SESSION IV PUBLIC POLICY CONSIDERATIONS

Introduction

Maxine L Stitzer

I am currently professor of behavioural biology in the Department of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine. My research has examined both pharmacological and behavioural treatment of drug abuse, and specifically their combination for the treatment of tobacco dependence. I am pleased to be both a presenter and a moderator this morning.

Our other presenter, who will follow the panel discussion, is Mike Synar. Mr Synar served in the US House of Representatives from 1978-94, representing Oklahoma's second district. During his tenure, he was known for his willingness to pursue his convictions, even if that meant bucking established interests, particularly the tobacco industry. Mr Synar achieved passage of the Synar Amendment which links success at controlling youth access to tobacco at the state level with the receipt of federal aid dollars. We are really pleased to have you here to share your insights about policy initiatives and political reality.

Our first panelist is Michael C Fiore. He is director of the Center for Tobacco Research and Intervention, as well as an associate professor in the Department of Medicine at the University of Wisconsin Medical School. Dr Fiore worked as a medical epidemiologist at the Office on Smoking and Health, and he has published extensively on nicotine, and nicotine

replacement as a smoking cessation aid. He is also currently chair of the clinical guidelines panel on smoking prevention and cessation for the Agency for Health Care Policy and Research.

Ellen R Gritz is professor and chair of the Department of Behavioral Science at the University of Texas MD Anderson Cancer Center where she holds the Annie Laurie Howard research professorship. She has published extensively on cigarette smoking behaviour and is an expert on cessation issues in special populations including women, adolescents, ethnic minorities, and medical populations. Dr Gritz was also the first recipient of the Joseph W Cullen Memorial Award from the American Society of Preventive Oncology.

Finally, we have our third panelist. Michael Pertschuk is co-director of the Advocacy Institute, a non-profit organisation "dedicated to strengthening the advocacy capacity of the least powerful citizen groups and communities so that their voices will be heard and heeded." From 1965 to 1977, in various capacities, Mr Pertschuk worked for the Senate Commerce Committee. Here, he helped guide landmark consumer legislation, including the broadcast ban on cigarette advertising. He served as chairman of the Federal Trade Commission from 1977 to 1984, and we are really fortunate to have him here today.

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Policy initiatives to enhance smoking cessation and harm reduction

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The overall goal of the conference reported in this supplement is to consider new strategies and interventions expected to lower the harm to society that result from tobacco smoking. In general, there are two ways to achieve a harm reduction goal. The first is to reduce the prevalence of smoking by using interventions that reduce smoking initiation, promote attempts to stop smoking, and increase the success of these attempts once initiated. A second approach to harm reduction is to limit exposure to the most harmful substances or behaviours related to an addiction, while

conceding that the addiction itself will continue in some form.

Harm reduction has received serious consideration and discussion as a strategy for dealing with hard drug abuse, where limiting the risk of exposure to HIV infection is an important concern. The concept of harm reduction has had a more limited application to tobacco dependence; thus its consideration represents a novel contribution of the present meeting. Harm reduction to continuing smokers might be accomplished by changing the nature of the cigarettes so that fewer

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harmful products or smaller quantities of these products are derived from each cigarette, or by lowering the number of cigarettes smoked per day, or both.

There are various specific policy initiatives and strategies that could effectively promote these harm reduction goals. The purpose of this session is to describe some of the most promising strategies and policy initiatives that have been suggested to date, outline what these are likely to accomplish, and discuss the political realities surrounding implementation of these proposals. In this first paper of the session, I shall give an overview summary of the initiatives to provide a framework for the material and a basis for subsequent discussion by panel members and our invited speaker.

I have organised the policy initiatives into four categories: (1) improving access to treatment to improve cessation success rates; (2) altering the characteristics of cigarettes to reduce exposure to harmful products; (3) imposing environmental smoking bans to limit smoking opportunities; and (4) increasing cost of tobacco products to reduce consumption. Within each of these categories, I shall describe one or two specific proposals.

Improved treatment access

The first set of policy initiatives focus on improving treatment access. It is widely recognised that the best results from smoking cessation treatment can be achieved using a combination of behavioural and pharmacological treatments. Thus access to both types of treatment should be addressed in order to improve smoking cessation outcomes in the general population. Several innovative approaches are possible that would make each important element of smoking cessation treatment more convenient and accessible.

BEHAVIOUR THERAPY

If face to face treatment is to be delivered, it will be important to establish an infrastructure for its delivery as well as a funding mechanism. Inclusion of smoking cessation therapy as a recognised service within the purview of managed care would be most helpful in this regard. It may also be possible to adopt innovative methods to deliver behaviour therapy without face to face contact with a therapist, and these strategies could greatly improve access to treatment interventions. Media programmes,¹ telephone counselling services,^{2,3} and individualised computer generated relapse prevention plans⁴ are among the methods that have already been developed and received at least initial evaluation. Additional evaluation of efficacy is needed for treatment delivery approaches that do not use face to face contact. If effective, however, such delivery approaches could be implemented through support from the business community or as a fee for service enterprise, and would not require regulatory or legislative action.

NICOTINE REPLACEMENT: OTC STATUS

Nicotine replacement is the second important element in successful smoking cessation treatment. Nicotine replacement can double cessation success rates when combined with a variety of specific types and intensities of concurrent behaviour therapy.⁵⁻⁷ A proposal is being considered by the Food and Drug Administration (FDA) to approve over-the-counter status of nicotine gum and if this application is successful over-the-counter patches may follow.

One important question is whether population-wide smoking cessation rates would in fact be influenced as a result of improved availability of nicotine replacement products. Survey data from Sweden and the United Kingdom⁸ suggest that respectable (20–30%) smoking abstinence rates can be observed in an environment where gum is available over the counter, although these cessation rates may not be any higher than the rates seen when gum is available only by prescription. Studies of smoking cessation with over-the-counter medication in the United States are not available at present.

Over-the-counter availability of nicotine replacement could also have implications for harm reduction through reduced exposure among individuals who continue to smoke. Data are available from two sources showing that smoking is reduced during periods of maintenance on nicotine replacement products. One source of data is laboratory studies where nicotine replacement has been given under experimental conditions while subjects are allowed to smoke. Under these circumstances, small but reliable reductions in smoking have been observed. For example, one laboratory study by Nemeth-Coslett and colleagues⁹ found that nicotine gum pretreatment produced dose related decreases in cigarette smoking. Subjects smoked three cigarettes on average during a 90 minute test session following placebo pretreatment, but 2.76 and 2.64 cigarettes after pretreatment with 4 and 8 mg gum doses, respectively. Foulds and colleagues¹⁰ had subjects record their smoking while they were maintained for one week on an active patch (delivering 15 mg over 16 hours) versus a placebo patch and found a small (approximately one cigarette per day) reduction in smoking during active patch maintenance; and Pickworth and colleagues¹¹ observed a dose related decrease of 1.7 and 3.6 cigarettes per day when subjects were maintained on 22 and 44 mg patches respectively during a residential research study. A higher dose model of nicotine replacement was investigated by Benowitz and Jacob,¹² who gave a 14 hour infusion of nicotine or placebo, the nicotine infusion dose being designed to match nicotine levels obtained by the individual during normal smoking. In this high dose model of nicotine replacement, the average smoking reduction observed was 5.5 cigarettes per day. Thus smoking reduction during nicotine replacement seems to be reliable and dose related but relatively small in magnitude.

There are also data from clinical smoking

cessation studies showing that individuals who return to smoking while on nicotine replacement smoke at reduced rates compared with their precessation baselines. A good example comes from the Lung Health study¹³ where data are reported for smoking relapsers who did and did not continue to use nicotine gum. At the 1 year follow up, relapsers using gum were smoking half as many cigarettes (12.4 cigarettes per day) as subjects who had ceased using gum (23.5 cigarettes per day).

Although neither of these examples tells us directly whether over-the-counter nicotine products would in fact support smoking reduction, the analogies are suggestive. Further, the logic is straightforward and compelling: by having nicotine replacement available, smoking reduction would be more acceptable because smokers could use the replacement products to suppress withdrawal during extended periods of temporary abstinence. Thus over-the-counter nicotine replacement products, should they be approved, will provide an intriguing natural experiment that may have an important impact on smoking rates and consequent harm reduction within the smoking population.

Overall, improvements in the availability of effective components of smoking cessation treatment should have benefits for achieving harm reduction goals. Specifically, improved availability of treatments that can benefit dependent smokers may result in higher cessation success rates which in turn contribute to reductions in smoking prevalence. Furthermore, improved availability of nicotine replacement products could have a harm reduction impact even on individuals who continue to smoke.

Altered cigarette characteristics

If people are going to smoke, then altering the characteristics of cigarettes in ways that force reduced exposure per cigarette would be the most direct way of producing a harm reduction outcome. It should be noted in this regard that there are cigarettes currently marketed as "lights" and having Federal Trade Commission (FTC) nicotine yields of 0.4–0.7 mg per cigarette where the labelling and advertising implies that smokers will reduce health risks through their use. This implication is not substantiated by data. In fact, it is well established that over the range of yields cited above, there is no correlation between nicotine exposure levels of smokers and the nicotine yield of their cigarettes.^{14,15} Further, smokers even of lowest yield brands (that is, those with FTC yields of 0.1–0.2 mg nicotine) obtain much more nicotine from their cigarettes than expected from published yields.¹⁶ These observations arise because smokers can and do alter their smoking behaviour to compensate for reduced cigarette yield characteristics. Compensation is accomplished by taking more and larger puffs from the cigarettes¹⁷ and by blocking filter vent holes.^{18,19}

Currently, cigarette yield characteristics are determined primarily by burn rates and filter

ventilation technologies rather than by alteration in the types or amounts of constituent products contained in the cigarette tobacco. It may be possible, however, to manufacture cigarettes that deliver fewer harmful products or smaller amounts of these products such that harm reduction is accomplished at the source. Two specific proposals have been put forward in this regard. Interestingly, these two proposals suggest diametrically opposed manipulations of the amount of nicotine contained in cigarettes.

LOW NICOTINE CIGARETTES

The first proposal to be considered is that put forward recently by Benowitz and Henningfield.²⁰ This proposal calls for a gradual reduction in the nicotine content of tobacco cigarettes from 9 mg, where it currently stands, to about 0.5 mg per cigarette. This would represent such a low content of nicotine that smokers would be unable to extract the nicotine doses that they typically obtain from each cigarette of currently marketed types, even if compensation in smoking behaviour did occur. The goal of severely restricting nicotine content of cigarettes is to create a non-addictive cigarette, that is, a cigarette where the nicotine yield is so low that it does not support dependence. This is meant to reduce dramatically the number of adolescents who begin smoking while promoting attempts to quit and making it easier for established smokers to quit. The mechanism envisioned for implementing the low nicotine cigarette proposal is regulation of tobacco cigarettes by the FDA. At present, the FDA is considering the case for regulation of tobacco cigarettes as a drug (that is, nicotine) delivery product.

There are currently no cigarettes available with the characteristics described above that could be used to test the hypotheses generated from the low nicotine proposal. It should be noted, however, that there are currently cigarettes marketed with some of the characteristics desirable for implementing and testing a harm reduction model. I am referring here to the ultra low yield cigarettes which are represented by just two or three brand names including "Carlton" and "Now". These are cigarettes that receive an FTC delivery rating of 0.1 mg nicotine or less. This yield determination is not based on altered tobacco characteristics but rather on the fact that the filters are so extensively ventilated that it is difficult for smokers to compensate fully by more intensive smoking.²¹

In studies that have measured biological exposure levels in smokers of ultra low yield cigarettes it has been found that individuals who smoke 30–35 ultra low yield cigarettes per day have plasma cotinine concentrations (a convenient and specific marker of nicotine exposure) that average approximately 200 ng/ml.^{16,22} This contrast with cotinine levels of 250 ng/ml or higher that would typically be documented in heavy smokers of higher yield cigarette brands.^{16,22} Thus the amount of nicotine and tar that smokers can extract when

using ultra low yield cigarettes appears to be limited by the difficulty of full compensation through smoking behaviour change. It might be possible to encourage more smokers to switch to ultra low yield cigarettes as a harm reduction strategy, using price differentials for example. However, acceptance of these cigarettes by smokers given current market choices is low and they capture only a very small share of the market.²³

HIGH NICOTINE/LOW TAR CIGARETTES

The other side of the coin has also been advocated. The proposal, originally articulated in the 1970s by Michael Russell,^{24,25} is to change the tar to nicotine ratio of cigarettes, reducing tar levels in order to lower cancer risks, while leaving enough nicotine in the cigarette to provide adequate pharmacological reinforcement. The tobacco industry, R J Reynolds Company in particular, has been pursuing this strategy in their development of alternative, high tech nicotine delivery products including previously test marketed "Favor" and "Premier" cigarettes, and more recently "Eclipse" (*New York Times*, November 27, 1994). These products are engineered to deliver nicotine without tar and have used various strategies to accomplish this, the most recent of which is heating rather than burning the tobacco.

It is too early to draw any conclusions about the viability or utility of the altered cigarette approach. We do not know, for example, what the consumer acceptability would be for a low tar or tar-free cigarette, nor do we know whether there would be any benefits with regard to reduction of heart disease, where both nicotine and carbon monoxide are risk factors. The effort to develop these alternative cigarette products is, however, illustrative of the fact that technology exists or can be developed to create cigarettes or nicotine delivery products with dramatically different characteristics than those presently marketed. Furthermore, private enterprise, either with or without the cooperation of the tobacco industry, could be brought to bear in this regard to pursue harm reduction goals.

OTHER CIGARETTE CHARACTERISTICS

Up to now, I have been discussing primarily the alteration of nicotine and tar content of cigarettes as a means for accomplishing harm reduction goals. For completeness, however, it is important to remember that there are other characteristics of cigarettes besides the tar and nicotine that might be considered in efforts to achieve harm reduction goals. Flavour additives, for example, are included in cigarettes to make them more acceptable to smokers, and these could be altered to make cigarettes less pleasant to use. Also, pH is adjusted to facilitate optimum nicotine absorption, and this could be altered to reduce the dose of nicotine absorbed per cigarette. Again, it might be possible to encourage private enterprise initiatives to compete with

tobacco companies in the design and manufacture of truly safer cigarettes.

Overall, the concept of altering cigarette characteristics to achieve harm reduction goals is an intriguing one. Technology innovation could certainly be brought to bear on this problem, although the funding source would have to be worked out. Importantly, it would first be necessary to decide on the best avenue to pursue for achieving a harm reduction goal. The fact that proposals including diametrically opposed alterations in nicotine yield have been put forward suggests that there is as yet no agreement as to the best approach. In fact, an experimental protocol in which cigarettes with a variety of altered characteristics were produced and tested would no doubt be the optimum approach to the problem since this would provide empirical data on which to base future policy decisions.

Up to now, I have been discussing harm reduction policies that target characteristics of cigarettes and characteristics of the quitting environment. The remainder of this paper will describe policy initiatives that influence smoking indirectly by altering either the opportunities to smoke in public settings or the price of cigarettes. These are important policy initiatives because they can exert a substantial influence on the behaviour of smokers.

Limited smoking environments

We live in a rather remarkable time when there has been a sea change in the social attitude towards smoking. One area in which this has been quite visible is in the proliferation of environmental smoking bans. Over the past 10 years, private sector employers have been adopting non-smoking policies in increasing numbers. Both employer and employee surveys have shown a marked trend toward increasing number and severity of restrictions adopted. For example, Bureau of National Affairs surveys show a greater than 16-fold increase in the percentage of companies reporting total worksite smoking bans during the period from 1986 to 1991; by 1991, 85 % of worksites surveyed reported having some type of non-smoking policies in place.²⁶ At the same time, there has been a parallel acceleration of cities enacting restrictive ordinances on smoking in restaurants and other public places. Originally intended to limit non-smokers' passive exposure to tobacco products, smoking bans have also had an influence on the behaviour of smokers.

One area of influence is on smoking cessation rates. Several studies using cross sectional pre-post designs have documented substantial reductions in smoking prevalence at worksites after implementation of a smoking ban,^{27,28} although an overall reduction of only 1 % was observed by Borland and colleagues²⁹ in an Australian study. A well designed prospective survey study conducted when the New England Telephone Company went smoke-free in 1987 documented a 21 % cessation rate at the 20 week follow up, with 18 % reporting 3 months or more of abstinence.³⁰ This study

shows that workplace bans can promote cessation attempts. However, it is unclear whether this is a sustained effect or a one time effect when a smoking ban goes into place.

Environmental bans, particularly worksite bans, may also have important effects on exposure levels of individual smokers. Studies using self report to gather data have uniformly found a reduction in daytime as well as overall smoking rates associated with workplace bans.^{27-29,31} An intensive study conducted when the Francis Scott Key hospital went smoke-free in 1989 documented a four cigarette per day reduction in daytime weekday smoking, with no compensation reported in smoking during off-work hours. A 15% decrease observed in mean saliva cotinine levels was consistent with an overall reduction in smoke exposure.³²

Overall, environmental bans appear to produce effects favourable to harm reduction goals. They may stimulate cessation attempts, at least when initially implemented, and produce some reduction in total exposure to tobacco smoke products among individual smokers. There can be little question that smoking bans send a strong message about the undesirability of smoking behaviour, at least when it occurs in public. Environmental bans make smoking more inconvenient and enhance the pressure on smokers to consider stopping. It seems likely that smoking bans have been instrumental in part for promoting the gradual decline in smoking prevalence that has been observed in the USA over recent years.

Increased cost of smoking

The final policy initiatives that I shall describe focus on increasing the financial cost of smoking as a strategy to reduce prevalence and amount of smoking. Under this umbrella, there are two specific proposals: differential insurance premiums and tobacco taxation.

DIFFERENTIAL INSURANCE PREMIUMS

It is clear that smokers pay more for life insurance than non-smokers and further, that these price differentials are large. Recent quotes obtained from a major life insurance provider indicated that smoker/non-smoker cost differentials are of the order of 50%; that is, smokers pay twice as much for their life insurance as non-smokers. The differential on life insurance premiums, being based on actuarial mortality data, is very consistently implemented across insurance companies including, I understand, a particular insurance company called CNA Financial Corporation, which is a sister corporation of the cigarette manufacturer Lorillard. Both companies are owned by Loews Corporation. So not only are smokers likely to die at a younger age than non-smokers, but they must pay more to protect their family against this eventuality. Smokers have apparently accepted this as a fact of life and there is no direct evidence that differential cost of life insurance has had any impact on overall smoking prevalence in this

country. However, it is possible that these costs contribute to the higher cessation rates that have been observed in more educated and higher income smokers, who may be the ones most likely to purchase life insurance.

With regard to health insurance, a survey of Delaware insurance companies conducted in 1989 revealed that smoker/non-smoker differentials were small – of the order of 10–15% – and inconsistently offered across companies.³³ There are some practical difficulties here. One is that many health insurance schemes are based on group rather than individual coverage, so that cost differentials do not have a direct impact on the individual smoker. Along the same line, the impact on smokers may depend on the extent to which they pay for their own health insurance in the first place (versus employer supported insurance programmes). Finally, the difficulties of verifying smoking status are cited by the industry as a barrier to more effective implementation of cost differentials. In spite of these difficulties, policy initiatives that impose higher health care costs on smokers could lead to further declines in smoking prevalence rates.

CIGARETTE TAXATION

It is quite a well known principle of behavioural psychology that if the response cost for a behaviour is increased, the incidence of that behaviour will decline. So it follows that increasing the price of cigarettes could have a significant impact on cigarette smoking behaviour. It should be noted that with regard to cigarette taxation, the USA is far behind most industrialised nations in that it has one of the lowest cigarette tax rates. For example, the Coalition on Smoking OR Health published figures on relative cigarette taxation rates adjusted to US dollars.³⁴ The analysis showed an average tobacco tax among major industrialised nations of \$2 or more. In contrast, the USA taxes tobacco at about \$0.56 per pack, including state and federal taxes. So the general concept is to bring the USA into better conformity with other industrialised nations by raising state and federal taxes on cigarettes and other tobacco products. Specific values suggested in recent taxation proposals have ranged from \$0.75 to \$2.00 per pack.

It is also well documented that the cost of cigarettes has an important impact on smoking prevalence. Smoking prevalence data from California have been published illustrating a sharp decline coincident with the imposition of a \$0.25 per pack additional tax in January 1989.³⁵ Data from Canada also show an impressive change in per capita cigarette consumption coincident with increasing the price. Canada increased federal and provincial cigarette taxes from an average of \$0.46 in 1980 to \$3.72 in 1991. During this time, cigarette sales fell 39% faster and tobacco consumption decreased 30% faster than in the USA.³⁶ The Coalition on Smoking OR Health has calculated that an increase of \$2 per pack in cigarette taxes, tied thereafter to inflation, would result in 7.6 million fewer smokers in the USA.³⁴

When the price of cigarettes increases, consumption declines both because some people choose not to smoke and because some smokers choose to smoke fewer cigarettes. Approximately two thirds of the decline in consumption is estimated to be the result of people choosing not to smoke at all. This includes current smokers who stop and adolescents who do not start.^{37,38} It also has been suggested that price influences the amount of smoking by individuals who remain smokers. Data from Canada are particularly convincing in the case of teenagers and young adults, where there has been a sharp decline in rates of regular smokers, but an increase in occasional smokers.^{39,40} Furthermore, one study from the United Kingdom documented a greater sensitivity to cigarette prices among people with lower incomes.⁴¹ If true, this would be important since it is lower income groups that show a disproportionately high rate of cigarette smoking and bear a disproportionate share of the burden of smoking related illness and death. Another study from the USA,³⁸ however, failed to support differential price sensitivity in low income populations.

Overall, price seems to exert an important influence on the prevalence of smoking and may also influence some individual smokers to reduce their consumption. Both mechanisms can contribute to harm reduction goals. Although potentially effective, taxation is a controversial issue that requires political consensus to achieve.

Summary

In this paper I have reviewed a variety of strategies and policy initiatives that have been put forward and discussed in public forums during the past several years. It is clear that there are many possible approaches in attempting to achieve further reductions in smoking prevalence as well as possible harm reduction through lowered exposure levels in those who continue to smoke. It is important to note that these goals are not mutually exclusive and that the various strategies are generally expected to influence both parts of the harm reduction goal. That is, interventions designed to reduce smoking prevalence may also reduce individual exposure among continuing smokers and vice versa. This brief overview has provided some structure and organisation to the plethora of policy strategies available for achieving harm reduction goals. Now it is important to consider priorities and realities. Specifically, how important are the results likely to be achieved by implementing various policies and what are the political realities that will determine the feasibility of implementing these policies? In general, for example, policies that affect smoking cessation rates or rates of smoking initiation may be more productive than those that target harm reduction for continuing smokers. With regard to implementation, policies that can be implemented on a local level (state, city, individual workplaces) appear more feasible than policies

that require federal intervention, while on the federal level, policies that require regulation may be more feasible to implement than those that require legislation. The most useful immediate benefit of this meeting may be to open a forum for discussion of these important policy issues.

- Warnecke RB, Langenverg P, Wong SC, Flay BR, Cook TD. The second Chicago televised smoking cessation program: a 24 month follow-up. *Am J Public Health* 1992; 82: 835-40.
- Lando HA, Hellerstedt WL, Pirie PL, McGovern PG. Brief supportive telephone outreach as a recruitment and intervention strategy for smoking cessation. *Am J Public Health* 1992; 82: 41-6.
- Orleans TC, Schoenbach VJ, Wagner EH, Quade D, Salmon MA, Pearson DC, et al. Self-help quit smoking interventions: effects of self-help materials, social support instructions and telephone counseling. *J Consult Clin Psychol* 1991; 59: 439-48.
- Strecher VJ, Kreuter M, Den Boer DJ, Korbin S, Hospers JH, Skinner CS. The effects of computer-tailored smoking cessation messages in family practice settings. *J Fam Pract* 1994; 39: 262-70.
- Cepeda-Benito A. Meta-analytical review of the efficacy of nicotine chewing gum in smoking treatment programs. *J Consult Clin Psychol* 1993; 61: 822-30.
- Silagy C, Mant D, Fowler G, Lodge M. The effectiveness of nicotine replacement therapies in smoking cessation. *J Curr Clin Trials* 1994 January, document No 113.
- Silagy C, Mant D, Fowler G, Lodge M. Meta-analysis on efficacy of nicotine replacement therapies in smoking cessation. *Lancet* 1994; 343: 139-42.
- Ramstrom LM. Use of nicotine replacement therapy with and without prescription. In: *Future directions in nicotine replacement therapy*. Chester: Adis International, 1994: 28-34.
- Nemeth-Coslett R, Henningfield JE, O'Keefe MK, Griffiths RR. Nicotine gum: dose-related effects on cigarette smoking and subjective ratings. *Psychopharmacology* 1987; 92: 424-30.
- Foulds J, Stapleton J, Feyerabend C, Vesey C, Jarvis M, Russell MAH. Effects of transdermal nicotine patches on cigarette smoking: a double blind crossover study. *Psychopharmacology* 1992; 106: 421-7.
- Pickworth WB, Bunker EB, Henningfield JE. Transdermal nicotine: reduction of smoking with minimal abuse liability. *Psychopharmacology* 1994; 115: 9-14.
- Benowitz NL, Jacob P. Intravenous nicotine replacement suppresses nicotine intake from cigarette smoking. *J Pharmacol Exp Ther* 1990; 254: 1000-5.
- Bjornson-Benson W, Nides M, Dolce J, Rand C, Lindgren P, O'Hara P, et al. Nicotine gum use in the first year of the Lung Health Study. *Addict Behav* 1993; 18: 491-502.
- Benowitz NL, Hall SM, Herning RI, Jacob P, Jones RT, Osman AL. Smokers of low-yield cigarettes do not consume less nicotine. *N Engl J Med* 1983; 309: 139-42.
- Coulas DB, Stidley CA, Samet JM. Cigarette yields of tar and nicotine and markers of exposure to tobacco smoke. *Am Rev Respir Dis* 1993; 148: 435-40.
- Gori GB, Lynch CJ. Smoker intake from cigarettes in the 1-mg Federal Trade Commission tar class. *Regul Toxicol Pharmacol* 1983; 3: 110-20.
- US Department of Health and Human Services. *The health consequences of smoking: nicotine addiction. A report of the Surgeon General, 1988*. Rockville, Maryland, Public Health Service, Centers for Disease Control, Office on Smoking and Health, 1988. (DHHS Publication No (CDC) 88-8406.)
- Kozlowski LT, Rickert WS, Pope MA, Robinson JC, Frecker RC. Estimating the yield to smokers of tar, nicotine and carbon monoxide from the "lowest yield" ventilated filter-cigarettes. *Br J Addict* 1982; 77: 159-65.
- Kozlowski LT, Heatherton TF, Frecker RC, Holte HE. Self-selected blocking of vents on low-yield cigarettes. *Pharmacol Biochem Behav* 1989; 33: 815-9.
- Benowitz NL, Henningfield JE. Establishing a nicotine threshold for addiction. *N Engl J Med* 1994; 331: 123-5.
- Weinhold LL, Stitzer ML. Effects of puff number and puff spacing on carbon monoxide exposure from commercial brand cigarettes. *Pharmacol Biochem Behav* 1989; 33: 853-8.
- Benowitz NL, Jacob P, Yu L, Talcott R, Hall S, Jones RT. Reduced tar, nicotine and carbon monoxide exposure while smoking ultralow- but not low-yield cigarettes. *JAMA* 1986; 256: 241-6.
- Kozlowski LT. Evidence for limits on the acceptability of lowest-tar cigarettes. *Am J Public Health* 1989; 79: 198-9.
- Russell MAH. Realistic goals for smoking and health. A case for safer smoking. *Lancet* 1974; i: 254-8.
- Russell MAH. Low-tar medium-nicotine cigarettes: a new approach to safer smoking. *BMJ* 1976; ii: 1430-3.
- Bureau of National Affairs. SHRM-BNA Survey No 55: Smoking in the workplace, 1991. *Bulletin to Management*. BNA, 1991.
- Kinne S, Kristal AR, White E, Hunt J. Work-site smoking policies: their population impact in Washington state. *Am J Public Health* 1993; 83: 1031-3.

- 28 Stillman FA, Becker DM, Swank RT, Hantula D, Moses H, Glantz S, *et al.* Ending smoking at The Johns Hopkins medical institutions. *JAMA* 1990; **264**: 1565-9.
- 29 Borland R, Chapman S, Owen N, Hill D. Effects of workplace smoking bans on cigarette consumption. *Am J Public Health* 1990; **80**: 178-80.
- 30 Sorensen G, Rigotti N, Rosen A, Pinney J, Prible R. Effects of a worksite nonsmoking policy: evidence for increased cessation. *Am J Public Health* 1991; **81**: 202-4.
- 31 Becker DM, Conner HF, Waranch HR, Stillman F, Pennington L, Lees PSJ, *et al.* The impact of a total ban on smoking in The Johns Hopkins Children's Center. *JAMA* 1989; **262**: 799-802.
- 32 Brigham J, Gross J, Stitzer ML, Felch LJ. Effects of a restricted work-site smoking policy on employees who smoke. *Am J Public Health* 1994; **84**: 773-8.
- 33 Levinson, DN. Financing cessation services. In: *Smoking cessation: the organization, delivery, and financing of services*. Cambridge, MA: Institute for the study of smoking behavior and policy, 1990: 63-75.
- 34 Coalition on Smoking OR Health. *Saving lives and raising revenue: the case for major increases in state and federal tobacco taxes*. Washington, DC: Coalition on Smoking OR Health, February, 1995.
- 35 National Cancer Institute. *The impact of cigarette excise taxes on smoking among children and adults*. Summary report of a National Cancer Institute expert panel, August 1993.
- 36 MacKenzie TD, Bartecchi CE, Schrier RW. The human costs of tobacco use. *N Engl J Med* 1994; **330**: 975-80.
- 37 Lewit EM, Coate D. The potential for using excise taxes to reduce smoking. *J Health Econ* 1982; **1**: 121-45.
- 38 Wasserman J, Manning WG, Newhouse JP, Winkler JD. The effects of excise taxes and regulations on cigarette smoking. *J Health Econ* 1991; **10**: 43-64.
- 39 Sweanor DT, Martial LR, Dossetor JB. The Canadian tobacco tax experience: a case study. Report prepared for the Non-Smokers' Rights Association (Canada) and the Smoking and Health Action Foundation (Canada). Ottawa, Ontario. August, 1993.
- 40 Lewit EM, Coate D, Grossman M. The effects of government regulation on teenage smoking. *J Law Econ* 198; **24**: 545-69.
- 41 Townsend JL. Cigarette tax, economic welfare and social class patterns of smoking. *Appl Econ* 1987; **19**: 355-65.

Panel discussion

Moderator: Maxine L Stitzer

Panellists: Michael C Fiore, Ellen R Gritz, Michael Pertschuk

Michael C Fiore

I shall briefly summarise the process involved in preparing the *Smoking cessation and prevention clinical practice guideline*, sponsored by the US Agency for Health Care Policy and Research (AHCPR), including its rationale, process, intended audiences, implications, and schedule.

Effective clinical treatment of tobacco addiction is a necessary component of our overall national tobacco policy. While frequently stated, clinicians as well as health care managers and administrators have been reluctant participants in achieving this key goal. John Pinney summarised some of those data yesterday when he said that 70 % of smokers see a clinician every year, but up to half of them report they have never been asked and advised by their clinician to quit. In a survey of health care delivery systems and HMOs, only 65 % offered any coverage in their basic benefits package for smoking cessation and prevention. In contrast, virtually 100 % of them offered coverage for the outcomes of smoking, whether they be pulmonary disease, acute myocardial infarction, or cancer.

Both clinicians and health care administrators frequently cite two reasons for their lack of participation: first, they say that there are no known and effective treatments for smoking cessation; and secondly, there is no consensus on what is effective treatment. The rationale for the smoking cessation guideline, therefore, is to produce a consensus statement based on current knowledge, with specific recommendations on how to implement the guidelines.

The process includes a panel of about 25 individuals – experts in smoking cessation, clinical practitioners, and consumers. While sponsored by AHCPR, this is a non-government panel. We have been charged with systematically reviewing all of the data on smoking cessation – more than 3000 articles.

Virtually every article that has been published on clinical smoking cessation since 1975 has been reviewed.

We have done meta-analyses and used other strategies to determine which treatments are effective. The panel is using these data to make a recommendation on what is state-of-the-art treatment; in the absence of data, panel expert opinion will serve as the basis for recommendations.

We are now in the process of actually writing the guideline. It will be peer reviewed and then disseminated by AHCPR. It will be widely available to both clinicians and policy makers.

There will be three products from this process: a guideline of about 100 pages, quick reference guides for key audiences, and a patient guide to help those considering quitting.

There are three key audiences for the guideline and quick reference guides. The first is the primary care clinician. With this audience, our goal is to increase the number of smokers who receive a clinical cessation message. We hope to change the current status quo that allows smoking to be ignored with impunity in clinical practice and, instead, to put it more in the context of a serious medical condition. The second audience is clinical managers, managed care administrators, and insurance providers. These individuals have the capacity to institutionalise smoking assessment and intervention in every clinic in America. The third audience is smoking cessation experts, for whom we shall provide a synopsis of effective cessation treatments. It should be noted that the guideline will focus on cessation and not on primary prevention and is limited to clinical, not policy, interventions.

What, then, are some of the implications of producing a clinical practice guideline on smoking cessation? The first one is that we

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