

Recommendations for the treatment of nicotine dependency

NORMAN J. MONTALTO, DO

The US Public Health Service (PHS) Clinical Practice Guideline *Treating Tobacco Use and Dependence*, published in June 2000, is a clinician-targeted resource that encourages physicians to apply evidence-based interventions when treating tobacco-dependent patients.

Issued by the PHS Surgeon General, the guideline recommends a new standard of care in treating tobacco dependency, the chief cause of preventable death and disease in the United States. It calls on clinicians to more consistently identify and evaluate tobacco-dependent patients and to provide treatment, motivation to quit, and referrals to smoking cessation specialists. The guideline also serves as a mandate for healthcare insurers to offer pharmacologic and behavioral treatment modalities as benefits to insured persons and to provide education and reimbursement for clinicians.

(Key words: cessation of tobacco use, clinical practice guideline, nicotine dependency, Public Health Service [PHS], smoking cessation, tobacco dependence, tobacco use)

Primary care physicians are on the front line of national goals for smoking cessation, as outlined in *Healthy People 2010*, published January 25, 2000, by the Office of Disease Prevention and Health Promotion, Office of Public Health and Science, Office of the Secretary, US Department of Health and Human Services.¹ Seventy percent of smokers visit healthcare providers annually.^{1,2} Approximately 70% of current smokers indicate a desire to quit smoking, and nearly half (45%) of current smokers attempt to quit each year.^{1,3,4}

After a review of more than 6000 articles published between 1975 and 1999, the Guideline Panel chaired by Michael C. Fiore, MD, MPH, drafted the June 2000 Public Health Service (PHS) Clinical Practice Guideline *Treating Tobacco Use and Dependence*.⁵ To increase the number of smoking cessation attempts and the rate of successful cessa-

tion, the guideline recommends protocols and interventions for all forms of tobacco dependency.

In the United States, smoking cessation rates range from 2.5% to 7% without intervention.^{6,7} When physicians provide advice alone, the odds of abstinence increase 30%.⁵ Low-intensity counseling for 3 to 10 minutes increases abstinence rates by 60%.⁵ Pharmacologic support increases success rates by 50%.^{5,8,9}

This article underscores key points (*Figure 1*) in the PHS's *Treating Tobacco Use and Dependence*.^{5,8} It also provides new information released since the 1996 guideline, *Smoking Cessation, Clinical Practice Guideline, No 18*, sponsored by the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality).¹⁰

Tobacco use and dependence status

The basic strategy for treating nicotine dependency is structured around the "Five A's" outlined in the recent Clinical Practice Guideline (*Figure 2*). If healthcare providers follow the tobacco intervention algorithm illustrated in *Figure 3* and document the Five A's items in patients' medical records, patients will receive more effective treatment, reviewers for cessation services will be satisfied, and the criteria for reimbursement will be met.

Providing appropriate treatment modalities

When tobacco use is documented in a patient's chart, counseling occurs more frequently and is more effective. If the patient is willing to quit now, providing the appropriate treatment modalities for tobacco dependency is indicated (*Figure 3*, box 1). Clinicians can become more effective counselors to patients who wish to quit using tobacco by:

- identifying barriers to stopping tobacco use,
- educating patients about diseases related to tobacco use and dependence,
- discussing reasons and situations that put individuals at high risk for tobacco use, and
- assisting patients with learning and applying new coping skills.

To prevent relapse, clinicians should assist patients in developing plans to cope with the emotional states and events that trigger tobacco use. In addition, physicians should provide patients with information about smoking and the cessation process. Clinicians should encourage patients in a caring and concerned way and communicate their support of each ces-

Dr Montalto is an associate professor of family medicine at West Virginia University/Charleston Division, clinical assistant professor at West Virginia School of Osteopathic Medicine in Lewisburg, WV, and the director of the Freedom from Tobacco Program at Charleston Area Medical Center, Charleston, WV.

Address correspondence to Norman J. Montalto, DO, 1201 Washington St E, Suite 108, Charleston, WV 25301-1834.

E-mail: norman.montalto@camc.org

Checklist

- Tobacco dependency is a chronic illness.
- Brief interventions are effective and evidence-based treatments should be offered to every patient.
- Behavioral counseling is effective and should be used with all patients.
- Five first-line medications (nicotine gum, nicotine transdermal patches, nicotine nasal sprays, nicotine inhalers, and sustained-release bupropion hydrochloride) are approved by the Food and Drug Administration (FDA) for smoking cessation. Two second-line agents (not FDA approved for cessation), clonidine and nortriptyline hydrochloride could be used if first-line agents fail.
- Standards of care and healthcare delivery systems should be instituted for identification, documentation, and treatment of tobacco dependency when seen at every clinical encounter (inpatient and outpatient).
- Reimbursement for clinicians providing clinically effective treatment. Counseling treatment and pharmacologic therapy are cost-effective interventions and should be a covered benefit for patients and include reimbursement for clinicians.

Figure 1. Key points from Fiore MC, Bailey WC, Cohen SJ, Dorfman SF, Goldstein MG, Gritz ER, et al. Smoking Cessation. Clinical Practice Guideline No. 18. Rockville, Md: US Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, Centers for Disease Control and Prevention. April 1996. AHCPR Publication No 96-0692.

sation attempt. They should also encourage patients to find support outside of the clinical setting by:

- establishing a smoke-free home, workplace, or car;
- seeking support from family, friends, and coworkers;
- finding a “quit buddy”;
- using the resources offered by cessation products, smokers’ telephone hotlines (“quit lines”), and other help lines; and
- joining community support groups.

Pharmacologic and behavioral support

The Clinical Practice Guideline recommends pharmacologic support for most patients because it improves cessation success. Five first-line agents have been approved by the US Food and Drug Administration (*Table*). The guidelines recommend nicotine gum, nicotine transdermal patches, nicotine nasal sprays, nicotine inhalers, and sustained-release bupropion hydrochloride (Zyban SR). When first-line agents are not successful, two second-line agents should be considered: clonidine and nortriptyline hydrochloride.

The five first-line agents are supported by strong evidence of clinical effectiveness (level of Evidence A). The level of evidence on second-line agents suggests they are efficacious but have more potential for side effects. They are not currently FDA-approved for tobacco cessation indications. However, data analyzed by the guideline panel suggest second-line agents may be helpful in selected patients. Using nicotine gum, nicotine transdermal patches, nicotine nasal sprays, nicotine inhalers, or sustained-release bupropion hydrochloride doubles cessation rates when compared to placebo. These pharmacologic agents should be provided to patients to increase the likelihood of successful smoking cessation.⁵

Cessation rates also increase with the intensity of support provided (*Figure 2*, “Assist”). Group, individual, telephone, or other counseling produces higher cessation rates than pharmacologic support alone. Clinicians should encourage patients to use the toll-free telephone help lines provided with all smoking cessation products for complimentary support during nicotine withdrawal. Patients could also be referred to local programs for behavioral support, such as a chapter of the American Lung Association, the American Cancer Society, or the American Heart Association; hospitals; church groups; wellness programs; or cessation specialists.

Supporting the motivation to quit—The “Five R’s”

During encounters with patients who are not ready to quit now (*Figure 3*, box 2), physicians can use the “Five R’s” mnemonic as a patient-focused motivational device. The majority of tobacco-dependent patients will require motivational interventions to encourage cessation attempts. The Five R’s are designed to motivate patients to quit, and they provide patients with a better understanding of and insight into the dynamics that influence tobacco use:

■ **Relevance**—Engage patients in a dialogue about why quitting is important to them. Encourage patients to be as specific and detailed as possible. Health concerns, tobacco-related expenses, role modeling, and concerns about tobacco exposure to others may be areas to explore.

■ **Risk**—Discussing risks may increase patients’ awareness of the negative aspects and personal hazards of tobacco use. Explore patients’ perceptions of the short-term health risks of smoking, including exacerbation of asthma, reproductive difficulty or complications, worsening angina, or vascular disease. Also review the long-term effects of smoking, including cancer, lung and cardiovascular disease, decline in quality of life, and increased disability.

Discuss the not-so-obvious risks of passive smoking to others, especially family and friends. These risks include exacerbation of asthma, respiratory tract infections, low birth weight in neonates, sudden infant death syndrome, and middle ear disease in children.

Calculate costs associated with tobacco use and dependence, and discuss how this money could otherwise be saved or spent.

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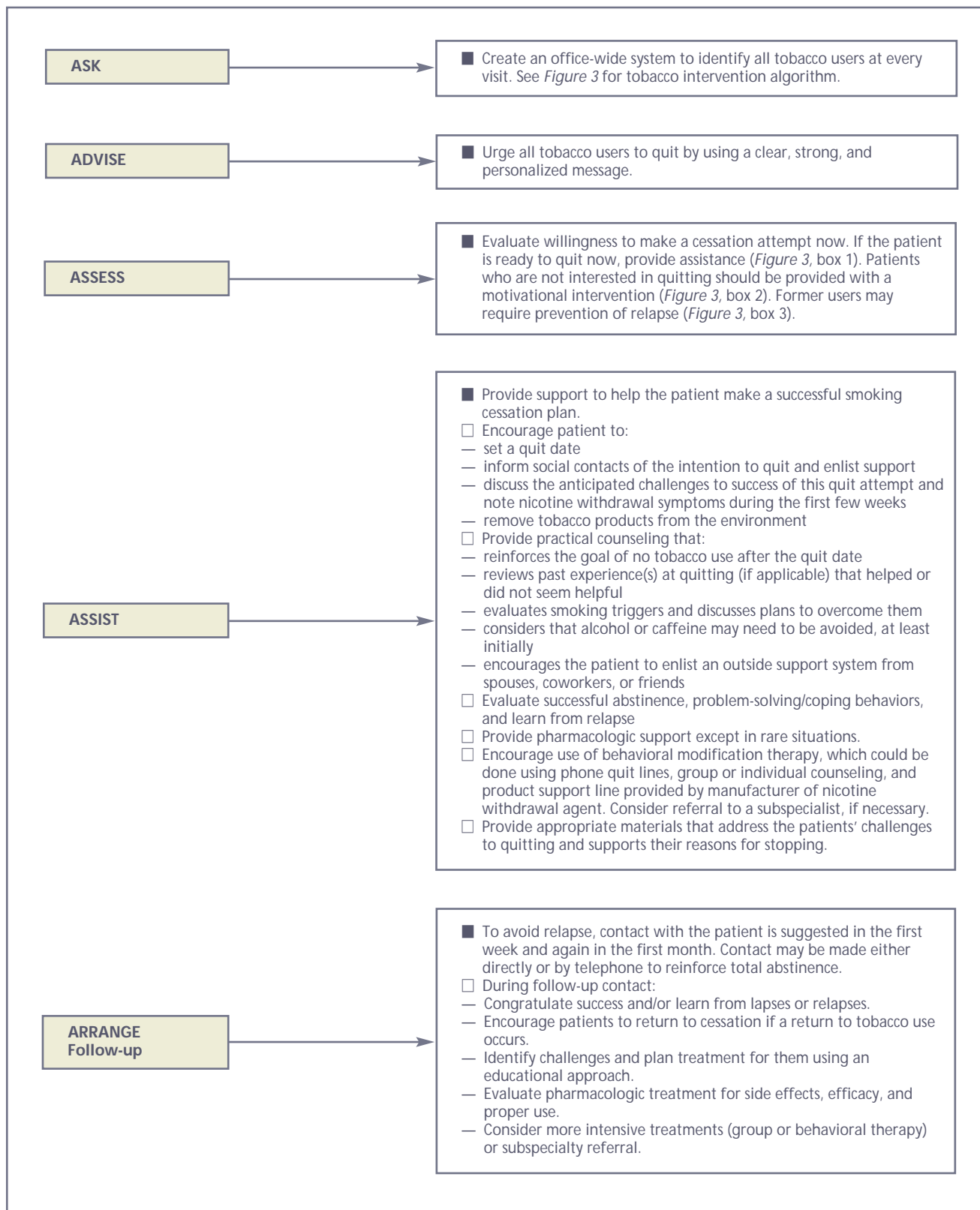


Figure 2. The “Five A’s” of smoking intervention. (Adapted from Fiore MC, Bailey WC, Cohen SJ, Dorfman SF, Goldstein MG, Gritz ER, et al. Smoking Cessation. Clinical Practice Guideline No. 18. Rockville, Md: US Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, Centers for Disease Control and Prevention. April 1996:22-25. AHCPR Publication No 96-0692.)

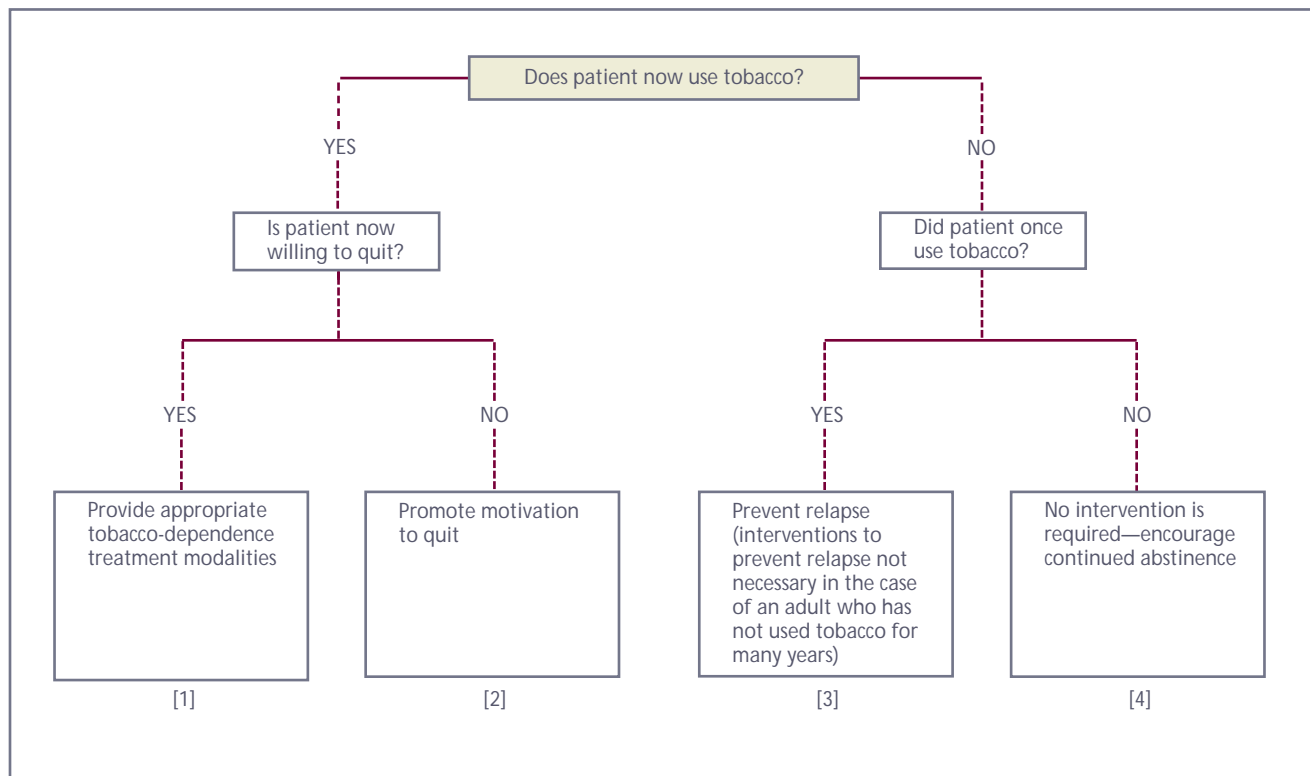


Figure 3. Tobacco intervention algorithm. (Adapted from Fiore MC, Bailey WC, Cohen SJ, Dorfman SF, Goldstein MG, Gritz ER, et al. Treating Tobacco Use and Dependence. Clinical Practice Guideline. Rockville, Md: US Department of Health and Human Services. Public Health Service. June 2000. Available at: <http://www.surgeongeneral.gov/tobacco/default.htm>. Accessed May 24, 2002.)

Inform patients that they cannot eliminate their risk by using low-tar or low-nicotine products, or by cutting down on the amount of tobacco they use. However, praise patients for cutting down tobacco consumption. Then, attempt to negotiate further reductions in tobacco use.

■ **Rewards**—Encourage patients to list specific personal benefits and advantages associated with quitting. Ask them to identify those benefits that provide them with the most personal motivation to quit. Then have patients select one or two items of utmost importance. Promote these personal benefits or rewards as a positive motivation to reinforce goals through cessation attempts and prevent relapse once an attempt has been initiated.

■ **Roadblocks**—Ask patients to list barriers and challenges to quitting. These roadblocks can be ones they may have experienced or ones they have concerns about. Patients should prioritize roadblocks in the order of difficulty.

Address roadblocks one by one. Each item should be discussed and removed or made more manageable with appropriate behavioral or pharmacologic interventions. Knowing patients' roadblocks helps physicians assist their patients in reducing these concerns or barriers, thereby increasing patients' chances for initiating cessation attempts and achieving long-term success.

Common roadblocks for patients include fear of failure, inability to handle stressful situations, concerns about weight gain, the pleasures associated with tobacco use, associations between tobacco and caffeine or alcohol, withdrawal symptoms, social situations, and the expense of nicotine-replacement products. Patients may require considerable support to overcome these barriers.

■ **Repetition**—Repeat the previous four steps (Relevance, Risk, Rewards, and Roadblocks), or review previous responses with patients at subsequent visits. During follow-up visits, evaluate patients' shifts in motivation that may support cessation attempts. If a patient is willing to quit, proceed with providing assistance. If not, review the Five R's, and inform him or her that effective treatment modalities are available and that you are ready to help when he or she is ready to quit. Continue to negotiate reductions in tobacco use, and explore avenues to motivate patients to quit.

Program referrals

The more intense an intervention, the more likely a patient is to succeed. Patients willing to quit and motivated to receive intervention should be referred to a more intensive intervention, such as formal classes, or individual or group counseling. In selected cases, teenagers, pregnant women, individuals

Table
Clinical Use of Pharmaceutical Agents for Smoking Cessation*

Pharmacotherapy/dosage	Duration	Availability†	Cost for 30-day supply‡	Precautions/contraindications	Adverse effects
■ First-line agents					
<input type="checkbox"/> Nicotine gum, 2-mg gum (up to 24 pieces per day) for smokers of 1 to 24 cigarettes per day	Up to 12 weeks	OTC only	\$38.00 for 108 2-mg pieces, \$45.00 for 108 4-mg pieces	————	Mouth soreness, dyspepsia
<input type="checkbox"/> Nicotine transdermal patch, 21 mg/24 h 14 mg/24 h 7 mg/24 h 15 mg/16 h	4 weeks then 2 weeks then 2 weeks 8 weeks	Rx and OTC	\$84.00 for 28 21-mg patches, \$90.00 for 28 7-mg patches§	————	Local skin reaction, insomnia
<input type="checkbox"/> Nicotine nasal spray, 8 to 40 doses per day	3 to 6 months	Rx only	\$44.00 for bottle	————	Nasal irritation
<input type="checkbox"/> Nicotine inhaler, 6 to 16 cartridges per day	Up to 6 months	Rx only	\$43.00 for box of 10 cartridges	————	Local irritation of mouth and throat
<input type="checkbox"/> Sustained-release bupropion hydrochloride, 150 mg every morning for 3 days then 150 mg twice daily (begin treatment 1 to 2 weeks before quitting)	7 to 12 weeks; maintenance up to 6 months	Rx only	\$98.51 for 60 tablets	History of seizure or eating disorders	Insomnia, dry mouth
■ Second-line agents					
<input type="checkbox"/> Clonidine, 0.15 mg/d to 0.75 mg/d	3 to 10 weeks	Rx only (oral formulation or transdermal patch)	\$9.00 to \$12.00 for 60 tablets, \$40.00 to \$111.00 for 4 patches	Rebound hypertension	Dry mouth, drowsiness, dizziness, sedation
<input type="checkbox"/> Nortriptyline hydrochloride, 75 mg/d to 100 mg/d	12 weeks	Rx only	\$9.50 to \$13.50 for 30 capsules	Risk of arrhythmias	Sedation, dry mouth
<p>*The information contained here is not comprehensive. Readers should see package inserts for additional information. Prices given are based on May 24, 2002, prices at drugstore.com (see http://www.drugstore.com) and a national chain pharmacy in Chicago, Ill. First-line pharmacotherapy agents have been approved for smoking cessation by the Food and Drug Administration; second-line pharmacotherapy agents have not been approved for smoking cessation.</p> <p>†Rx indicates prescription; OTC indicates over the counter.</p> <p>‡Prescription medication is often significantly less expensive when purchased through online pharmacies than from their "brick-and-mortar" counterparts.</p> <p>§Generic brands of the nicotine transdermal patch may be less expensive.</p> <p>Source: Fiore MC, Bailey WC, Cohen SJ, Dorfman SF, Goldstein MG, Gritz ER, et al. <i>Treating Tobacco Use and Dependence. Clinical Practice Guideline.</i> Rockville, Md: US Department of Health and Human Services. Public Health Service. June 2000. Available at: http://jama.ama-assn.org/issues/v283n24/abs/jst00005.html. Accessed May 24, 2002.</p>					

Checklist

■ Assessments

- Should ensure that tobacco users are willing to make a cessation attempt by using an intensive treatment program.
- Other assessments can provide information useful in counseling (eg, level of stress, presence of comorbidity).

■ Program clinicians

- Multiple types of clinicians are effective and should be used.
- One counseling strategy would be to have a medical/healthcare clinician deliver messages about health risks and benefits and deliver pharmacotherapy, while nonmedical clinicians deliver additional psychosocial or behavioral interventions.

■ Program intensity

- Because of evidence of a strong dose-response relationship, the program should consist of:
 - four or more sessions
 - sessions longer than 10 minutes
 - total contact time longer than 30 minutes

■ Program format

- Individual or group counseling
- Proactive counseling via telephone
- Optional use of adjuvant self-help material
- Follow-up assessment of intervention procedures

■ Type of counseling and behavioral modification modalities

- Practical counseling (problem solving/skill training)
- Intratreatment and extratreatment social support

■ Pharmacotherapy

- Encouragement of every smoker to use pharmacotherapy modalities endorsed in the 2000 guideline except in the presence of special circumstances
- Special consideration given before using pharmacotherapy in selected populations (eg, pregnancy, adolescents)
- Clinician should explain how these medications increase success in smoking cessation and reduce withdrawal symptoms
- First-line pharmacotherapy agents include:
 - sustained-release bupropion hydrochloride
 - nicotine gum
 - nicotine inhaler
 - nicotine nasal spray
 - nicotine transdermal patch

■ Population

- Intensive intervention programs may be instituted with all tobacco users willing to participate in such efforts.

Figure 4. Components of an intensive smoking cessation program. (Adapted from Fiore MC, Bailey WC, Cohen SJ, Dorfman SF, Goldstein MG, Gritz ER, et al. Treating Tobacco Use and Dependence. Clinical Practice Guideline. Rockville, Md: US Department of Health and Human Services. Public Health Service. June 2000. Available at: <http://www.surgeongeneral.gov/tobacco/default.htm>. Accessed May 24, 2002.)

■ **Smoking, Tobacco, and Health Information Line**
Office on Smoking and Health
Centers for Disease Control and Prevention
 1-800-CDC-1311 (1-800-232-1311)
<http://www.cdc.gov/tobacco>

■ **Cancer Information Service**
National Cancer Institute
 1-800-4-CANCER (1-800-422-6237)
<http://www.nci.nih.gov/>

Figure 5. Resources. Toll-free telephone numbers and Web site addresses for public health service organizations that provide information on smoking cessation in English and Spanish. Accessed May 24, 2002.

with psychiatric comorbidity, or drug dependency—or recalcitrant smokers who need and want to quit—should be referred to subspecialty programs. These programs should include the components of an intensive smoking-cessation intervention outlined in *Figure 4*.

Prevention of relapse

At a minimum, clinicians should work to prevent relapse by acknowledging the decision to quit, celebrating the success to date, and reinforcing the goal of abstinence (*Figure 3*, box 3). Clinicians can also help prevent relapse by reinforcing the benefits and rewards of quitting, inquiring how patients feel about their progress to date, identifying problems, and promoting self-management.

Patient-specific, relapse-prevention strategies may address lack of support for cessation, negative mood or depression, strong or prolonged withdrawal symptoms, weight gain, reduction in motivation, and increased desire for nicotine. Assess the severity of these concerns, and approach them as part of the withdrawal process. Provide behavioral or pharmacologic interventions to reduce the severity of these concerns. Management of these topics is detailed in the PHS guideline.⁵

Recommended changes to the healthcare system to support smoking cessation

Multiple system changes are recommended by the guideline panel for insurance providers and health system administrators to effect policy change and provide resources to support smoking-cessation efforts:

- implement a system to identify the level of tobacco use and dependence of all patients at each clinical visit;
- provide education, resources, and feedback to promote provider intervention;
- dedicate staff at multiple levels to providing tobacco-dependency treatment;

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- develop hospital policies that support treatment of tobacco dependency;
- make counseling and pharmacotherapy for nicotine dependency covered services for all subscribers to all health insurance plans; and
- reimburse clinicians for treating patients with tobacco dependency.

As more of the recommendations from the PHS guideline are adopted by insurance carriers, the more likely patients will be to request and use tobacco-cessation services. What seems like a simple intervention (eg, identification of tobacco-use status) triples the odds ratio of clinician intervention and doubles abstinence rates compared with control groups treated by clinicians who do not systematically identify patient tobacco-use status.⁵

Comment

All clinicians—not just primary care physicians—need to identify and evaluate every tobacco-dependent patient to more consistently provide treatment, motivation to quit, or referral to cessation specialists. The PHS Clinical Practice Guideline *Treating Tobacco Use and Dependence* characterizes nicotine dependency as a chronic disease that needs to be addressed in a focused, organized, and comprehensive fashion. Clinicians now have evidence-based tools to treat patients more effectively for tobacco use and dependence.

The full text of the PHS guideline and the meta-analysis reference for online retrieval are available on the “Tobacco Cessation Guideline” Web site of the Office of the Surgeon General, Office of Public Health and Science, US Department of Health and Human Services at: <http://www.surgeongeneral.gov/tobacco/default.htm>.

Single copies of the PHS guideline and derivative products can be obtained by calling the toll-free numbers for the resources listed in *Figure 5*.

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