SESSION II TREATMENT ISSUES

Introduction

Maxine Stitzer

Our second panel this morning is going to have the opportunity to consider some of the aspects of comprehensive smoking cessation treatment. We've come a long way in developing a consensus about what some of the elements of comprehensive treatment are for smoking cessation, and we have this excellent opportunity to spend a couple of hours this morning considering the behavioural and counselling components of smoking cessation treatment.

Here are some of the specific questions this session will address: Why are behavioural and counselling treatments important as part of a comprehensive approach to smoking cessation? What are the contents and format of the currently available treatments? What are the characteristics of the smokers that we're trying to reach with these treatments? And how can we achieve the optimal cost-effective match between smokers and treatments?

Let me introduce the panellists. First we have Dr Richard Clayton, Director and Scientific Director of the Center for Prevention Research at the University of Kentucky. Dr Clayton is probably best known for his prevention research activities. Carole Hudgings is a Senior Health Policy Analyst in the Agency for Health Care Policy and Research. We're really pleased to have Carole here today because she's involved with the Agency in developing practice guidelines, and they have just started addressing guidelines for smoking cessation programmes.

Judith Ockene is Professor of Medicine and

Director of the Division of Preventive and Behavioural Medicine at the University of Massachusetts Medical School. Dr Ockene is best known for her professional activities in the area of physician interventions.

Finally, Dr Tracy Orleans is currently Clinical Assistant Professor in the Department of Psychiatry at the University of Pennsylvania Medical School and Director of Tobacco Control Research, Division of Cancer Control, at the Fox Chase Cancer Center. She's also known for her efforts in the development of self-help, minimal contact smoking cessation interventions, and also particularly with special populations.

And now I'd like to introduce the speaker, Dr David Abrams. Dr Abrams is Professor in the Department of Psychiatry and Human Behavior at Brown University School of Medicine, and he's also Director of the Division of Behavioral Medicine at the Miriam Hospital and Co-director of the Cancer Prevention and Control Program at Brown University, Roger Williams Comprehensive Cancer Research Center. Dr Abrams is a nationally recognised researcher in addictive behaviours and chronic disease prevention who has contributed much to our understanding of substance abuse treatment, both empirically and conceptually. I'm particularly pleased that he will be making the presentation this morning that will set the stage for our discussion of the behavioural therapy components of smoking cessation treatment.

Treatment issues: towards a stepped-care model*

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Introduction

The winds of change in health care in the US place us on the edge of a decade of opportunity to make a difference in prevention of chronic diseases related to lifestyle. The philosophy that prevention be fully integrated into mainstream health care practice is central to these winds of change. We must ensure the optimisation of health care practice in terms of quality of life, quality of services, access, and cost for all citizens. This presentation focuses on the essential elements to be considered in making

wise choices about comprehensive treatment of tobacco dependence. My goals for this presentation are threefold: First, I will highlight general conceptual principles. Second, I will provide specific recommendations for optimal treatment of tobacco dependence using a stepped-care approach. Third, I conclude with an exploration of selected concerns about barriers to treatment implementation, service delivery, and to standards of care and cost-effectiveness.

Key conceptual considerations

Even in this age of high technology communications, there's a natural insularity among disciplines. Insularity in three broad domains has slowed progress toward a comprehensive approach to the treatment of all smokers in the population. The domains are the biological, clinical, and public health sciences. In the biological domain, genetic, biobehavioural science, and neurochemistry research is conducted. Concepts include genetic vulnerability and the key neuroregulatory adaptive mechanisms in tobacco dependence.^{1,2} In the clinical domain, many treatment programmes and relapse prevention techniques are researched.^{3,4} They range from nicotine replacement to behaviour modification to hypnosis.^{5,6} In the public health arena are the more macro-domains of public policy, organisational systems, epidemiology, economics, and health communications/education.^{7,8} We have to integrate key concepts from all three areas to do justice to a comprehensive treatment approach.^{9,10} Otherwise, important factors for optimal treatments can slip through the cracks, and we fall into either/or kinds of situations. Examples include self-help *versus* clinic treatment and nicotine replacement *versus* behaviour therapy. The specific challenge is to integrate individual (clinical) and population (public health) perspectives.^{9,10,11}

A simple way to conceptualise this integration is in a two-dimensional matrix⁹ along the dimensions of *social structure* and *intervention intensity*¹⁰ (see table 1). Specifically, the different levels of social structure range from individual biobehavioural factors (such as degree of nicotine dependence) to the proximal social network (of close family and friends), to the more distal social and physical environment (workplace, schools), and on through to the community and societal factors (sociodemographics, policy, taxation).⁸

A number of related elements comprise the dimension of treatment intensity. These include: intervention goals, treatment complexity, costs, modes of delivery, and ease of dissemination. There are three key intervention objectives: (1) marketing and promotion to *increase motivation* to change; (2) the provision of *coping skills training* to help smokers who are ready to quit; and (3) sustaining the change – *maintenance* and *relapse prevention* (at the individual level) and *institutionalisation* into social norms and policies (at the societal level). Ideally, the core essential elements in treatment efficacy, should be in all treatment programmes at all levels of

intensity and cost.^{12–16} Questions about what types of treatments, levels of intensity, modes of delivery and costs can then be overlaid on these three essential elements.¹⁷

Conceptual integration: individual and population factors

Although many biobehavioural, sociodemographic and other parameters are important for tailoring interventions, in the final analysis they operate on the dimensions of degree of motivation and opportunity for access to care. A key construct for understanding motivation is the Stage of Change Model published by Prochaska and co-workers.^{18,19} The five stages that a smoker goes through in his/her odyssey towards cessation are *pre-contemplation*, *contemplation*, *preparation*, *action*, and *maintenance* (see figure 1). If unsuccessful, the smoker relapses but can recycle to an earlier stage to try to quit again in the future.

There are some key questions for treatment planning that emerge from the stage model (see table 2): How long does it take to move through each stage? It may take three to ten years for a precontemplator to move into the action phase where he/she is ready to take advantage of any kind of treatment. Other questions include: How does each stage interact with other smoker individual differences (eg, sociodemographics, cultural norms, degree of dependence) and with treatment components (such as self-help versus clinic)? For example, over 50 % of smokers will relapse within three months to a year of quitting in formal treatment clinics and between 80 to 95 % will relapse with self-help or brief interventions. Should individuals who relapse be recycled to the same treatment or should something be added to their treatment during their next attempt to quit (eg, nicotine replacement)? How does one use the answers to these kinds of questions at both the population and individual levels to inform policy regarding cost-effective treatment delivery over time?

The main conceptual points to make regarding stage are, first, that there are different processes used to move smokers through the stages. The skills needed to resist temptations after cessation are different from those processes needed to prepare for quitting. Second, if one delivers action-oriented treatments (self-help, nicotine replacement or behaviour modification) to smokers in precontemplation in the general population, then less than 10–20 % will be receptive to the treatment. The vast majority of smokers, over 80 %, are in the pre-action stages (see table 2).^{20–22} Thus, when we integrate the individual level and the population or public health level, the treatment goal is to *accelerate* stage movement to action prior to providing any action-oriented treatment. This acceleration involves two concepts: (a) moving people faster from pre-contemplation to action; and (b) trying to reduce the high relapse rates and/or encouraging more rapid recycling after a quit attempt, ie, back into preparation/action rather than into precon-

Table 1 Individual/public health conceptual model

Levels of social structure	Intervention intensity		
	Promotion	Skills training	Maintenance
Individual	contemplation	action	maintenance
Social network			
Organisational	laggards	later adopters	early adopters
Community	unfreezing	flux	refreezing
Societal	old norms	shifting norms	new norms

Figure 1 Transtheoretical stages of change model and domains for integration

Table 2 Stages and motivation cycles

Stage name	% population smokers	Time in stage	Time to change
immotive	? < 5	since onset	??
precontemplation	35+	since onset	3–10 yr
contemplation	30+	6 mo – > 2 yr	1–2 yr
preparation	10+	30 days	? > 30%/yr
action	10–	quit–6 mo	30%/yr
fail 24 h quit	15–70		
relapse < 14 days	30		
< 3 months	30–80		
< 1 year	50–95		
< 5 yrs	60–98		
maintenance	10+		
termination	not applicable		

templation or contemplation.^{9,10,23} Those are the two bottom-line objectives for maximising treatment efficacy at a public health level.

The related concept of public health impact follows from this analysis.²⁴ Let's assume that an average treatment programme has 40% efficacy, but it can reach only 10% of smokers per year. The overall public health impact would be quite low (4%). By contrast, a self-help treatment could be widely disseminated to whole populations, but it has lower efficacy. Thus, less costly self-help or more costly clinic treatments would have similar public health impact and cost-effectiveness. An ideal treatment strategy should combine the ability to proactively reach and motivate as many smokers as possible followed with treatments that have high efficacy for cessation. The bottom line is that a treatment strategy must be broadly disseminable *and* reasonably effective in order to make a cost-effective public health impact (see figure 2).

Another related point emerges from this stage analysis, that is, the importance of how we measure early treatment effects.²⁴ We

should look at intermediate outcomes and short-term behaviour changes, such as whether we are changing the precontemplator smokers' cognitions.^{25,26} An outcome measure like the decisional balance scale – pros and cons – is important at a population level.^{25,26} Measures of change need to be more sensitive to early movement through the stages rather than be based on the traditional metric of treatment outcome such as 7-day or 12-month continuous abstinence.²⁴ If we do not see smoking cessation as a long process of change, then the consequence for health policy decision-making might be to conclude falsely that an intervention was not working. The time frame for evaluation of change also needs to be adjusted from 1 year or less to several years or more (ideally 5–10).

As I mentioned earlier, the other important, indeed crucial, dimension that feeds into the stages of motivation theory is access to care and sociocultural factors. If motivational stage is the 'final common pathway' that leads to action, then the factors that correlate with lower motivation, such as education, age, income and special and underserved populations, must be targeted. We need to develop specially tailored programmes for defined populations based on age, gender, education, as well as on culture and on other factors such as associated medical illness, pregnancy, hospital patients, and so forth. This is essential to fully maximise the stage of change model at a public health level. There is research evidence that programmes which are specifically tailored to the defined population (ie, culturally sensitive, addressing the concerns of the pregnant or elderly smoker, or cancer or post myocardial infarction patient) will be more likely to accelerate and sustain higher quit rates.^{10,25–33}

Treatment factors: intensity

Besides stages of change, sociodemographics, special populations and cultural factors, there are other key concepts about smokers that are crucial for treatment optimisation. These concepts include degree of nicotine dependence, psychological vulnerability to relapse, and medical and psychological co-morbidity (mood disorders, substance abuse).^{1,9,10,34-46} Although scientists disagree over the specifics of many of these factors, I think there is consensus about the concept of a continuum of 'difficulty with quitting'.⁴⁷ We can define this *vulnerability* as a multivariate construct incorporating physical dependence, withdrawal severity, psychological vulnerability, social supports, and family and lifetime personal history of comorbidity. At the two extremes of the vulnerability continuum, the smoker's degree of vulnerability makes a difference in treatment efficacy and type of treatment programme (eg, self-help alone versus a clinic programme with nicotine replacement). Cohen *et al.*'s data suggest, for example, that light smokers are 2.1 times more likely to quit with self-help than heavy smokers.⁴⁸ Conversely, heavy smokers have significantly superior outcomes with formal behaviour modification clinics and pharmacological adjuncts, such as nicotine polacrilex.^{34,35,49} That's important in terms of a potential for matching smokers to cost-effective treatments. I believe some form of patient-treatment matching should be considered in any comprehensive stepped-care or other approach.

The problem lies with the large 'grey' area between the two extremes of smoker vulnerability (see figure 2). It's tempting to propose a 'middle-of-the-road' standard treatment for these 'middle-of-the-road' smokers. Since they are in the majority, one could argue for a single, moderate treatment programme (with or without nicotine replacement) as the best single treatment recommendation. The less vulnerable smokers will benefit from a moderate intensity treatment (even if they don't really need such an intensive or costly programme). The heaviest smokers, who are most vulnerable (highly dependent, with comorbidity), are a subgroup who will admittedly not receive optimal care. The fact that such high-risk smokers will not receive adequate care is of concern, since they are likely to use a disproportionate amount of health care dollars, tend to be less healthy overall, and are likely to be lower in income, education and have inferior or no health insurance for prevention. They are also more difficult to reach, come from underserved populations, and have inadequate access and resources necessary to take advantage of preventive health services. They are also less motivated to change their lifestyles than their less heavy smoking counterparts.²¹

This concludes the identification of some key principles derived from a conceptual analysis. These principles will help us make cut-off points and decisions about levels of clinical care and their likely reach, efficacy and cost in terms of equitable and optimal treatment for the smoking population as a whole.

This kind of analysis presents a dilemma for those who must determine policy in a just society. Generally, more intensive, more costly treatments work better with all types of smokers. The key question we must ask is: How can we reach the most people, especially the underserved and most vulnerable, within a finite budget in the most effective way? The issues of quality, cost, access and penetration are at the core of the rationale for a treatment policy.

As one reads from the top to the bottom of figure 2, smokers become more difficult to reach and treat. They are increasingly from underserved groups, lower in motivation, education and income, and have limited access to health care. They are probably also more nicotine dependent. Many will probably have other risk factors that are disproportionately associated with smoking, such as co-morbid medical, psychiatric, or substance abuse disorders, poorer diets and sedentary lifestyles. The heavy smoker who is alcoholic, sedentary and has a poor diet is at greater risk and is a larger burden on the health care system.

Rationale for cost-effective stepped-care treatment

Not only is there insularity between individual and public health sciences,⁹ there is also insularity due to a single risk factor approach (alcohol or smoking or diet) and due to a narrow (specialised) chronic disease-specific focus in the US health care system (cancer, heart disease, pulmonary disease, etc). The system makes it difficult to coordinate care for the most vulnerable smoker. Co-morbidity of substance abuse, of mood disorder, or other chronic illnesses can all increase the risk for premature death and chronic disability in the smoker.³ Smokers use 14% more health care costs than non-smokers.¹² Over 85% of alcoholics also smoke.^{6,31,39,44,45,50} The combined users costs of alcohol abuse and tobacco exceed \$140 billion annually in the US.³ Eventually we will have to reach and help treat those smokers with other clusters of health and psychological complications. The sooner they are treated the better from quality of life, longevity and cost perspectives.

Thus, in terms of the smoker individual-population dimensions, I believe in rough terms (see figure 3), that as the smoker vulnerability continuum goes from low to high, the population characteristics go from high socioeconomic status (SES) to lower SES, that individuals vary from less vulnerable to more vulnerable, that access goes from easy to more difficult, and that ideal treatment options range from inexpensive self-change/self-help (ie, less intensive and easier to disseminate) to more costly, intensive and more difficult to disseminate (see figure 4).

Here I want to make a related point about selection of treatment options. I think we've underemphasised the consequences of smokers failing to quit repeatedly. Failure may be more iatrogenic than we previously thought from a long-term population-change perspective. The

Figure 2 Treatment continuum versus smoker vulnerability

research evidence shows that within the highly selected clinical samples, numerous quit attempts either don't predict future behaviour or may predict success. It is commonly believed that the more one learns the better one gets the next time.²³ In general I concur. But is this true, for example, for people with ten or more failed quit attempts over many years in the general population, as well as in biased clinical samples of convenience? Do some smokers indeed get so discouraged that they give up trying altogether? Perhaps we need more research on this question using longitudinal, representative community samples.

To summarise, the treatment continuum of options from intensive/expensive to minimal/inexpensive and the smoking population continuum of options from high to low vulnerability, forces the difficult decision about where to place the cut-off points. The smoker needs and the treatment intensity/costs are in the opposite directions. The advantages of self-help treatment include facility of delivery, facility of widespread dissemination, smoker preference, and low cost; but the disadvantages are that it's least effective, and it's difficult to tailor to stages and other individual needs without added expense. Some tailoring, of course, is possible, but heavier smokers with psychiatric, medical, or substance abuse co-

morbidity will need more than selfhelp or even brief interventions. Given our current state of knowledge a reasonable case can be made for three to four levels of qualitatively different treatment options to meet the needs of smokers who are low, moderate, high, and very high in vulnerability and cost to society due to their lifestyle habit (figures 2–4).

A stepped-care model

A stepped-care model requires the assessment of differences among smokers along the individual-population continuum to serve as the basis for screening and triage.^{10,11,13} This applies at the gross level of assignment to a specific step, analogous to differential diagnosis, and also to the 'fine-tuning' of treatment to individual patient variations *within* a step. The latter is analogous to modifying the dose of medication to a patient's body weight. The approach begins with the goal to provide smokers with the least intensive/costly treatment. There are additional screening questions used to assign a smoker directly to a higher level of care if indicated. The present model is therefore a hybrid that combines ideas about stepped-care with those of client-treatment matching.

The stepped-care model proposed has three

TREATMENT CONTINUUM

Figure 3 The smoker continuum

levels of intensity of care: (1) minimal – self-change/self-help; 2) moderate – brief counselling plus follow-up; and (3) maximal – specialised intensive clinic treatment with both in- and out-patient options (figure 5). Both steps 2 and 3 include nicotine replacement pharmacotherapy. Step 3 includes both in- and out-patient clinics where professionals can provide other medications, specialists and specialised treatments for smokers with heavy dependence, co-morbidity of psychiatric disorder, substance abuse, medical complications and other lifestyle risk factors.^{9–11,13} Smokers are not triaged into step 2 or step 3 care until they meet stringent and specific entry criteria. Within each level of step care, there remains a range of flexible treatment options for the smoker. I have intentionally kept the stepped-care model broad and general rather than specific. It is not set in stone, and I hope it will be modified by open debate and by new evidence (see figure 5).

What are the core essential elements of treatment that can form a common base for all quality programmes? Two decades of research suggest that a basic cognitive-behavioural approach (behaviour modification) combined with the transtheoretical (stage) model can provide the core components for a high quality treatment programme at any level of stepped care (see table 3). Indeed, these elements can

form the basis for developing programmes and materials, training of providers, and be used as guidelines in the certification of both counsellors and licensed specialists.

STEP 1: SELF-CHANGE AND SELF-HELP

Many smokers prefer quitting on their own. The least intensive, costly, and effective approach is self-change, based on self-reliance with no expertly developed programmes, professional guidance, or prescriptions.^{17,18} About 3 to 8% of smokers per year are successful at cessation using a pure self-change strategy.^{48,51} Self-change could be considered a 'background' to stepped-care since it is always available to all smokers. Other adjunctive programmes, commercial clinics, hypnosis, acupuncture, and over-the-counter aids are also available but are difficult to classify in terms of treatment components due to their diversity.^{6,17,51} Face-to-face but minimal counselling, telephone support, and computer expert systems are possible ways to enhance self-change impact.^{7,3,10,31,33,52–54}

Self-change is an approach that can involve considerable medical risks and excess cost to society because it takes so long. Personalised feedback about actual health damage and family concerns ('motivational enhancement') can help accelerate this movement towards

Figure 4 The treatment continuum

cessation.^{10,56} Other strategies/modalities to help accelerate the movement of precontemplators into the action stage include patient education, community activation, advocacy and mobilisation, use of mass media channels, incentives to quit and disincentives to smoke, and social marketing strategies. Environmental and policy changes are crucial, such as smoking bans in the worksite, office, and hospital, and increased taxation and the testing of air quality levels in order to show that second-hand smoke – a Class ‘A’ carcinogen – is present.^{3,7–11,55–57} Other ideas include promotion of alternative lifestyles (eg, exercise, diet) as an entrée or gateway to introduce smoking behaviour change.⁵⁵

Self-help programmes are usually materials that smokers can obtain and use at home. The smokers must initiate some brief contact with a provider or whatever delivery system offers the materials they desire to use. The best of these programmes typically involve the use of

self-help manuals. The essential elements and core features in self-help, as well as a description of enhancements, is more fully presented elsewhere by Glynn, Boyd and Gruman, Orleans and others.^{3,10,16,58,59} These self-help programmes typically produce 8–15% cessation rates at 12 month follow-up.^{3,51} Participation rates in a defined population (eg, a worksite) average around 4 to 7%.⁵⁵ From the public health viewpoint of penetration, efficacy and cost, this rate of dissemination still leaves room for improvement.

A promising innovation to the self-help approach involves the use of computerised expert system programs.⁵⁴ Interactive computer programs can provide smokers at each stage of change with individualised feedback. These approaches can be used without having to see a provider face to face. They can be delivered through the mail or by telephone and typically involve a series of three 15-minute surveys followed by computer-generated ex-

Figure 5 (a-c) Steps 1–4 of the stepped-care model

Table 3 Behavioural treatments for nicotine dependence

Preparation

- Motivation
- Health information
- Reasons for quitting and for smoking
- Contingency contracting
- Target quit date
- Self-monitoring
- Nicotine fading

Quitting

- Self-management
- Alter/avoid smoking cues
- Substitute alternative behaviours
- Stimulus control techniques
- Relaxation techniques
- Aversion strategies
- Satiation
- Rapid smoking

Maintenance

- Coping skills training
- Social support
- Cue exposure
- Exercise
- Coping with negative affect/depression
- Avoiding weight gain

pert system feedback. For example, one programme being researched by Prochaska and colleagues is designed to maximise smokers' self-change efforts. The programmes provide feedback on 14 variables that have been found to be more important for progressing through the stages, including ten processes of change, the pros and cons of quitting, self-efficacy, tempting situations and tips for applying each of the relevant variables.^{53,54} It is important to note that no pharmacological replacement therapies such as the nicotine patch or nicotine polacrilex are recommended at the Step 1 level of care.

STEP 2: MODERATE INTERVENTIONS

Step 2 (moderate intensity) interventions combine self-help with one or more of the following: brief counselling – face-to-face or by phone, personalised feedback, social support or any of the above with or without nicotine replacement therapy.¹⁰ The distinguishing feature of Step 2 is a higher level of face-to-face contact, social support and treatment tailoring. Step 2 interventions are suitable for more vulnerable or moderate risk subgroups of smokers (more nicotine dependence, repeated failure to quit with self-help). Both brief contact, in the clinic or office-based, and

trained counsellor/volunteer-led group treatments, such as those led by the Voluntary Agencies (Lung, Heart, Cancer), are classified as Step 2.

Brief, office-based treatments

The essential elements for effective physician office-based treatments have been summarised into four techniques: physicians should *ask* about smoking, *advise* all smokers to quit, *assist* them, and *arrange* for follow-up.¹⁵ There are outcome differences between physician advice alone and combined with brief counselling treatment. Brief counselling produces significantly higher quit rates (20–25 %) than advice alone (5–10 %).^{59,60} A review of brief counselling by physicians reported that the better interventions used (a) more than one modality (eg, face-to-face advice, self-help materials, nicotine replacement), (b) a combination of physician and non-physician providers, and (c) more follow-up visits and contacts.⁶⁰ Especially important were the practices of advising patients to set a quit date, and scheduling follow-up contacts.^{58–60} Programmes tailored to specific patient populations such as patients recovering from a heart attack have sometimes demonstrated efficacy as high as 60 % in follow-up quit rates.^{27,29,30} Special programmes can all capitalise on the ‘teachable moment’ created by the illness.^{7,10,27,31–33} Office/hospital systems and environments may also need to be modified, such as by banning smoking. More to the point, we need to develop ways to help routinely identify smokers upon their entry or admission.^{31,33,56,57} By making smoking status a ‘vital sign’⁶² for all patients, an enormous start can be made on enhancing smokers’ motivation to accelerate change. This kind of routine practice would dramatically elevate the status of lifestyle factors into mainstream health care practice and is strongly recommended.

Proactive (provider-initiated) follow-up telephone counselling is included in the better Step 2 treatments. Orleans⁵⁸ found that *four brief calls* by trained telephone counsellors boosted long-term quit rates among Health Maintenance Organisation smokers by 50 %. Reactive (smoker-initiated) telephone hot lines are increasingly available in communities and managed care settings but very few smokers call them.⁶³ The impact of the hotlines is therefore very low, because they are reactive rather than proactive. That is they wait for the smoker to take the initiative to contact rather than reaching out to the smoker proactively.

Pharmacological adjuncts

Nicotine replacement via nicotine polacrilex (gum) or transdermal nicotine (patches) is an effective pharmacological adjunct to treatment for nicotine-dependent smokers. I will not cover this in detail here because a later presentation by Dr Sachs is scheduled to accomplish that goal. However, when used alone or with only brief medical advice (ie, no skills counselling or follow-up), nicotine replacement has no advantage over a placebo. Research also suggests that many physicians

fail to provide adequate instruction in the proper use of either transdermal nicotine or nicotine polacrilex, nor do they offer detailed behaviour modification counselling or referrals to clinic treatment to accompany their prescription. They also rarely proactively follow-up on patients. There is a need for professionals to complete a diagnosis and some brief counselling (in the order of 2–5 minutes), and to have extensive support from trained office staff (30 minutes) in counselling, or else refer to a qualified counsellor or clinic. At least four proactive counsellor follow-ups are also required as an integral part of any Step 2 treatment.⁵⁸

Volunteer-led clinics

The presence of family members, close friends, and worksite colleagues who smoke tends to predict poor outcome.⁶⁴ But positive social support from family and friends predicts a positive outcome of smoking cessation treatments. Efforts to enhance *natural* support by involving significant others in self-help or using social skills training in treatment programmes have not proven successful.^{17,58,59,64} Volunteer-led or trained counselor-led groups combine ‘artificial’ social support (from leader and members) with a structured introduction to behavioural quitting methods. This may be especially helpful for smokers lacking ‘natural’ quitting supports at home or at work.^{16,58,59,65,66} The materials and quitting methods used are usually state-of-the-art (eg, American Lung Association). The quit rates can range from 10–15 % at 12 months.^{16,58,59} Lando *et al.*, in an exemplary, cost-effective, and innovative intervention, evaluated volunteer-led American Cancer Society and American Lung Association clinics.⁶⁶ They reported up to 25 % 12-month quit rates, using a formal volunteer training programme that can easily be used nationwide.^{65,66}

As was the case with the boundary between Steps 1 and 2, at the more intensive end of the spectrum of Step 2 interventions, there is overlap with Step 3. At the least intensive end, there is overlap with Step 1. I believe that Step 2 interventions form the backbone of the stepped-care model since they can reach a large majority of the ‘middle of the road’ smokers in the population at a moderate cost, with moderate to good efficacy.^{3,7,58,65,66}

STEP 3: INTENSIVE CLINICAL INTERVENTIONS

Intensive clinical interventions in the proposed three-step model should include the following treatment providers and components in an interdisciplinary team setting: professional specialists with training and certification in the assessment and treatment of nicotine dependence, addictive behaviours and the delivery of medical psychiatric or behavioural and preventive medicine interventions; physicians with experience in pharmacologic agents used to treat both nicotine dependence and associated psychiatric co-morbidity (eg, depression, substance abuse disorder), and counsellors experienced in mental health or health psychology and with certified training in the core

cognitive-behavioural skills for treatment of behavioural risk factors such as smoking.¹³ I believe it's important to note that this recommended clinical programme goes well beyond the current approach to smoking which keeps individual risk factors separate from one another in treatment and in research.^{4,7} One could envision two separate steps of care here. Step 3 would be a traditional smoking cessation clinic and Step 4 the interdisciplinary combined clinic that can address the issues of co-morbidity, substance abuse, medical complications and multiple risk factors or lifestyle habits. I would suggest that one comprehensive preventive health clinic, programme or service would be more cost-effective. It could deliver higher quality care than two separate steps of care at this point. Treatment programmes or clinics could include current substance abuse/alcoholism programmes and interdisciplinary in- and out-patient hospital clinics with specialty Behavioural Medicine or Medical Psychiatry units for the combined treatment approach.^{6,9,11,15,23,38,44,45,67} The disciplines of medical psychiatry, health psychology and behavioural, preventive and internal medicine can usually contribute to these programmes in significant ways, along with nutritionists, exercise physiologists, social workers, respiratory therapists, nurses and other health professionals.^{9,13,55,67-73}

Cognitive-behavioural treatment strategies are an essential component of Step 3 interventions as their inclusion in treatment programmes have been consistently associated with long-term success at cessation (25-40% at one year).^{3,4,6,7,9,51} During the early stages of treatment, behavioural strategies such as contingency contracting, nicotine fading, choosing a definite quit date, and self-monitoring smoking rates and behaviours associated with smoking are useful.⁶ Once the quitting phase of treatment has been reached, other major social-learning based approaches are typically introduced,^{5,10,11,13,14} such as self-management, stimulus control, dealing with environmental cues that trigger smoking (eg, by avoiding or coping with the cue)⁷⁴ or altering the consequence of smoking (eg, by substituting alternative behaviours). The inclusion of maintenance/relapse prevention strategies is also critical in formal behavioural treatment programmes.^{1,4,5,6,10,23} These strategies include teaching specific cognitive and behavioural relapse prevention skills, enhancing social support, and using cue exposure and exercise training. In general, cognitive-behavioural programmes which combine strategies (eg, nicotine fading, stimulus control, relapse prevention) have better outcomes than single component programmes.^{4,9} However, too many interventions may overwhelm subjects and reduce adherence to treatment.

Step 3 care is indicated for those individuals who may have failed Step 1 or Step 2 interventions repeatedly or who have associated co-morbidity that is likely to complicate treatment (ie, alcohol or other substance abuse, mood disorders, chronic medical conditions, some anxiety disorders).^{6,9,13,68} Patients with

acute medical conditions are candidates because of the urgency of the need for smoking cessation (eg, severe coronary, cerebrovascular or peripheral vascular disease) or the need for intensive medical care for an associated medical condition (eg, cancer patients, patients with severe chronic obstructive pulmonary disease, post-myocardial infarction).^{14,30-38,58,59}

Patients in Step 3 are typically offered an out-patient cognitive-behavioural treatment (CBT) of 8-20 weeks duration. Studies show that adding nicotine gum to CBT increases long-term quit rates, which can range from 25%-60%.^{6,7,9-11,13} There is also evidence that the addition of the nicotine patch to CBT treatment enhances outcome, though the evidence to date is not as compelling as for nicotine polacrilex.^{1,34,49,75,76}

Smokers with other co-morbid psychiatric disorders who attempt cessation seem to be at increased risk for exacerbation of their associated disorder. If they are currently under treatment, medications may have to be adjusted, both to treat emerging symptoms and because nicotine affects the metabolism of several psychopharmacological agents.^{1,2,38} Other pharmacological agents could also be considered in Step 3 clinics, such as antidepressants. Doxepin hydrochloride has been shown to be effective in attenuating withdrawal symptoms after smoking cessation.^{71,76}

Some smokers, especially women, smoke to prevent weight gain, and the weight gain that frequently accompanies smoking cessation may trigger relapse.^{55,72,77} Pharmacological agents, or an adjunctive behavioural approach to both increase physical activity and decrease calories, may help.^{55,72} There is some evidence that the use of nicotine gum during smoking cessation limits post-cessation weight gain.⁷⁸ This is another example of why I favour Step 3 to be a comprehensive interdisciplinary clinic for treatment of co-morbidity and other lifestyle risk factors. This clinic would have the facilities and specialist expertise to accommodate all of the above complications in smokers who are the most vulnerable to chronic disease risk and who probably use health care services disproportionately.

Stepped care is more easily presented in theory than in practice. Several system barriers are readily apparent. Turf issues are ever present and they need to be set aside. Providers and consumer advocates must work together with experts ranging from disciplines as diverse as behavioural research to community activation and from substance abuse services to behavioural medicine risk factor clinics, from mental health professionals to primary care providers, to specialists in cardiovascular disease, oncology, and pulmonary medicine. Government and state agencies, hospitals, insurance administrators, and worksites will all need to get involved and be a part of the coordinated and collaborative plan.

Service providers, materials, and costs

I believe we should consider procedures to ensure that all materials used (or recommended

for use) adhere to minimum quality standards with respect to core content, cultural and ethnic sensitivity, and clarity of communication. Interventions that require providers to deliver interventions and make follow-up calls will need to have guidelines for standards of clinical care, training, evaluation of performance, certification and ongoing continuing education. For the clinics in Step 3, additional and more formal professional standards are suggested for certification. It is recommended that clinics be registered to ensure they can indeed provide the full spectrum of interdisciplinary services. Quality assurance will be needed and programmes must be monitored to ensure appropriate cross-referrals are made. Well-established procedures in medicine can be used to develop standards of care, such as the current practice of certification of radiologists who wish to specialise in cardiac catheterization. The Agency for Health Care Policy and Research of the Federal government (AHCPR), working with the American Medical Association, American Psychological Association, American Public Health Association, the Voluntary Agencies (Heart, Lung, Cancer) and other relevant constituencies could help to develop guidelines for standards of care. I would suggest this be done for the entire stepped-care model as an integrated whole rather than for individual steps or components in a piecemeal fashion.

Although improving quality of life is the ultimate goal of health care, cost factors cannot be ignored any longer. Table 4 provides some indicators of cost per quality-adjusted life years saved of tobacco dependence treatment programmes and other preventive medical practices.^{8,17,79-86} As you can see, the costs of smoking treatments at all levels of comparison are extremely reasonable given the potential cost-savings and quality of life improvements that might accrue.

The most expensive tobacco treatment programme only approaches the cost of other well-accepted preventive medical practices such as management of moderate hypertension, or hypercholesterolemia. The cost of Step 2 brief interventions for smokers are orders of magnitude cheaper than these other traditional preventive medicine practices. If

Step 3 programmes also take into account the simultaneous treatment of co-morbidity, substance abuse and other risk factors, such as poor diet and exercise, then the savings and economy of scale that is achieved would be quite impressive. This is another good reason to make a strong argument for creating a multiple risk factor, interdisciplinary specialty clinic that is, from a cost viewpoint as well as from a quality of care perspective. Patients with multiple other health risk factors, substance abuse, psychiatric co-morbidity and other chronic disease sequelae can be treated in one coordinated place. The 'whole person' is treated efficiently and cost-effectively, and all the problems related to poor quality of life and to excess health care utilisation can be addressed simultaneously, efficiently, and probably more effectively due to coordinated case management.

Conclusions and future directions

Most of the essential elements for the three-step model are well developed, researched, and available. Since the proposed stepped-care model is intentionally a broad-based algorithm, it is both sufficiently flexible and capable of change in the light of new research evidence. It is a place to begin, based on the currently available theory, empirical and clinical state of knowledge. This stepped-care model provides a blueprint for accelerating the movement of smokers towards cessation. It ensures that once smokers are motivated, they remain in the system, receive the appropriate level and quality of care, and eventually are given the very best chance of permanent cessation. Modern computer technology can be helpful at keeping track of the flow of patients through the system.

A stepped-care model will only be successful if both providers and consumers use it and agree with its rationale. It is vital that consumers be educated about the precise reasons and criteria used for assignment to each level of stepped care. They should be informed about what to reasonably expect from a particular level of treatment, for how long they should try it, and when to request being stepped up to higher levels of care. The full trust, participation and partnership of consumers is crucial to the overall success.

In addition, training and certification of providers, and quality assurance procedures are important to ensure high quality of delivery of care. Financial barriers for the uninsured and consumers of lower socioeconomic status should not be permitted to drive treatment decisions about level of care needed. This is of concern for the more costly (Step 3) specialty clinics. I believe that an integrated approach to preventive health care is needed to truly improve quality of life and also have a chance of containing health care cost escalation. This is possible if we ensure access to all levels of care for all citizens.

There are many other factors outside of mainstream health care services that can powerfully influence our society towards

Table 4 Cost effectiveness and cost per life years saved

Treatment	Cost effectiveness
Self help	\$22-144
Brief + support (pregnancy)	\$100-325
Self help (worksites)	\$22-144
Clinic worksite (ALA)	\$235-399
ALA cess. + main. manual	\$126-699
<i>Cost savings per quality adjusted life year saved</i>	
Physician smoking counselling	\$748-2020
Nicotine gum + behav. Tx	\$4113-9437
Moderate hypertension	\$11 300-24 408
High cholesterol	\$6511-108 189
<i>Smoker's cost to health care system</i>	
14% higher for health care utilisation	
\$650-1200 more per year to worksites	
Pregnancy: smokers - cost of delivery is \$46 less if quit in first trimester (with wide dissemination) = \$22-56 million savings in the USA (due to prevention of low birth weight)	

ALA: American Lung Association.

improved health and quality of life. Environmental and public health strategies, such as taxation, smoking bans in physicians' offices, hospitals, airlines and public places are crucial to help move the vast majority of precontemplator smokers into action. Taxation of tobacco products, bans on chewing tobacco in Little League and studies of the dangers of environmental tobacco exposure are all encouraging trends, and I hope they will continue. However, we will still need a comprehensive, rational strategic plan for treatment services. The results of these public health and environmental initiatives (to accelerate movement towards quitting) can then be used to maximal advantage by the health care system. For example, pediatricians could confidently advocate smoke-free households and cessation among parents who smoke, especially for their patients with asthma or other respiratory illness. The point is that a stepped-care model is but one piece of a larger system in society to help improve the quality of life for all at reasonable cost in an equitable manner.^{3,7,8,10,13,17} It is an important piece if done well and with the full integration of individual and public health perspectives.^{9,10}

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