

relation indicating a reduction of risk when smoking lower yield cigarettes. Therefore, I am sceptical about lower yield cigarettes as a viable approach to nicotine reduction.

The last issue is whether a regulatory strategy to reduce the content of nicotine in cigarettes is safe. Henningfield and I proposed gradually reducing the content of nicotine in cigarettes in order to make cigarettes non-addictive.<sup>14</sup> Such a strategy, if it worked, would reduce the prevalence of cigarette smoking and substantially reduce harm. There are of course concerns about compensatory smoking of cigarettes during the weaning phase, which could result in periods with greater exposure to tar and carbon monoxide. The magnitude of this problem would need to be addressed as the strategy was implemented.

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- 1 Doll R, Peto R. Cigarette smoking and bronchial carcinoma: dose and time relationships among regular smokers and lifelong non-smokers. *J Epidemiol Community Health* 1978; **32**: 303-13.
- 2 Rosengren A, Wilhelmsen L, Wedel H. Coronary heart

- disease, cancer and mortality in male middle-aged light smokers. *J Intern Med* 1992; **231**: 357-62.
- 3 Wilhelmsen L. Coronary heart disease: epidemiology of smoking and intervention studies of smoking. *Am Heart J* 1988; **115**: 242-9.
- 4 Willett WC, Green A, Stampfer MJ, Speizer FE, Colditz GA, Rosner B, *et al*. Relative and absolute excess risks of coronary heart disease among women who smoke cigarettes. *N Engl J Med* 1987; **317**: 1303-9.
- 5 Benowitz NL, Jacob P III, Kozlowski LT, Yu L. Influence of smoking fewer cigarettes on exposure to tar, nicotine, and carbon monoxide. *N Engl J Med* 1986; **315**: 1310-3.
- 6 Benowitz NL. Nicotine and coronary heart disease. *Trends Cardiovasc Med* 1991; **1**: 315-21.
- 7 Holm H, Jarvis MJ, Russell MAH, Feyerabend C. Nicotine intake and dependence in Swedish snuff takers. *Psychopharmacology* 1992; **108**: 507-11.
- 8 Huhtasaari F, Asplund K, Lundberg V, Stegmayr B, Wester PO. Tobacco and myocardial infarction: is snuff less dangerous than cigarettes? *BMJ* 1992; **305**: 1252-6.
- 9 Wennmalm A, Benthin G, Granström EF, Persson L, Petersson A-S, Winell S. Relation between tobacco use and urinary excretion of thromboxane A<sub>2</sub> and prostacyclin metabolites in young men. *Circulation* 1991; **83**: 1698-704.
- 10 Benowitz NL, FitzGerald GA, Wilson M, Zhang Q. Nicotine effects on eicosanoid formation and hemostatic function: comparison of transdermal nicotine and cigarette smoking. *J Am Coll Cardiol* 1993; **22**: 1159-67.
- 11 Benowitz NL. Nicotine replacement therapy during pregnancy. *JAMA* 1991; **266**: 3174-7.
- 12 Benowitz NL, Kuyt F, Jacob P. Influence of nicotine on cardiovascular and hormonal effects of cigarette smoking. *Clin Pharmacol Ther* 1984; **36**: 74-81.
- 13 Benowitz NL, Jacob P III. Intravenous nicotine replacement suppresses nicotine intake from cigarette smoking. *J Pharmacol Exp Ther* 1990; **254**: 1000-5.
- 14 Benowitz NL, Henningfield JE. Establishing a nicotine threshold for addiction - the implications for tobacco regulation. *N Engl J Med* 1994; **331**: 123-5.

## Public health implications

Judith K Ockene

I am pleased to be wearing my public health hat. Sometimes I wear my clinician's hat, and the two overlap quite a bit. Those of us who see ourselves as public health practitioners believe that we have a responsibility for developing and delivering smoking intervention treatments and policies which decrease risk for as many people as possible. That is the bottom line when we consider public health approaches.

Earlier we heard that a major problem is lack of success in smoking cessation for the poorer, less educated smokers in our country; and that is the issue on which I shall focus most of my comments. Attention to public health requires that we attend to those individuals who are most in need of assistance for making changes and are most able to benefit from our efforts. From a public health perspective, I believe that we do not necessarily lack appropriate and adequate interventions. There are in fact interventions which are effective for all groups of smokers when delivered as intended.

The problems in the public health arena are lack of adequate ways of delivering interventions which are appropriate and acceptable to the providers and consumers who need them, and lack of adequate access to treatment. The latter includes lack of adequate methods of delivery. Improved methods of delivery improve access.

An optimal public health approach could improve delivery of services and access for all

consumers. This approach includes five components: the first component, education for the smokers and providers about smoking treatment, is the most important aspect of public health. Education must be delivered in a form or mode which is acceptable to the target population. For example, for a low income adolescent inner city population, it is important for education and other interventions to be delivered in places where inner city youth gather, and the messages need to be in a form that they can hear. For example, Dr Vic Streicher told me about a wonderful rap group which he heard which put antismoking messages into their music. Another example is the media campaign in Massachusetts which has developed targeted educational messages directed at particular populations such as teenagers to grab their attention.

The second component, development of social norms and an environment that supports change, is necessary since individual change (for smokers and health care providers) does not occur in a vacuum.

The third component, coordination and integration of services and efforts in multiple community channels, which include worksites, health care settings, media and voluntary organisations, allows services and programmes to optimise each other.

The fourth component, the creation of infrastructures, allows for and facilitates the delivery of messages and services for health

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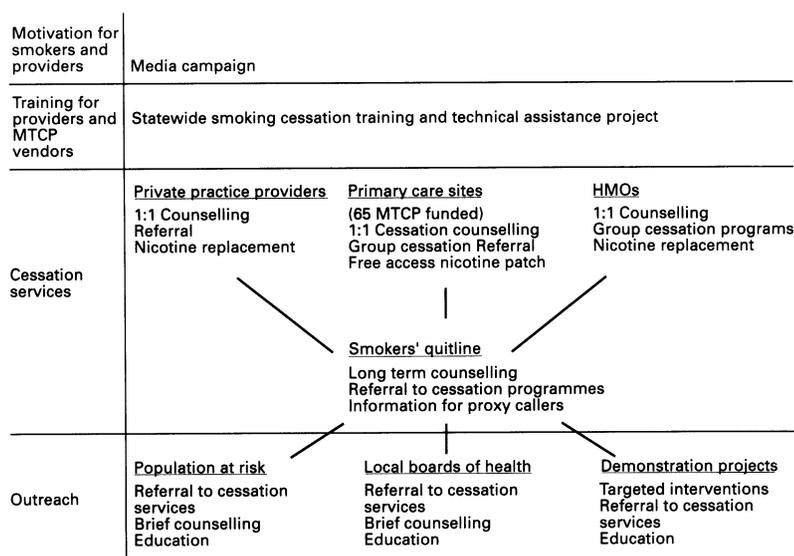


Figure 1 Massachusetts Tobacco Control Program: comprehensive cessation plan

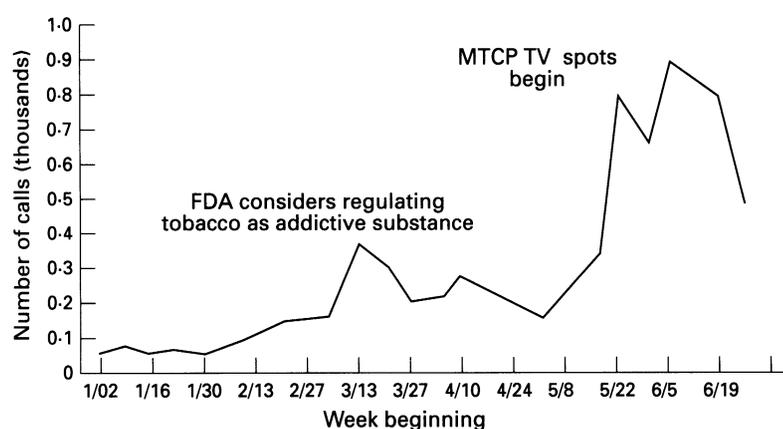


Figure 2 ACS Smokers' Quitline, 1/94-6/94. Number of calls received by week, Massachusetts Tobacco Control Program

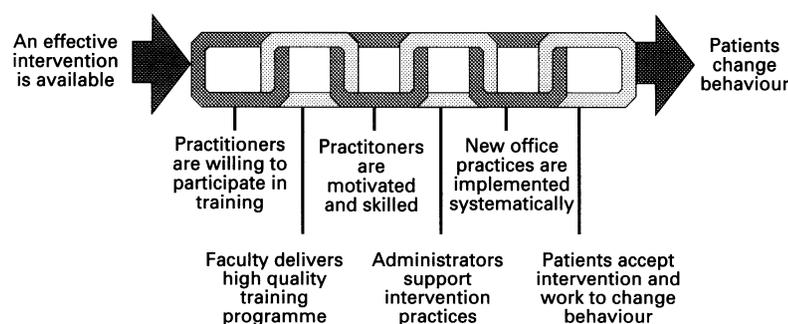


Figure 3 A chain of events which enables health professionals to help patients make behavioural changes

care providers and smokers that can have an effect on smokers. This component is often missing and requires resources which often are not available. Without the infrastructure, even when there are effective interventions, they are not or cannot be implemented. For example, we had an experience in Massachusetts – and Dr Ron Davis has told of a similar experience in Michigan – where free nicotine patches were made available by a pharmaceutical company, but there was no available infrastructure to facilitate their delivery to individuals who could use them.

One of the questions we need to ask is, how can we provide an infrastructure? It is very difficult to develop one if there are no economic or personnel resources available in the clinics. Earmarking tobacco tax is one way of doing it. My own state, Massachusetts, has a very good programme where the recent increase in the tobacco excise tax, for which several groups, especially the American Cancer Society, worked very hard, has been earmarked for the Massachusetts tobacco control programme (MTCP). Last year, over \$90 million was made available to the MTCP to help reduce smoking in Massachusetts. Part of these funds was used to help with the development of the needed infrastructure in public health settings. This year, over \$60 million from the tobacco tax was allocated to MTCP; again part of it helps to provide for infrastructure and services in community health centres. Dr Ron Davis informed me that in Michigan the tobacco excise tax also is being used for smoking intervention programmes and we know that it is happening in California.

In Massachusetts we developed what I think is a very complete and comprehensive plan and infrastructure, where on one level we have an extensive media campaign, on another level, training about cessation services and interventions for health care providers and staff in other kinds of settings, on a third level, services that are provided through the community health centres, and on another level, outreach services such as a quit line (figure 1). The individuals working on each of these levels meet in a “cluster meeting” to facilitate integration of the different activities. We have also developed several common themes for messages on which we all focus our efforts. The smoking cessation services are co-ordinated through the Massachusetts Department of Public Health under Dr Gregory Connolly. Another important player who has been working hard to coordinate the cessation services has been Dr Jeannine Muldoon.

One of the questions for which more research is required is, what are the outcomes when services are integrated? Do they actually optimise or synergise each other? There are data to indicate that they certainly influence each other. One good example of such synergy is shown by some data on the use of the Massachusetts quitline gathered by ABT Associates in Cambridge, MA. The quitline was started in January of 1994. We can see from figure 2 that there was very little usage initially. When the US Food and Drug Administration (FDA) indicated that it was considering the regulation of tobacco as an addictive substance, quitline usage increased, and then, when the media campaign began on television, the figure shows that use of quitline services increased again. This impact of media on the quitline demonstrates that coordination of interventions can have a substantial effect.

The fifth component of an optimal public health model, provision of incentives for high quality delivery of interventions to a large number of people, especially smokers of lower economic status, includes regulations

The COMMIT trial-wide smoking cessation outcomes for ages 25–64 years :  
light/moderate smoker cohort

	Intervention		Comparison		Difference (% quit)	p value
	n	% quit	n	% quit		
No college	1332	30.2	1443	24.3	5.5	0.007
Some college	1975	30.9	1889	30.6	0.4	0.33

Data sources: 1988 COMMIT baseline prevalence survey; 1993 COMMIT endpoint cohort survey.

mandating services and standards of performance such as in HMOs, and HCFA for quality standards. If you know you won't get paid unless you deliver a certain standard of care, you'll deliver it. Even though there have been guidelines, no teeth have been put into them. In other words, there is no way to enforce them. They are not standards of practice. For guidelines to have an effect they must be enforceable. If there are no incentives to deliver services and there is no infrastructure in which they can be delivered, then we can have all of the interventions known, but they are not going to work because they will not be delivered.

In figure 3 I show pictorially that all of the links or events need to be connected in a chain before an effective intervention (at one end of the chain) actually gets delivered to the patient (at the other end of the chain). Dr Elisabeth Lindsay developed this chain which I took the liberty to build on.<sup>1</sup> This particular chain addresses the events that need to happen for health care providers to intervene with smokers. This is a complex process and breakdown at any step will compromise the overall effect on patient outcomes. Training is needed, providers need to be motivated, an infrastructure needs to exist in order to make intervention happen, and eventually, these services need to be delivered to the smoker, and the smoker needs to be ready to receive them.

For an optimal structure for public health care delivery we need to include chains for each of the community sectors, which themselves eventually need to be connected. Therefore, the chain for health care providers should optimally be connected to chains for worksites, the media, schools, and voluntary organisations. These services can work together and synergise each other.

In a previous paper (p. S3) Dr Orleans described the COMMIT study results reported in the scientific literature.<sup>2</sup> As I noted this morning, there are some other results that we need to be mindful of as well, particularly that for the light and moderate smokers the greatest effect is in those individuals with a high school education or less. For this group of smokers we see a 5.5 percentage point difference in cessation between the intervention and comparison conditions (table). This is certainly an outcome that should encourage us and make us enthusiastic about building on it.

The COMMIT study was an excellent example of the first three components of a public health approach, providing information and education, developing social norms and an environment that supports change, and co-

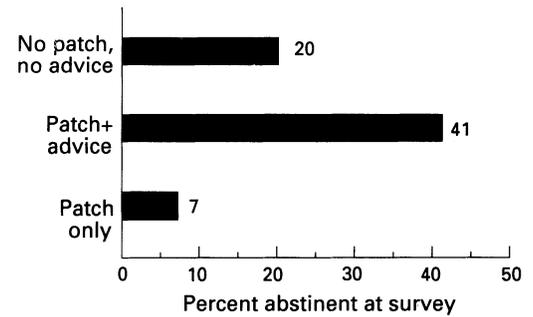


Figure 4 Massachusetts Tobacco Survey, 1993. Physician advice, nicotine patch use, and cessation for heavy smokers (n = 269)

ordinating services. However, it did not have the resources necessary, nor was it intended to have them, to provide an infrastructure through which services could be delivered, for example, in community health centres. In addition, it did not have the mandate nor was it able to develop policies or regulations that would demand that interventions occur; that was not part of the COMMIT model. Therefore these two important components, infrastructure and regulations, should be used to build on the COMMIT results.

With regard to improving access to treatment for all smokers, in addition to the need for the presence of the noted components of an optimal public health approach, I think there also needs to be coverage for services and pharmacological aides, especially for low income smokers. Data provided to Dr Michael Cummings by the manufacturers of Nicoderm®, which are applicable to any of the nicotine replacement treatments, indicate that as of March 1995, 28 states did not reimburse for nicotine replacement treatments through Medicaid. Only 22 states did reimburse. I recall that Dr Ron Davis presented data two years ago at this conference indicating that 25 states were reimbursing. So either we have wrong figures or there has been no change in the reimbursement through Medicaid.

Another way of improving access is by making treatments easily and quickly available, such as by making products available over the counter (OTC) or by using telephone counselling as a good outreach. I am hesitant about the issue of making nicotine replacement treatments OTC. The data are not yet sufficient to make a reasoned decision. The reason for my conflict is that there are data to support the idea that the more health care providers intervene with smokers who are using nicotine replacement therapy, the more likely it is that this intervention will be effective. There are no randomised studies to provide information, but there are some observational studies such as one using data from the Massachusetts tobacco survey.<sup>3</sup> In this study a telephone interview was conducted with former heavy smokers. They were asked, among other things, whether they had received a prescription for a nicotine patch and advice regarding smoking from their physician. From figure 4 it can be seen that those smokers who had received both the patch and advice were

about six times more likely to report having stopped smoking than those who only received the patch. It is important to note that these are self reported retrospective data and therefore they have limitations.

There are other data that provide support for the statement that the more intervention is available from health care providers about the use of nicotine replacement therapy, the more likely it is that these products will be effective. However, this does not mean that making them available OTC will not increase access. My concern is that while it increases access it may decrease efficacy. From a public health perspective, important questions are does having nicotine replacement therapy OTC decrease efficacy, and will increased access but decreased efficacy improve the public health impact? I hope that perhaps our Canadian colleagues can provide some answers since nicotine containing gum has gone OTC in Canada.

From the PACE study,<sup>4</sup> it could be shown that when respondents received advice from their physician or their pharmacist – and pharmacists are a very important channel for delivery of smoking interventions – they were more likely to use the product than were those respondents who did not report receiving advice.

Another area for improving access is outreach. Dr Orleans informed us in her presentation (p. S3) that there are telephone counselling studies with very good outcomes. We did one such study at the University of Massachusetts Medical School, the CASIS study, which included patients who had coronary artery disease.<sup>5</sup> We showed a significant difference in cessation rates for individuals who received telephone counselling compared to those who did not receive such counselling. It is important to note that there are also several studies which do not support telephone counselling as a method to improve outcomes. Telephone counselling should be pursued as part of our aim of improving access for lower income smokers.

In summary, from a public health perspective there are effective smoking cessation interventions available which have by no means been given an adequate test. Given an optimal public health approach, with improved delivery and access, we are likely to see improved outcomes. However, we do not yet have definitive data. We need to look at what happens when you do provide an optimal public health approach, including education, integration of services, a facilitative environment, an adequate infrastructure to deliver appropriate services, and incentives to deliver them. Are lower income, less educated individuals able to have improved access and when they do have improved access do they stop smoking?

Another question I was asked to respond to is, what are the public health implications of a harm reduction model? First, there are two studies that I want to point out. One is a study that I did with the multiple risk factor intervention trial (MRFIT) data, looking at

individuals who stopped smoking and maintained cessation for two years<sup>6</sup>; what I called “continuing stoppers”. I compared them to recidivists, that is, smokers who had stopped smoking initially and returned to smoking at some time within the two year follow up period. The continuing stoppers and the recidivists had been, at the time in the past when they were smoking at their heaviest, smoking the same number of cigarettes (38 and 40 cigarettes per day, respectively, at their heaviest consumption). The difference between the two groups was that the individuals who were eventually successful long term had made much larger changes in the natural history of their smoking between the time they were smoking at their heaviest and the time they entered the study than those who were not successful long term (two years). The continuing stoppers had decreased by about 10 cigarettes a day, while the recidivists had decreased by only about four cigarettes a day. So if we look at the natural history of change we find that, indeed, individuals gradually reduce their cigarettes before they are eventually successful at stopping. Pierce also showed that individuals who are eventually successful quitters are individuals who actually have decreased their number of cigarettes over a period of time.<sup>7</sup> I think that the natural history of cessation provides us with much valuable information as we ponder harm reduction as an alternative outcome.

Regarding some of the philosophical concerns that we hear about harm reduction, that it is a surrender in the fight against drugs and that it sends the wrong message, I do not think that we necessarily need to look at it as a surrender. It does not need to be an either/or approach. From a public health perspective, we need to consider what is the best approach for the many smokers who may not be able to stop smoking completely. To ignore harm reduction is a way of blaming the victim. It also denies the existence of a large segment of our smoking population who may eventually be successful long term, but may not be able to stop smoking in the present.

In summary, as we formulate a public health strategy, we need to consider that there are some smokers who cannot stop smoking; that a comprehensive plan using a public health approach is needed to accommodate the diversity of smokers; that access to treatment is needed for all smokers; that the method of delivery needs to be acceptable to the target population; and that the best way of totally alleviating smoking problems is to prevent the onset of smoking or to reduce the likelihood of addiction to tobacco by our youth.

1 Linsday E, Hymowitz N, Mecklenburg R, Churchill L, Poland B. Activities to promote health care providers as participants in community-based tobacco control. In: *National Cancer Institute STCP monograph: community-based interventions for smokers: The COMMIT field experience* (in press).

2 COMMIT. Community Intervention Trial for Smoking Cessation (COMMIT): cohort results from a four-year community intervention. *Am J Public Health* 1995; **84**: 183–92.

3 Ockene J, Hebert J, Hurley T, Biener L, Fowley J, Roman

- 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, Brill 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?<sup>1</sup> Can we envision a legitimate role for novel tobacco company products, such as Eclipse<sup>2</sup> and its predecessor, Premier?<sup>3</sup> 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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