- MA. Helping smokers quit: a role for health care providers. In: 1993 *Massachusetts tobacco survey*. Boston: Massachusetts Department of Public Health, 1994.
- 4 Orleans CT, Resch N, Noll E, Keintz MK, Rimer BK, Brown TV, *et al*. Use of transdermal nicotine in a state-level prescription plan for the elderly: A first look at real-world patch users. *JAMA* 1994; 271: 601–7.
- 5 Ockene J, Kristeller J, Goldberg R, Ockene IS, Merriam P, Barrett S. Smoking cessation and severity of disease: the Coronary Artery Smoking Intervention Study. *Health Psychol* 1992; 11: 119–26.
- 6 Ockene J, Benfari R, Hurwits I, Nuttall R, Ockene IS. Relationship of psychosocial factors to smoking behavior change in an intervention programme. *Prev Med* 1982; 11: 13–28.
- 7 Crooks C, Kenny E, Elder J, Levitz MD, Bril DG. Tobacco control of primary care physicians in California. *Evaluation and the Health Professions* 1993; 16: 311–21.

Financial implications

Kenneth E Warner

Evaluating the financial implications of alternative strategies for dealing with nicotine addiction is a more challenging assignment than one might initially infer. The difficulty lies not so much in projecting the financial implications of a specific strategy, but rather in trying to narrow the field of candidate strategies to a manageable and likely subset of a myriad of diverse possibilities. In contemplating my assignment, I concluded that it would be less useful, at this stage, to offer specific financial “guesstimates” on individual strategies than to provide a context for later financial analysis, reflecting the nature of the as-now elusive future.

As such, with one exception, I shall not present dollar estimates of financial implications. Rather, I shall examine the future context of dealing with nicotine addiction, beginning with goals and then focusing on means of achieving these goals. As will be obvious throughout this discussion, different goals, approached by different means, will have very different sets of financial implications, for very different organisations and individuals. I shall identify these diverse groups and contemplate a dimension of “financial implications” that may not have occurred to the typical reader, whether these implications are socially desirable or not. Finally, I shall turn to the one arena in which financial implications can be considered somewhat less abstractly: the cost-effectiveness of contemporary smoking cessation treatments and policies.

Goals

This conference has explored the full range of nicotine control objectives, everything from the traditional goal of “zero tolerance” to the contemporary interest in harm reduction. Indeed, an important message of the conference is that the tobacco control community is less certain today than a few years ago precisely what it is that we shall be trying to accomplish in the future. What should be the objective in dealing with nicotine addicted tobacco consumers? Should we strive to overcome addiction in all cases (the clear objective until recently)? Should we consider “harm reduction” as a desirable end point? Or, perhaps most realistically, what is the appropriate mix of cessation and harm reduction

and how do we chart the course to achieve the optimum mix?

More challenging is the task of determining what constitute appropriate harm reduction strategies. Does “harm reduction” consist exclusively of nicotine maintenance achieved through use of relatively low risk pharmaceutical products such as nicotine gum, patches, nasal sprays, and inhalants? Or does it include encouraging cigarette smokers to switch to using oral tobacco?¹ Can we envision a legitimate role for novel tobacco company products, such as Eclipse² and its predecessor, Premier?³ Are we content, at least for some smokers, to encourage the use of nicotine based pharmaceuticals even when these individuals will continue smoking, albeit less intensively?

Regardless of what we, as tobacco control professionals, might *like* to see happen (if indeed we can agree on a specific set of goals), we must recognise that we shall have only limited control over what actually *does* happen. Social and market forces ranging from government regulation to media portrayals of tobacco use, to tobacco (and possibly pharmaceutical) company advertising will shape consumers' future demand for tobacco products, for nicotine replacement products, and for other smoking cessation products and programmes. There is little doubt that the tobacco control community can and should influence these future demands; but there is also little doubt that we will not control them. Rather, we shall need to be prepared to work with them, however they develop. Different developments will imply different nicotine control strategies, with potentially radically different financial implications.

Means

If there are diverse and potentially conflicting goals, there is an even larger set of means to achieve the varied goals. The means adopted will define the context for a future evaluation of financial implications. Consider, for example, traditional approaches to cessation. These range from voluntary society self help manuals to “Cadillac care” nicotine replacement therapy with physician counselling and professional follow up. In between lie a myriad of treatment techniques and technologies involving behavioural modification,

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hypnosis, over-the-counter products, and so on. Obviously, these entail dramatically different costs, going to very different segments of the economy, and they produce significantly different quit rates. This is discussed later in this paper.

Public health interventions constitute a class of alternatives to the traditional client-provider interaction. Health oriented tobacco tax increases may do more to promote smoking cessation than all the formal cessation programmes combined. Laws or private policies restricting smoking in workplaces may promote cessation, although the magnitude of this effect is unknown to date. Other policy measures, including restrictions on tobacco product advertising and promotion, may also contribute to cessation.⁴ A traditional public health intervention – school health education – might be refocused in part from its usual emphasis on preventing the onset of nicotine addiction to assisting addicted teenage smokers to quit.⁵ I shall return later to the comparative advantages of individual cessation treatment and public health interventions.

If cessation constitutes the conventional goal, alternative visions of nicotine substitution or maintenance frame the harm reduction debate. In contemplating means of substituting for cigarette smoking less harmful methods of satisfying nicotine addictions, one can consider four possible scenarios:

- (1) As explained at this meeting, selected nicotine replacement products may become available on an over-the-counter (OTC) basis. This would be expected to increase the prevalence of an already existing phenomenon: former tobacco users who rely continually on nicotine based pharmaceutical products. These nicotine dependent individuals remain nicotine dependent, but the substitute presumably has less hazardous means of satisfying the dependency. OTC availability would also increase the likelihood that other nicotine dependent people, quite possibly in large numbers, might use these products when smoking is illegal or inconvenient for them (for example, at work or on aeroplanes), while continuing to smoke at other times (for example, while at home). Such individuals will not stop smoking, but they may reduce their exposure to toxic tars and carbon monoxide. In both instances, the harmful effects of tobacco products may be reduced, possibly considerably, but the nicotine addiction will be sustained, producing a stream of expenditures that may cease only upon the demise of the nicotine replacement products' consumers.
- (2) Pharmacological substitutes for nicotine may be developed. These would be true nicotine replacement products, substitutes for both tobacco products and nicotine based pharmaceuticals. As in the preceding case, a continual flow of expenditures might result from this method of dealing with nicotine dependence.
- (3) We also have the possibility of greater reliance on other existing tobacco products. For example, Rodu¹ argues that cigarette smokers who cannot successfully stop smoking

should be encouraged to substitute smokeless tobacco products for their cigarettes. He believes that the net adverse health consequences of nicotine dependence will be greatly reduced. In this variant on the substitution theme, a principal financial implication would be the shift in revenues from the cigarette manufacturers to the purveyors of smokeless tobacco products.

(4) The final variant on the substitution/harm reduction theme is the adoption of new cigarette-like products produced by the major cigarette manufacturers. Eclipse and its predecessor, Premier, represent technological innovations in nicotine delivery created by the tobacco industry with the apparent intent of satisfying smokers' cravings for nicotine, in lieu of their stopping smoking for fear of the health hazards. Each of these products, as well as others on the drawing board, is designed to deliver nicotine along with the behavioural aspects of smoking, while diminishing carcinogenic tar delivery. Far from healthful, these devices may possibly reduce health risks for consumers who otherwise would continue to smoke regular cigarettes.

A major financial implication of successful development and marketing of this class of products would be that the tobacco companies would continue to see the tens of billions of dollars of revenues to which they have become accustomed through cigarette sales. A qualitatively similar story relates to the transition from unfiltered to filtered cigarettes in the 1950s and 1960s, and the subsequent growth of low tar/low nicotine cigarettes in the 1970s and 1980s,⁶ although the net impact on health is debatable.⁴

Financial implications. For whom? For better or worse?

As the preceding discussion suggests, the financial implications of dealing with the toll of tobacco will depend centrally on the route or routes that we choose to take. Once again, it is imperative to appreciate that the "we" in this sentence refers to the broader society, swayed by a wide variety of social and marketing influences. The community of health professionals will constitute one of these influences, but there is no reason to think that they will be the pre-eminent factor.

Financial implications will be experienced by numerous sectors of the economy, regardless of the route taken. However, the specifics of society's approach will define the degree and even the direction of the financial impact experienced by each sector. Each of the following will be affected:

- (1) *Consumers* – In the absence of full insurance coverage of smoking cessation treatment, smokers will bear some share of the financial burden of quitting or of switching, partially or completely, to alternative products. Many of those who "kick the habit" will experience an indirect financial implication, involving a modified pattern of health care costs in future years resulting from their avoidance of tobacco related diseases. (Indeed,

those who avoid tobacco related diseases will experience a modified pattern of expenditures for virtually all goods and services.)

(2) *Governments* – The state and federal governments may be affected in three ways: (a) they may share in the direct cost of cessation treatment if, for example, Medicare and Medicaid decide to cover treatment services; (b) they may lose tobacco tax revenues if consumption of taxed tobacco products declines; and (c) they may experience a different pattern of future health care costs, attributable to decreasing smoking among the beneficiaries of government funded health care programmes. Note that the precise nature of this pattern is difficult to predict, dependent on the nature of the altered consumption behaviours (cessation, reduction in use of tobacco products, shift to less hazardous nicotine-only products, and so on) and on the resultant pattern of health and disease and associated use of medical services. Widespread cessation would be expected to reduce the financial burden on Medicaid programmes, for example. Less clear is the anticipated impact on Medicare: reduced smoking would relieve the substantial burden of smoking related diseases among senior citizens, but it would also help former-smoking seniors to live longer during their Medicare-eligible years.^{7,8} As with the impact on consumers, the indirect effects on governments could include shifting patterns of other financial liabilities. Most notably, any significant reduction in the incidence of tobacco related diseases would increase Social Security expenditures.⁹

(3) *Insurers* – Insurers will be affected to the extent that they choose (or are forced by regulations) to cover cessation treatments. In addition, as in the case of government agencies financing care, insurers would experience an altered mix of claims in future years. Although there is reason to believe that as a whole the insurance industry would incur fewer cost liabilities as cessation increased,⁷ there is also reason to expect that individual insurers might experience a net increase in expenditures associated with the cessation that they fund directly.¹⁰

(4) *Health care providers* – Physicians, nurses, health educators, and others stand to gain directly if interest in smoking cessation increases, either “spontaneously” or through expanded public or private insurance coverage. They would gain in the form of additional revenues for cessation services provided. Indirectly, the mix of health care expenditures in the future would change somewhat in response to widespread smoking cessation. Some medical specialties might be expected to benefit (geriatricians, for example), while others would be likely to lose (for example, oncologists).¹¹

(5) *Pharmaceutical companies* – A few pharmaceutical companies have already generated revenues through sale of nicotine “gum” and patches. The availability of additional nicotine replacement products would be expected to increase pharmaceutical industry revenues. OTC availability would probably increase

revenues, although it is conceivable that decreased unit price would outweigh increased volume of sales. Certainly, use of nicotine replacement products as ongoing complete or partial substitutes for tobacco products would increase industry earnings, possibly substantially. And, as with the preceding interest groups, the pharmaceutical industry would eventually experience a shift in the demand for drugs used during the additional years of life of former smokers who avoided smoking related illnesses.

(6) *Tobacco companies* – Tobacco companies’ fortunes will vary dramatically, depending on how society chooses to deal with nicotine addiction. A nationwide pattern of cessation of tobacco product use, without substitution of alternative industry produced products, would obviously greatly damage the tobacco companies’ bottom lines. Conversely, a shift in the direction of alternative industry produced products might sustain revenues and profitability, as has been the case with filtered and later low tar and nicotine cigarettes. At least one recommended approach to nicotine addiction, switching from cigarette smoking to oral tobacco use,¹ would redistribute revenues among the companies within the tobacco industry, away from the dominant cigarette companies.

Contemplating the two final parties identified above, the pharmaceutical and tobacco industries, one must recognise that a series of highly plausible developments could create a unique strange bedfellows situation. With the introduction of such products as Premier and Eclipse, the tobacco industry has already shown that it is desirous of capturing the market of smokers who might stop smoking in the absence of a less hazardous alternative to cigarettes. With selected nicotine replacement products already on the market and others in various stages of development, and with OTC availability of nicotine replacement products a distinct possibility, the pharmaceutical industry may find itself in the position of vying with the tobacco industry for the market of nicotine *maintainers*. That is, these two industries could go head-to-head competing for a potentially lucrative market of former cigarette smokers who choose not to forego nicotine. In effect, nicotine “replacement” products could become alternative nicotine *maintenance* products, competing with products like Eclipse to satisfy the nicotine cravings of millions of former cigarette smokers.

Members of the tobacco control community (and certainly the pharmaceutical industry) might find this an objectionable notion, at minimum an affront to the good citizens of the ethical drug companies. But pharmaceutical companies might well appeal to the harm reduction principle, arguing that nicotine maintainers’ health interests would be better served by (permanent) reliance on their nicotine-only products than on more “dirty” tobacco company products. (Eclipse is reported to have a low tar yield and a relatively normal yield of carbon monoxide.²) Furthermore, other things being equal, it is un-

deniable that a sustained revenue flow would be more desirable than the one time only revenue generated by products that successfully free smokers of their dependence on nicotine.

The increasingly "high tech" character of approaches to grappling with nicotine addiction, vividly illustrated by the new products of these two industries, strongly suggests that the financial implications of the smoking cessation/maintenance market will be substantial in the future, even if it is currently impossible to predict the ultimate winners and losers. But herein lies a critical observation: there *will* be winners as well as losers. We have a tendency, in the abstract, to consider any costs of smoking cessation as a social negative, a drain on society's resources. Although the costs are real, we must also recognise that one person's expenditures are another person's revenues. Financial implications are positive or negative, depending on where you sit.

However society chooses to respond to nicotine addiction, individuals and industries will emerge as economic winners, at the same time that others emerge as losers. Indeed, even if everyone spontaneously stopped smoking entirely without the aid of any cessation products or programmes, industries outside of the tobacco industry would benefit, as monies previously devoted to tobacco products would instead be spent on other goods and services.¹² In an ideal world (or perhaps I should say in *our* ideal world), the economic beneficiaries of the response to nicotine addiction would include the community of health educators, physicians and other medical personnel, and the pharmaceutical companies, all of whom would gain financially. The economic losers would be some combination of consumers, governments, and insurers, and of course the tobacco companies.

This leaves us with one essential observation concerning the distribution of costs and benefits. Although the financial implications are considerable, the ultimate balance sheet for the nation's approach to nicotine addiction must feature the non-monetary outcomes that drive interest in this subject in the first place: the health implications of tobacco use and of its control. These are the costs and benefits of greatest consequence.

Cost-effectiveness of smoking cessation treatments

The technique of cost-effectiveness analysis (CEA) marries an interest in the financial and the health implications of methods of dealing with nicotine addiction. Unlike the implications of an unpredictable future, we do know something about the cost-effectiveness of traditional methods of treating nicotine dependence in individuals. Thus, having devoted the lion's share of this paper to a conceptual discussion pertaining to the future, I conclude with a more tangible examination of knowledge gleaned to date from CEAs of smoking cessation techniques. This review will offer lessons relevant to the analysis of future interventions

Cost per year of life saved (approximate 1993 U.S. \$)^a

Smoking cessation	
Low intensity ^b	\$100–500
Brief advice, MD	\$1000–3000
High intensity ^c	\$6000–15000
Common disease prevention	\$1500–15000
Secondary and tertiary care	\$20000–100000

^a Author's estimates, based on review of published reports, updated to approximate 1993 US dollars.

^b Self help cessation guides; brief advice, non-physician; broadcast media campaign; etc.

^c Nicotine replacement as adjunct to office based physician counselling.

Source: reference 13

and to contemplation of the future environment for tobacco control more generally.

The table presents estimates of the cost per year of life saved, in 1993 dollars, for three categories of smoking cessation techniques and for other common preventive and secondary and tertiary health care measures. All of the numbers should be viewed as crude approximations, since they represent generalisations derived from a number of different studies.¹³ As such, the figures should be interpreted qualitatively, as indications of the relative orders of magnitude of the different health care interventions.

Among the three categories of smoking cessation techniques, the data indicate that low tech (or low intensity) techniques – including self help guides, brief advice from non-physician health professionals, and some public health interventions – save life years at a cost of from about \$100 to \$500. At the upper end of the intensity and cost spectrum, "Cadillac care," use of nicotine replacement treatment along with physician counselling and professional follow up, costs approximately \$6000 to \$15000 per year of life saved.

These are good health care buys, regardless of the level of intensity. Note that common disease prevention measures range from \$1500 to \$15000 per year of life saved, while secondary and tertiary care cost from \$20000 to \$100000 for each life year saved. The prevention and secondary and tertiary care categories represent widely accepted medical interventions that are performed regularly, and reimbursed regularly, without question.

Several lessons can be drawn from these comparisons. In general, public health interventions and the least intensive of the individual care techniques are likely to be the most cost-effective smoking cessation methods. They are also, however, the least effective in terms of the sustained quit rate within the exposed population.¹³ This should be interpreted as follows. If you take a given population of smokers, a public health intervention applied to that population will produce fewer quitters than more intensive provider-client approaches. However, if you consider the size of the population that can be reached with a given budget, it will be so much greater with the public health intervention that the intervention will produce more quitters, and a lower cost per quitter, than virtually all of the one-on-one techniques.

The same holds true among the standard

treatment interventions: handing out brochures to smokers is the least effective but the most cost-effective of the individual interventions, at least for the data that we have to this point.¹³ As one moves up the technology and complexity scale toward the high intensity interventions, one finds that effectiveness increases but cost rises even more rapidly. That explains why the cost-effectiveness is least for the sophisticated behavioural programmes mixed with nicotine replacement.

This does not mean that the high resource interventions are undesirable. For individuals who cannot stop with less intensive interventions, Cadillac care may constitute the only effective intervention and therefore the only cost-effective technique for dealing with nicotine addiction. More generally, compared to the other accepted medical interventions represented by the final two lines of the table, or considered more abstractly by asking how much we ought to be willing to pay to preserve a year of healthy life, the Cadillac care techniques appear to be very sound investments in better health. Who, for example, would not deem \$15000 a worthwhile expenditure to save a year of a patient's life?

The real financial question thus becomes how much we as a society, and smokers as individuals, are willing to devote to smoking cessation, or to harm reduction for that matter. If the resources are to be limited, we must think seriously about the relative cost-effectiveness of different interventions, in essence how we can maximise bang for the buck (or, more technically, how we can maximise the amount of smoking cessation for the limited resources available). A very constrained budget for smoking cessation should force serious consideration to devoting resources to broad scale public health measures, including campaigns to increase tobacco taxes, media campaigns to discourage smoking, and so on. In such a tight fiscal environment, somewhat less attention can be paid to the relatively high cost treatment of individual patients.¹⁴

If resources are to be more liberally available, as they should be when one considers the health and economic importance of tobacco use and of its cessation, one can then move more aggressively in the direction of getting more resource intensive treatments to individuals. Given the cost-effectiveness of even the high intensity smoking cessation interventions compared to other widely accepted medical interventions, any allocation of resources that does not permit both public health interventions and the full range of individual smoking cessation treatments is socially inefficient.

A concluding thought: resource availability and insurance coverage

Resource availability is a function not only of policy decisions to fund smoking cessation, either through public funding or requiring coverage by insurers; it is also a function of individual smokers' willingness to pay for value received in treatment. The tobacco

control community accepts as an article of faith that cessation treatment should be covered by health insurance. As I have pointed out elsewhere, however, if smokers believed that treatment worked, if they truly wanted to stop smoking, and if they had the resources to pay for treatment, the issue of coverage would be largely irrelevant.¹⁰

Aside from equity concerns for poor smokers, for whom self funded treatment might be unduly burdensome, it is difficult to find an unambiguously compelling reason for mandating insurance coverage. Two arguments are offered frequently: first, third party reimbursement would "nudge" smokers into treatment, an argument grounded in paternalism that must itself be justified; second, if health insurance covers so many procedures that are demonstrably less effective and less cost-effective than smoking cessation, it should not discriminate against smoking cessation.

I have considerable sympathy for the second argument, although it reminds me of the admonition that "two wrongs don't make a right". (True insurance is intended to provide protection against extremely costly, very low probability events that are not affected by the existence of the insurance; for most people, fire insurance on one's home is an example. Smoking cessation meets none of these criteria. Neither, however, do many medical services covered by health insurance.) Still, there is little doubt that preventive services, and specifically behavioural counselling, are judged against a more stringent standard than are other medical procedures. Whereas the latter are expected to be safe and effective, with attention to cost-effectiveness rare, counselling interventions must be shown to be safe, effective, and *cost-saving*. This is a standard that few procedures within medicine could meet today.

Regardless of how one feels about the legitimacy of mandating insurance coverage of smoking cessation treatment, an affirmative decision would probably change the nature of how society grapples with nicotine addiction. Such a decision might alter the amount of resources devoted to this issue; it would certainly alter the distribution of resources. Here, as with the more far reaching implications of harm reduction strategies involving pharmaceutical and tobacco industry nicotine maintenance products, the future promises a vigorous battle for a market of substantial proportions.

And what of harm reduction strategies? Acknowledgment of this alternative to cessation raises a myriad of challenging questions. If we believe that smoking cessation should be reimbursed by health insurance, should sustained, perhaps lifetime, use of nicotine replacement products be likewise reimbursed? The health benefit could be substantial (as could be the cost of "treatment"). In the extreme, this line of reasoning could lead to a rather remarkable, if seemingly absurd, conclusion. Perhaps it is best phrased as a question: If tobacco industry products like Eclipse ultimately demonstrably reduced ag-

gregate health risk, would tobacco control advocates support subsidies for their consumption?

1 Rodu B. An alternative approach to smoking control. *Am J Med Sci* 1994; 308: 32-4.
2 Another try for a low-smoke cigarette. *Newsweek* Dec 12, 1994: 69.
3 *Chemical and biological studies on new cigarette prototypes that heat instead of burn tobacco*. Winston-Salem, NC: RJ Reynolds Tobacco Co, 1988.
4 US Department of Health and Human Services. *Reducing the health consequences of smoking: 25 years of progress. A report of the Surgeon General*, 1989. Rockville, MD: Public Health Service, Centers for Disease Control, Office on Smoking and Health, 1989. (DHHS Publication No (CDC) 89-8411.)
5 US Department of Health and Human Services. *Preventing tobacco use among young people. A report of the Surgeon General*. Atlanta, Georgia: Public Health Service, Centers for Disease Control and Prevention, Office on

Smoking and Health, 1994. (US Government Printing Office No S/N 017-001-00491-0.)
6 Warner KE, Slade J. Low tar, high toll. *Am J Public Health* 1992; 82: 17-18.
7 Hodgson TA. Cigarette smoking and lifetime medical expenditures. *Milbank Q* 1992; 70: 81-125.
8 Pickett G, Bridgers WF. Prevention, declining mortality rates, and the cost of Medicare. *Am J Prev Med* 1987; 3: 76-80.
9 Shoven JB, Sundberg JO, Bunker JP. The Social Security cost of smoking. In: Wise DA, ed. *The economics of aging*. Chicago: University of Chicago Press, 1989.
10 Warner KE, Warner PA. Is an ounce of prevention worth a pound of cure? Disease prevention in health care reform. *J Ambul Care Mgt* 1993; 16(4): 38-49.
11 Warner KE. Health and economic implications of a tobacco-free society. *JAMA* 1987; 258: 2080-6.
12 Warner KE, Fulton GA. The economic implications of tobacco product sales in a nontobacco state. *JAMA* 1994; 271: 771-6.
13 Warner KE. Cost-effectiveness of nicotine replacement therapy. In: Fagerstrom KO, ed. *Future directions in nicotine replacement therapy*. Chester: Adis International, 1994: 35-40.
14 Chapman S. Stop smoking clinics: a case for their abandonment. *Lancet* 1985; i: 918-20.

Product implications

Charles W Gorodetzky

I shall begin with my conclusion: the major product implication of alternative treatment goals is the maintenance of flexibility. We need to develop a variety of pharmacotherapeutic options to allow individualised treatment, both for the particular smoker and for a particular treatment goal.

I refer to flexibility here over a number of different dimensions, which I refer to as corollaries of flexibility. The table shows these major areas of concern. The first and obviously most important of those corollaries of flexibility or dimensions of concern, is the pharmacotherapeutic agent, per se.

The figure shows cigarettes as well as the currently available, and perhaps soon to be available, nicotine replacement medications along a continuum of those that are the shortest acting and most rapid to reach their peak to those that are of longest duration and reach their peak the slowest. The first line indicates the dosage form; the second line shows the number of dosage units (cigarettes, sprays, pieces, systems) used per day; the third line is the approximate time to reach peak concentration; and the last line indicates approximate duration of significant plasma levels of nicotine.

Of course, there are also several other important variables along this continuum,

including the total administered dose, the degree of active patient participation, or the degree to which the medication is passive, as well as the side effect profile. Active participation by the patient is indicated to some degree by the frequency of administration. Those dosage forms on the left side of the continuum, requiring most frequent administration, involve the most active patient participation, while those requiring less frequent dosing, often referred to as passive medications, appear on the right side. Transdermal nicotine replacement, with only one daily dose, is currently the form requiring the least patient participation.

The total administered dose per unit is quite variable. Transdermal systems have 7, 14, and 21 mg available, while the gum provides 2 and 4 mg per piece. Nasal spray, as I understand, will be about 0.5 mg per spray per side,¹ (about 1 mg per administration), and the average amount of nicotine obtained from a cigarette is estimated to be about 1 mg.

Where are we going to go in the future here? What are we going to need? Although it is not totally clear at present, I propose that what we need is more products along this continuum. The continuum of nicotine replacement currently available, or soon to be available, goes roughly from the short acting nasal spray on the left to transdermal systems on the right. As referred by others, I think we are going to need some dosage form (or forms) even more rapid acting than the nasal spray. Perhaps we need something that begins to approach the rapid onset and short duration of the nicotine in the cigarette. Perhaps the low tar, high nicotine cigarette itself will be useful. Possibly it will be something on the order of a pure nicotine cigarette of some sort, and reference has been made to those as well.

Corollaries of flexibility

Pharmacotherapeutic options
Nicotine replacement
Non-nicotine products
Combination products
Dynamic clinical status
Research implications
Who is the treater?
Commercial implications

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