation were less likely to remain abstinent (Hill, Rice, Templin, et al, 1996). It is also encouraging that social support does not have to be a passive process. For example, Lindström and his colleagues (2000) found that smokers with low levels of social participation were less likely to quit smoking relative those with high social participation and well developed social networks ($OR_{unadusted}$ = 0.60; 95% CI 0.5 – 0.7). They concluded that an important reason why persons in lower socio-economic groups had a more difficult time quitting was because they tended to have lower levels of social participation. Lindström et al (2000) argued that increasing social capital and facilitating network development may be particularly important to aiding smokers from lower socio-economic groups.

- The importance of one's socio-physical environment on cessation and reduction is just beginning to emerge. A survey of more than 48,000 Californians found that smokers who lived in a smoke free home were 3.86 times (95% CI 3.51 - 4.18) more likely to make a quit attempt and 1.65 times (95% CI 1.43 – 1.91) more likely to remain abstinent for at least six months, relative to those who lived in homes without restrictions (Farkas, Gilpin, Disefan and Pierce, 1999). The odds of remaining smoke free were actually higher than the general population of adults who used nicotine replacement products (Pierce and Gilpin, 2002), although those who use NRT are a selective population with different characteristics than the general population of smokers. A recent systematic review of the literature concluded that smoke free workplaces are associated with reductions in smoking prevalence of 3.8 per cent (95% CI 2.8% to 4.7%) and reductions in daily cigarette consumption of 3.1 per cent (95% CI 2.4% - 3.8%). The authors estimated that to achieve the same net reduction in smoking, tobacco taxes would have to rise in the United States between $0.76 and $3.05 US per package (Fichtenberg and Glantz, 2002). Farkas and his colleagues (1999) concluded that smoke free workplaces increased the odds that a smoker would quit by 1.21 (95% CI 1.00 – 1.45).

- A recent clinical trial involving more than 505 Americans who were heavy smokers found that the most powerful predictor of long term abstinence was how much negative affect participants experienced, and their *expectations* of how well nicotine replacement products might ameliorate such symptoms. The tendency to experience negative affect was not only a more accurate predictor of abstinence than traditional measures of nicotine dependence, but it accounted for most of the predictive validity of these measures (Kenford, Smith, Wetter et al, 2002). This is part of a growing body of research demonstrating that how a quitter deals with negative emotions associated with their quit attempt (as opposed to pre-existing or coexistent affective and psychological distress) has a large impact on the ability to remain smoke free.

- Withdrawal symptoms are generally regarded to be a function of nicotine cessation. This is supported by studies showing that nicotine replacement products reduce withdrawal symptoms (e.g., Jorenby, Hatsukami, Smith et al, 1996; Abelin, Buehler, Muller et al., 1989). However, high doses of nicotine delivered by the patch or gum do not relieve withdrawal any better than low doses. Moreover, high doses of nicotine replacement therapy only have a marginally increased benefit on cessation outcomes (Hughes, Lesmes, Hatsukami et al., 1999). One explanation for this is that it is the patient's expectation of receiving an effective treatment that is responsible for the relief rather than an active pharmacological effect. Indeed, recent studies suggest that the instructions given to participants and the subsequent expectations created significantly reduce withdrawal effects independent of pharmacotherapy (e.g., Hughes, Gulliver, Amori et al, 1989; Juliano and Brandon, 2002).

- Expectancy produces consistently large placebo effects. For example, a recent meta-analysis of treatment effectiveness by Fiore et al (2000), suggests that placebo and control conditions consistency produce quit rates above 10 per cent. This is about twice as high as the quit rates obtained in general populations of smokers (cf, Statistics Canada,1999).

- A recent and growing body of literature shows that cues such as the presence of cigarette smoke, what smokers are told to expect when they quit, and other cognitive factors have profound effects on smokers' quitting experience. For example, one recent study found that participants who received either regular cigarettes or de-nicotinized cigarettes after a period of forced abstinence did not report any differences in craving or withdrawal (Perkins, 2003).

The aforementioned discussion is not intended to be exhaustive. Rather, it is meant to demonstrate that while many believe the primary difficulty in quitting rests with overcoming biological factors through pharmacotherapy, the influence of cognitive, affective, and environmental factors are substantial. Moreover, *while only some tobacco users are significantly influenced by biological factors, virtually all tobacco users are subject to cognitive, affective, and environmental influences*. Hence, an effective population strategy must do more than deal with the biological factors associated with quitting; rather, it must also address cognitive, social, economic and physical environmental issues.

Beyond Clinical Practice Guidelines

The majority of current interventions for tobacco users are clinical treatments. The primary goal of clinical tobacco treatments is to increase the odds that a given individual will quit smoking. Meta-analyses using strict inclusion criteria are used to identify treatments with the highest success rates. Results are used to construct clinical practice guidelines (CPGs). A number of CPGs for smoking cessation treatments have been developed in various countries around the world, including the United States (American Psychiatric Association, 1996; Fiore et al., 2000; Fiore et al, 1997) and the United Kingdom (Raw, McNeill and West, 1999). More recently, the

World Health Organization (2001) has also produced a set of recommendations for the treatment of tobacco "dependence".

In an admirable attempt to develop evidence-based strategies, an increasing number of countries appear to be using clinical practice guidelines as the foundation for a population framework. For example, CPGs for treating tobacco use typically suggest that smokers be routinely offered brief behavioural counseling (usually from a health care professional) plus some form of pharmacotherapy such as nicotine replacement or buproprion SR. By extrapolation, population strategies include increasing the availability of pharmaceutical aids and brief counseling through health care professionals. In turn, this gives rise to policies such as universal reimbursement for pharmacotherapy.

Pharmacotherapy

Using CPGs (and the meta-analyses upon which they are based) as the sole foundation for a population strategy for assisting current tobacco users has several important limitations. First, CPGs make the assumption that the vast majority of smokers are "addicted" to nicotine. While some CPGs include statements about lighter smokers or references to appropriate treatment, clearly the majority of recommendations and the overall tone of these documents are written with the understanding that nicotine addiction is the paramount barrier to abstinence. Several CPGs actually refer to themselves as guidelines for treating nicotine dependency. Pharmacotherapy such as nicotine replacement and/or buproprion is recommended by all CPGs as a means of reducing the effects of nicotine dependency (e.g., withdrawal and cravings). From a clinical perspective this makes sense because nicotine dependent smokers are more likely to seek out pharmaceutical aids (Pierce and Gilpin, 2002). However, as discussed previously, more than 30 per cent of current smokers in the population are not substantially affected by nicotine while another large proportion are moderately affected. Indeed, using a series of large population surveys Pierce and Gilpin recently reported that nicotine replacement did not appear to benefit persons who smoked less than 15 cigarettes per day. If this data is valid, then more than half of all smokers in Canada would not benefit from nicotine replacement products. Pierce and Gilpin's work has been criticized on the grounds that it is not a randomized trial. However, their study is never-the-less impressive in its design and execution.

Others have examined the impact of nicotine replacement moving from prescription to over-the-counter status. About half of the studies conducted to date suggested that moving NRT to over-the-counter may diminish its effectiveness, at least in part because of increased usage by light and moderate smokers (e.g., Shaw, Ferry, Pethica et al, 1998; Solberg, Boyle, Davidson et al., 2001). These results should not be an entire surprise. A review of the studies included in the meta-analyses used to develop clinical guidelines clearly indicates that most randomized trials using pharmacotherapy (including buproprion, clonoidine and other aids) systematically excluded persons who smoked less than 10 or 15 cigarettes per day. In other words, we have very little evidence on the effectiveness of pharmacotherapy in light smokers.

In sum, routinely recommending pharmacotherapy to virtually all smokers in clinical settings is reasonable in-so-far as heavier smokes are spontaneously more likely to seek out assistance.

However, a population strategy should attempt to motivate all types of smokers to quit and use appropriate quit aids. Therefore, as communication campaigns and policy interventions increase the proportion of lighter smokers who seek assistance from health care professionals (and other providers), CPGs may become less and less relevant, particularly with respect to routine recommendations to use pharmacotherapy. New decision making tools are required.

Effect on Environmental Factors

A second limitation of clinical approaches is that their effects are limited to dealing with intrapersonal factors (including biology, cognitions, affect, skills), but they are unable to address the social, economic and physical environmental factors that influence success in quitting or reducing. The best that counseling can do is to help an individual change their perception of and ability to cope with environmental factors. Clinicians are not in a position to change the precipitating environmental conditions. Individual smokers are not in a position to eradicate or attenuate many precipitating conditions either.

Utilization and Impact

A third problem is that the utilization and impact of clinically-based treatments are limited. As many as 30 per cent of tobacco users do not have regular contact with their physician or health care professional. Access may be a particular problem for groups with high smoking rates such as Aboriginals, those with low incomes or mental health issues, and those who live in rural areas. Those that do have contact are more likely to interact after the burden of smoking has begun to manifest itself (Thorndike et al, 1998). Adolescents and young adults provide the greatest opportunity to reduce tobacco related health burdens but are least likely to see a health care professional. The point of contact between clinicians and tobacco users may not be at an optimal time for tobacco counseling. The tobacco user may have more pressing and urgent medical and emotional issues to deal with. A related problem is that a large proportion of primary health professionals do not provide even basic, brief interventions. For example, only 43 per cent of Ontario smokers report that they had been advised by their physician to quit in the past 12 months (CAMH Ontario Drug Monitor, 2000). However, some of the barriers preventing higher compliance may be overcome with training.

While more than 90 per cent of smokers are willing to be asked about their smoking and are open to receiving advice to quit, less than half of smokers motivated to quit are interested in receiving an intervention through a health care professional. On the other hand, more than three quarters are open to referrals and follow-up (Kviz, Clark, Hope and Davis, 1997; McDonald, Carnide and Wolanowska, in preparation).

In sum, while treatments delivered through health professionals in clinical settings are effective, their ability to reduce the burden of tobacco use has signficant limitations, particularly among certain sub-populations.

Assisting Those Who Make Unsuccessful Quit Attempts

Even the most effective clinical treatments routinely have failure rates of 70 per cent or more (Fiore, Bailey, Cohen et al, 2000). CPGs are mostly silent on how to deal with the large proportion of tobacco users who do not succeed with a given treatment. Presumably clinicians could alter the intensity of pharmacotherapy (e.g., combination therapy could be used instead of a nicotine patch, nicotine chewing piece or buproprion alone). The content of the brief counseling may also change slightly (e.g., debriefing with respect to unsuccessful quit attempts). However, the range of options is relatively limited. This has the potential to demoralize smokers. It may be discouraging for a person who has earnestly tried to quit smoking using a given approach to be told that there is very little else that can be done except to basically repeat the process in the hope they have learned something new. Based on smokers' low outcome expectancies for cessation aids, one conclusion they might draw is that the treatment doesn't work (the alternative lesson may be even more demoralizing: "I'm a tobacco user who can't quit"). An alternative approach is to implement a stepped care procedure. Characteristics such as level of nicotine dependence, the presence of certain co-morbid conditions etc. are used to initially match a smoker to an appropriate treatment. They would only be encouraged to use increasingly intensive interventions with successive relapses (Abrams, 1993; Abrams, Orleans, Niaura et al., 1996).

Methodological Limitations

The meta-analyses on which CPGs are based also have limitations from a population perspective. First, they tend to be limited to randomized trails. While this is sufficient for comparing clinical interventions, it systematically excludes studies which are more relevant to population interventions. For example, RCTs are not practical for comparing the effects of community-based interventions. Projects like COMMIT which randomized communities to conditions are unique (largely because of its $30 million price tag). Many community interventions rely on quasi designs because of full coverage implementation (i.e., everyone in the population has the opportunity to use an intervention). While the ability to attribute cause and effect is reduced compared to randomized clinical trails, quasi designs, population surveys and other methods are essential for understanding the population impact of programs. Another limitation of the current evidence base is that studies rely on outcomes related to the probability of quitting at some specific point. For example, most studies in the meta-analysis that lead to the USDHHS guidelines compared quitting rates (or odds of quitting) 5 to 12 months after receipt of the intervention (Fiore et al, 2000). However, some quitters (albeit less than 10%) will relapse after the follow-up data collection (Gilpin and Pierce, 1997). The vast majority of studies are efficacy trials (i.e. studies conducted under ideal conditions). However, studies conducted under real world conditions (effectiveness trials) usually produce poorer results. Thus, the mean abstinence rates reported in documents such as the U.S. Clinical Guidelines, probably over-estimate the proportion of treatment users who quit.

Measures of Success (Quitting versus Health Burden)

A significant limitation of clinical approaches is related to the choice of outcome measures. Traditionally, the goal of treatment has been to increase the odds a given treatment user will quit smoking. However, quitting rates or odds may not be the optimal measure of outcome on which to select population interventions. Presumably, the only reason health advocates care about tobacco is because of its effect on individual and population health. In other words, the primary concern is not tobacco use; rather, it is the health burden associated with tobacco use. Given this, our primary outcome of interest should be to maximally reduce the health burden associated with tobacco use.

A notable challenge is that not all people who quit contribute equally to reducing the population health burden associated with tobacco. A person who quits after smoking 5 cigarettes per day for 1 year may not produce the same lifetime benefit as a person who quits after smoking 40 cigarettes per day for 40 years. A 20-year-old quitter does not produce the same net lifetime benefits as an 80-year-old quitter. The benefits of quitting vary enormously according to how much a person smokes, how long they have smoked, their gender, age and the presence of other co-morbid conditions, etc. (USDHHS, 1990).

In sum, while CPGs make recommendations based largely on quit rates or the odds a given person will quit, population health perspectives should select interventions based on their ability to relieve overall health burden. However, selecting interventions based on maximal benefit is more complicated than may first appear. For example, what should be the primary type of benefit and who should be the primary beneficiary? Should we select programs to maximally reduce costs to the health care system or reduce population mortality? Alternatively, should maximal reduction of morbidity or maximal improvement in quality adjusted life years be the focus? These are just some of the issues that must be considered and resolved. The reality is that different payers may expect different types of benefits. For example, a non-profit voluntary health organization may seek to minimize the mortality and morbidity associated with a particular disease. The federal government may seek to maximize overall health and wellbeing while provincial governments may wish to invest in interventions that produce the greatest savings to the health care system. Private sector stakeholders may seek to maximize profit and/or employee productivity.

Efficiency Versus Effectiveness

Another important challenge in using clinical guidelines as the basis of a population strategy is related to resource requirements. While clinicians are mindful of resource limitations, their primary motive for selecting treatments is driven by treatment effectiveness rather than cost. In a publicly funded health care system there is little incentive for clinicians to choose less effective but cheaper interventions over more effective and expensive alternatives. However, improving population health requires tough choices about how and where to allocate resources.

The most effective treatments are not always the most cost efficient. Consider two examples. According to the USDHHS Clinical Guidelines, approximately 18 per cent of smokers who use a

nicotine patch will quit smoking. If we assume that five per cent of individuals would have quit even without a patch (the "spontaneous" quit rate), then the marginal benefit for nicotine patches is 13 per cent. Lets further assume that the average cost of generic patches is $23 per week and that they will be used for an average of four weeks (although guidelines recommend using the patch for a minimum of 8 weeks, many smokers will relapse before this time and have no further need for the treatment). Using these assumptions, a treatment funder would have to pay $511 per quitter. In other words, a provider with 10 million dollars could theoretically help 19,569 tobacco users to quit. We can compare this to the use of a self help booklet, which according the USDHHS Guidelines has a success rate of 12 per cent. This represents a marginal benefit of seven percent. We can further assume that the cost of printing, warehousing and distributing the program is five dollars per user. Under these conditions you would need to spent $71 to help one person quit. Ten million dollars could theoretically help 140,845 tobacco users to quit, or more than seven times as many people as a nicotine patch. This represents a theoretical saving because not all smokers are equally likely to quit with a given intervention.

Let us consider another example involving persons with schizophrenia. Persons with schizophrenia and other mental health disorders face a greater difficulty in trying to quit than most other tobacco users. Indeed, it is highly unlikely that a self-help booklet or other low contact intervention would help. Hence, for schizophrenics, self-help approaches are infinitely cost inefficient. Pharmacotherapy and intense counseling represent the most cost effective approach for this sub-population.

Two points should be taken from these examples. First, the most effective strategies are not always the ones that will help the greatest number of tobacco users or maximally reduce tobacco related health burden. Second, cost efficiency varies across sub-populations. Therefore, population approaches must involve more than distributing self-help resources. Rather, we require a systematic means of matching tobacco users to treatment in a manner that balances effectiveness and cost efficiency.

A Final Word About Clinical Interventions

It is important to clarify that the previous discussion should not be interpreted as an argument against the use of clinical (or bio-medical) treatments and treatment guidelines. Rather, it is not always appropriate to use clinical evidence to construct a population strategy. Clinical interventions have an important role within a population strategy, but we must be realistic about what they can achieve.

Conclusions

There are compelling humanitarian and economic reasons for helping Canada's 5.4 million tobacco users to quit using tobacco. Well-designed self-help treatments plus recent efforts to expand telephone-based counseling and brief counseling through health care professionals represents a solid starting point. However, such approaches are largely passive in orientation.

That is, service providers often wait until tobacco users are motivated to quit and ask for assistance. This is problematic because only a small portion of tobacco users fall into this category. Moreover, those who do seek help face a potentially confusing array of services and treatments. The population impact of interventions can and must be improved by proactively motivating and assisting a larger proportion of tobacco users and coordinating treatment services. Coordinating referral through the use of a standard triage tool also has the potential to improve the cost efficiency of interventions. This is a paramount consideration given the relative scarcity of resources to help current tobacco users. Recent initiatives such as changes in warning labels on tobacco packages, small increases in tobacco taxes, and modest mass media campaigns are a welcome start but more must be done. Careful consideration must be given to the timing and intensity of new initiatives, as well as how to send clear, positive, consistent messages about quitting. Current interventions are also limited because they cannot deal with important social, economic, product, and environmental determinants of cessation and relapse prevention. We require a clear policy framework designed to create environments that encourage and support tobacco abstinence.

While future efforts must be based on a solid evidentiary foundation, we must be careful not to simply extrapolate findings from clinical practice guidelines as the foundation of a population strategy. Clinical guidelines are designed to increase the odds that a given individual will quit smoking. A population strategy should be concerned with reducing the health and economic burden associated with tobacco use, particularly among those who currently bare a disproportionate share of the net burden.

A companion discussion paper (McDonald, 2003a) addresses the aforementioned issues by suggesting population-based goals, objectives and actions. The plan makes recommendations for funding and who should exercise leadership in the implementation of various actions.

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