Effective Intervention for Smoking Cessation —Practical guidance for medical facilities including smoking cessation clinics—

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Masakazu NAKAMURA

Department of Health Promotion and Education, Osaka Medical Center for Health Science and Promotion

Abstract: The essential of tobacco use is nicotine dependence. It is important to understand that habitual smoking is a chronic dependency that is liable to relapse but is amenable to repeated treatment, and to incorporate the treatment of this dependency into the routine healthcare activities. The efficacy of therapeutic programs that deal with smoking cessation on the basis of approaches using behavioral science and pharmacology has been established, and it is apparent that the cost-effectiveness of such treatment is extremely high among the various healthcare programs available. This paper introduces a therapeutic approach (the "5 A's") that can be implemented within a short period of time at outpatient clinics and discusses the use of nicotine replacement therapy.

Key words: Smoking cessation; Nicotine replacement therapy; The "5 A's"; Smoking cessation clinic

Introduction

Tobacco has not always been recognized as an addictive substance, with claims having been made that there is no obvious physical dependence and that tobacco use does little harm to society. However, a number of recent studies have demonstrated the mental and physical dependence resulting from tobacco use, leading to general acceptance of the view that it is one of drug abuses. In Western countries, there has been a movement to deal with the treatment of nicotine dependence as part of routine healthcare activities, with the understanding that this condition is "a chronic disease which is liable to relapse, but can be cured by repeated treatment."

Thus, smoking cessation intervention is a treatment for nicotine dependence and represents a type of health service from which pre-

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ventive and prognostic benefit for various diseases related to smoking can be expected. Moreover, smoking cessation intervention can be regarded as a high-priority service in light of its extremely high cost-effectiveness relative to many health services.

Because the medical milieu is an environment in which many tobacco smokers are encountered, it is a good setting in which to provide smoking cessation intervention. If healthcare professionals were to provide such intervention to smokers as part of their routine procedures in the treatment of patients or in general health examinations, society as a whole would benefit from a reduced number of smokers even if the success rate of smoking cessation is not so high.

According the results of a meta-analysis of about 300 randomized controlled trials concerning smoking cessation,¹⁾ a clinician's advice to a general patient to stop smoking is effective even if it is as brief as 3 minutes. The percentage of smokers abstinent for 6 months or more was 2% higher when advice was given than when it was not. In addition, brief advice (up to 10 min) plus nicotine replacement therapy increased the corresponding abstinence rate by 9% as compared with no intervention. It has also been reported that a team approach involving physicians and other medical staffs increases the abstinence rate.

This paper describes methods of assisting smokers in overcoming their nicotine dependence and is aimed at those who work in clinical practice at general outpatient clinics or specialized outpatient clinics for tobacco dependence. Also included is a discussion of the effective use of nicotine replacement therapy.

Methods and Practical Aspects of Facilitating Smoking Cessation at Outpatient Clinics

This section introduces the therapeutic approach that employs the "5 A's" (Ask, Advise, Assess, Assist, Arrange) (Table 1), which is

commonly adopted in major guidelines on smoking cessation in the UK and US.²⁾ The "5 A's" method is well suited to a brief intervention for smoking cessation at outpatient clinic.

In the first step (Ask), the procedure is to implement an office-wide system which ensures that, for every patient at every clinic visit, tobacco-use status is asked and documented in order to assure the systematic screening of all patients for smoking cessation intervention. For this purpose, the guidelines recommend expanding the entries of vital signs to include tobacco use or the use of an identification system, such as placing tobacco-use status stickers on all patient charts.

In Step 2 (Advise), the procedure is to urge every tobacco user to quit, in a "clear, strong, and personalized" manner. Physicians and other healthcare professionals should be careful not to offer vague messages of smoking cessation, such as "it's better to quit smoking if possible" or "try to cut down if it doesn't seem possible for you to quit". These statements weaken the motivation of patients to quit smoking. The "strong" manner referred to here means in such a way that emphasizes the high priority of quitting smoking as a task for the patient to deal with.

The procedure in Step 3 (Assess) is to ask every tobacco user if he or she is willing to make a quit attempt at this time. If the patient is willing to do so, specific support (Steps 4 and 5) should be provided. If the patient is unwilling to make a quit attempt, motivational intervention such as that shown in Table 2 should be provided.

The procedure in Step 4 (Assist) is to aid the patient who is willing to make a quit attempt (1) by helping him or her to formulate a quit plan to set up a quit date and providing advice on how to prepare for quitting (creating an environment suitable for quitting, including asking for support from others; developing a perspective on nicotine withdrawal symptoms), (2) by providing practical counseling (concerning the clinical importance of total abstinence;

Step	Strategies for implementation		
Step 1: Ask (systematically identify all tobacco users at every visit)	 Implement an office-wide system that ensures that, for every patient at every clinic visit, tobacco-use status is queried and documented. Expand the entries of vital signs (blood pressure, pulse, weight, etc.) to include tobacco use (current, former, never) or use an alternative universal identification system (e.g., placing tobacco-use status stickers on all patient charts). 		
Step 2: Advise (Strongly urge all tobacco users to quit (in a clear, strong, and personalized manner))	 Advice should be: Clear: "I think it is important for you to quit smoking now and I can help you." "Cutting down while you are ill is not enough." Strong: "As your clinician, I want you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you." Personalized: Tie tobacco use to current health/illness, and/or its social and economic costs, motivation level/readiness to quit, and/or the impact of tobacco use on children and others in the household. 		
Step 3: Assess (determine willingness to make a quit attempt)	• Ask every tobacco user if he or she is willing to make a quit attempt at this time (e.g., within the next 30 days). If the patient is willing to make a quit attempt at this time, provide assistance. If the patient is unwilling to make a quit attempt at this time, provide a motivational intervention.		
Step 4: Assist	A patient's preparations for quitting:		
(aid the patient in quitting)Help the patient with a quit plan.	 Set a quit date (ideally, the quit date should be within 2 weeks). Tell family, friends, and coworkers about quitting and request understanding and support. Anticipate challenges to planned quit attempt, particularly during the critical first few weeks. These include nicotine withdrawal symptoms. Remove tobacco products from your environment. Prior to quitting, avoid smoking in places where you spend a lot of time (e.g., work, home, car). 		
• Provide practical counseling (problem solving/skills training).	 Abstinence: Total abstinence is essential. "Not even a single puff after the quit date." Past quit experience: Identify what helped and what hurt in previous quit attempts. Anticipate triggers or challenges in upcoming attempt: Discuss challenges/triggers and how patient will successfully overcome them. Alcohol: Since alcohol can cause relapse, the patient should consider limiting/abstaining from alcohol while quitting. Other smokers in the household — Quitting is more difficult when there is another smoker in the household. Patients should encourage housemates to quit with them or not smoke in their presence. 		
• Provide intra-treatment social support.			
• Help patient obtain extra-treatment social support.	• Help patient develop social support for his or her quit attempt in his or her environ- ments outside of treatment. "Ask your spouse/partner, friends, and coworkers to support you in your quit attempt."		
• Recommend the use of approved pharmacotherapy, except in special circumstances.	• Recommend the use of pharmacotherapies found to be effective. Explain how these medications increase smoking cessation success and reduce withdrawal symptoms. The first-line pharmacotherapy medications include: sustained-release bupropion hydrochloride (not approved in Japan), nicotine gum, nicotine inhaler, nicotine nasal spray, and nicotine patch.		
• Provide supplementary materials.	• Provide supplementary materials appropriate for the patient (Sources—Governmen- tal agencies, nonprofit agencies, or local/state health departments).		
Step 5: Arrange (Schedule followup contact)	 Timing: Followup contact should occur soon after the quit date, preferably during the first week. A second followup contact is recommended within the first month. Schedule further followup contacts as indicated. Actions during followup contact: Congratulate success. If tobacco use has occurred, review circumstances and elicit recommitment to total abstinence. Remind patient that a lapse can be used as a learning experience. Identify problems already encountered and anticipate challenges in the immediate future. Assess pharmacotherapy use and problems. Consider use or referral to more intensive treatment. 		

Table 1 Brief Strategies to Help the Patient Willing to Quit Tobacco Use—The "5 A's"	Table 1	Brief Strategies to Help the Patient Willing to Quit Tobacco Use-The "5 A's"
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(AHRQ: The Agency for Healthcare Research and Quality, 2000)

Relevance	Encourage the patient to indicate why quitting is personally relevant, being as specific as possible. Motivational information has the greatest impact if it is relevant to a patient's disease status or risk, family or social situation (e.g., having children in the home), health concerns, age, gender, and other important patient characteristics (e.g., prior quitting experience, personal barriers to cessation).
Risks	The clinician should ask the patient to identify potential negative consequences of tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient.
Rewards	The clinician should ask the patient to identify potential benefits of stopping tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient.
Road blocks	The clinician should ask the patient to identify barriers or impediments to quitting and note elements of treatment (problem solving, pharmacotherapy) that could address barriers.
Repetition	The motivational intervention should be repeated every time an unmotivated patient visits the clinic setting.

Table 2 Brief Strategies to Enhance Motivation to Quit Tobacco Use-The "5 R's"

(AHRQ, 2000)

limiting or abstaining from alcohol particularly immediately after the quit date; learning how to deal with other smokers, if any, in the household; identifying what interfered with previous quit attempts and providing advice on how to succeed), (3) by providing advice about the use of social support (concerning the use of support from healthcare professionals, family, friends, and coworkers), (4) by implementing pharmacotherapy, and (5) by providing supplementary educational materials on smoking cessation.

In Step 5 (Arrange), the procedure is to schedule follow-up contact for the patient with a quit plan to help him or her succeed in the quit attempt. It is recommended that the first follow-up contact occur soon after the quit date, preferably within the first week, and that a second follow-up contact take place within the first month. Congratulating the patient on his or her sustained abstinence provides great encouragement.

Role and Practical Aspects of Specialized Smoking Cessation Clinics

The role of outpatient clinics that specialize in helping patients overcome nicotine dependence is to provide special treatment to patients for whom brief intervention at a general outpatient clinic is insufficient to produce successful abstinence. Nicotine gum and the nicotine patch were introduced as a prescription drug to Japan in 1994 and 1999, respectively. As a result of these opportunities, an increasing number of outpatient clinics that specialize in treating nicotine dependence have been set up. A total of 247 institutions in this country as of January 2002 have such clinics (a list of outpatient clinics specializing in nicotine dependence in Japan is available at the URL of the Osaka Medical Center for Health Science and Promotion: http://www.kenkoukagaku.jp).

We opened a clinic specializing in the treatment of nicotine dependence in the Osaka Cancer Prevention and Detection Center in October 1998, and are continuing to treat patients in the clinic, which moved to the Osaka Medical Center for Health Science and Promotion in July 2001. More than 1,500 smokers have visited our clinic to date. In this clinic, a physician and counselor team is assigned to a particular patient, and methodology based on the results of research in two scientific fields, behavioral science and drug dependence, is used. A flowchart of the initial and subsequent visits to the clinic is shown in Fig. 1. The patient is interviewed individually for about 1 hour at the time of the first visit and for about 30-40 minutes at



Fig. 1 Flowchart of treatment in the specialized smoking cessation clinic of the Osaka Medical Center for Health Science and Promotion

subsequent visits.

Patient visits to the clinic are scheduled using an appointment system, with the date of visits scheduled at times convenient for the patient. Most patients attend the clinic once every 2-3 weeks during the first few months after the quit date, because they usually use nicotine replacement therapy and therefore require assessment of its efficacy and possible adverse reactions as well as additional prescriptions at such intervals. The frequency of visits decreases to once every 1-2 months after three months of abstinence, when prescriptions for nicotine replace-

Nicotine replacement therapy (No. of trials)		Quit rate odds ratio (95% CI)
Gum	(48)	1.63 (1.49–1.79)
Patch	(31)	1.75 (1.57–1.94)
Intranasal spray	(4)	2.27 (1.61-3.20)
Inhaler	(4)	2.08 (1.43-3.04)
Sublingual tablet	(2)	1.73 (1.07–2.80)
All formulations		1.71 (1.60–1.83)
		(Lancaster 2)

Table 3 Meta-Analysis of Studies on the Efficacy of Nicotine Replacement Therapy

(Lancaster, 2000)

ment therapy are generally terminated. In this clinic, patients "graduate" when abstinence from smoking has been maintained for 6 months from the quit date. On the day of the graduation ceremony, a photograph of the patient together with the physician and counselor is taken and placed on the certificate of course completion. This certificate is given to the patient to encourage continued abstinence.

Pharmacotherapy for Nicotine Dependence—Nicotine Replacement Therapy

Various drugs have been examined as pharmacotherapy for nicotine dependence. Among them, nicotine replacement therapy has been established as safe and efficacious and is in widespread use throughout the world.

Nicotine replacement therapy using chewing gum or other formulations of nicotine supplies the patient with nicotine to relieve the withdrawal symptoms that occur during abstinence. With this therapy, the patient initially is weaned from psychological dependence, then from physical dependence through adjustment of the nicotine supply. According to a metaanalysis of studies on the effect of nicotine replacement therapy carried out in various countries, the therapy increased the chances of quitting 1.7-fold in comparison with placebo, as shown in Table 3^{3}

	Nicotine gum	Nicotine patch
Advantages	 Allows self-regulation of the nicotine dose. Is short-acting. Offers both oral and tactile gratification. 	 Easy to use. Allows maintenance of stable nicotine concentrations in blood.
Disadvantages	 Requires instructions on proper use. May cause nausea and irritation of the mouth and throat. 	 Cannot handle abrupt surges of craving. May cause skin reddening or rash, and sleep disorder.

Table 4 Characteristic Features of Nicotine Gum and Patch

In Japan, chewing gum and patches are the currently available formulations of nicotine replacement therapy. The greatest merit of the nicotine patch is that it provides stable blood concentrations of nicotine when renewed every morning. On the other hand, nicotine gum is advantageous in that it provides a more rapid increase in the nicotine concentration in blood than the nicotine patch, so that it can better handle abrupt surges of craving for tobacco. Based on the characteristic features of these two formulations (Table 4), our clinic uses the nicotine patch as the basic formulation, and adds nicotine gum as supplementary dosing for surges of craving or for times when the effect of the nicotine patch is not adequate in the morning. In addition, we recommend concomitant use of nicotine gum for patients in whom the nicotine patch with the highest dose of nicotine (Nicotinel TTS30[®]) is considered to be insufficient. In selecting the dose of the nicotine patch, it is convenient to use a color test paper, NicCheck [Dynagen Inc., USA], which allows semi-quantitative measurement (0-14, 15 levels) of nicotine and its metabolites in urine. According to data from patients in our clinic who used the patch for 7 consecutive days without smoking, Nicotinel TTS30® (nicotine content 52.5 mg) provides a 4.8 ± 1.3 (mean \pm standard deviation) NicCheck level of nicotine, TTS20[®] provides a 3.4 ± 1.4 level, and TTS10[®] provides a 1.8 ± 0.7 level.⁴⁾ When the nicotine patch is prescribed to the patient at the first examination, these data are used as a yardstick, based on the NicCheck level determined.

In Japan, nicotine gum was formerly a prescription drug that was not covered under national health insurance. However, it was approved as an over-the-counter drug in June 2001, and has been available in drugstores since September 2001. Readers are referred to two of the author's papers for detailed usage of the nicotine patch and nicotine gum.^{5,6)}

Conclusion

Although tobacco epidemic became prevalent in Japan about 30 years later than in the West, its epidemic was substantial by the 1970s, and Japan currently has the highest level of tobacco consumption among the developed countries. It is therefore easy to predict that health hazards caused by tobacco use will become a serious social problem as the population ages.

Nicotine dependence treatment is an antismoking measure that can be implemented by healthcare professionals in routine clinical settings. The efficacy and cost-effectiveness of such intervention have been demonstrated by scientific evidence, and it is expected to have greater immediate effects on reducing smoking prevalence than smoking prevention. Health hazards caused by tobacco use in the first half of the 21st century occur mainly in those who are current smokers. Therefore, comprehensive anti-smoking measures, including nicotine dependence treatment, are urgently needed.

We have developed educational materials for medical institutions and healthcare profes-

Osaka Prefecture's guidelines for tobacco control (for medical institutions) [digest edition]

In May 2000, the Osaka Prefectural government developed guidelines to curtail tobacco use in medical institutions, with the goal of achieving the smoking ban or complete isolation of smokers in specified areas and providing support for smoking cessation in all medical institutions by 2005. The guidelines propose specific activities for this purpose.



- Osaka Prefecture's guidelines for tobacco control (for medical institutions) [digest edition]
- Educational materials useful for the support of smoking cessation

Material that allows medical institutions to self-assess the extent of their support for smoking cessation is available as well as various other materials including an instructor's manual describing how to provide support and leaflets to patients.



•Checking smoking cessation support activities "What is the level of preparedness and achievement in your institution?"



• Smoking cessation support: instructor's manual

 Educational materials useful for promoting the smoking ban or isolation of smoking in medical institutions

A pamphlet is available that allows individual medical institutions to self-assess their progress in smoking ban or isolating smoking in the institution.

Also available is illustrated material that introduces important points in promoting the smoking ban or isolation of smoking, specific practical procedures, and successful examples.



•Checking smoking restriction in medical institution "Is your institution progressing with the isolation of smoking?"



•Manual for smoking restriction in medical institutions



 Leaflet for patients
 "Keys to successful smoking cessation"



 Smoking cessation support procedures sheet
 "Five steps leading to successful smoking cessation"

Fig. 2 Educational materials for the promotion of tobacco control in medical institutions

sionals under the Osaka Executive Committee of the Cancer Prevention Campaign, which aims to promote the control of tobacco use in medical facilities (Fig. 2). Smoking ban in a medical institution provides "a cleaner, more comfortable hospital environment" and is also expected to increase the motivation of patients and personnel who smoke to give up the habit. To give greater credence to medical programs aimed at treating nicotine dependence, smoking ban in medical institutions needs to be addressed. These educational materials are available for reading and downloading on the URL of the Osaka Cancer Prevention and Detection Center (http://www.gan-osaka.or.jp) (in Japanese only).

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