A Clinical Practice Guideline for Treating Tobacco Use and Dependence

A US Public Health Service Report

The Tobacco Use and Dependence Clinical Practice Guideline Panel, Staff, and Consortium Representatives

Objective To summarize the recently published US Public Health Service report *Treating Tobacco Use and Dependence: A Clinical Practice Guideline,* which provides recommendations for brief clinical interventions, intensive clinical interventions, and system changes to promote the treatment of tobacco dependence.

Participants An independent panel of 18 scientists, clinicians, consumers, and methodologists selected by the US Agency for Healthcare Research and Quality. A consortium of 7 governmental and nonprofit organizations sponsored the update.

Evidence Approximately 6000 English-language, peer-reviewed articles and abstracts, published between 1975 and 1999, were reviewed for data that addressed assessment and treatment of tobacco dependence. This literature served as the basis for more than 50 meta-analyses.

Consensus Process One panel meeting and numerous conference calls and staff meetings were held to evaluate meta-analytic and other results, to synthesize the results, and to develop recommendations. The updated guideline was then externally reviewed by more than 70 experts and revised.

Conclusions This evidence-based, updated guideline provides specific recommendations regarding brief and intensive tobacco cessation interventions as well as system-level changes designed to promote the assessment and treatment of tobacco use. Brief clinical approaches for patients willing and unwilling to quit are described. Major conclusions and recommendations include: (1) Tobacco dependence is a chronic condition that warrants repeated treatment until long-term or permanent abstinence is achieved. (2) Effective treatments for tobacco dependence exist and all tobacco users should be offered those treatments. (3) Clinicians and health care delivery systems must institutionalize the consistent identification, documentation, and treatment of every tobacco user at every visit. (4) Brief tobacco dependence treatment is effective, and every tobacco user should be offered at least brief treatment. (5) There is a strong dose-response relationship between the intensity of tobacco dependence counseling and its effectiveness. (6) Three types of counseling were found to be especially effective—practical counseling, social support as part of treatment, and social support arranged outside of treatment. (7) Five first-line pharmacotherapies for tobacco dependence—sustained-release bupropion hydrochloride, nicotine gum, nicotine inhaler, nicotine nasal spray, and nicotine patch—are effective, and at least 1 of these medications should be prescribed in the absence of contraindications. (8) Tobacco dependence treatments are cost-effective relative to other medical and disease prevention interventions; as such, all health insurance plans should include as a reimbursed benefit the counseling and pharmacotherapeutic treatments identified as effective in the updated guideline.

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PRIMARY CARE CLINICIANS, tobacco dependence treatment specialists, and health care administrators, insurers, and purchasers now have an unprecedented opportunity to reduce tobacco use rates in the United States and consequently the burden of illness, death, and economic cost resulting from tobacco use. This opportunity is the result of an unusual confluence of circumstances: 70% of smokers now want to quit smoking completely, and 46% try to quit each year[1]; more than 70% of smokers visit a health care setting each year[2-4]; and effective treatments now exist.

Indeed, these circumstances challenge clinicians and health care delivery systems to fulfill the mandate of an unspoken contract regarding health care—to provide patients with effective interventions that will prevent needless illness and death. Both clinicians and health care delivery systems are at risk of breaking this fundamental contract. Currently, neither ensures that smokers consistently receive effective tobacco interventions. Therefore, most smokers trying to quit do so on their own, without the benefit of highly effective treatments. The health care system's neglect of the tobacco user exacts costs that sum to thousands of lives and billions of dollars in added health care expenditures each year.

Panel, Staff, and Consortium Representatives and Financial Disclosures are listed at the end of this article.
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In the past, a failure to intervene with tobacco users could have been attributed to a lack of effective treatments. The last 2 decades, however, have witnessed an explosion in research that has clarified the nature of tobacco dependence as a chronic disease, the addictive nature of nicotine, and the availability of numerous, effective pharmacotherapeutic and counseling strategies for tobacco dependence. Some of these findings led to the release of the Agency for Health Care Policy and Research Smoking Cessation Clinical Practice Guideline in 1996.[5] The development of new treatments since that time now warrants an update of that original guideline.

BACKGROUND

In 1998, a consortium of 7 governmental and nonprofit organizations agreed to sponsor an update to the original Smoking Cessation Clinical Practice Guideline, which was based on a review of published literature through 1994. These agencies—the US Agency for Healthcare Research and Quality; the Office on Smoking and Health at the Centers for Disease Control and Prevention; the National Cancer Institute; the National Institute on Drug Abuse; the National Heart, Lung, and Blood Institute; the Robert Wood Johnson Foundation; and the University of Wisconsin Medical School's Center for Tobacco Research and Intervention—reconvened the original expert panel to examine the tobacco dependence treatment literature published through 1999. Given the importance of this issue to the health of all Americans, the updated guideline has been published as a United States Public Health Service Report.[6]

The updated clinical practice guideline, *Treating Tobacco Use and Dependence*, is a product of the 18-member Tobacco Use and Dependence Clinical Practice Guideline Panel, consortium representatives, consultants, and staff. These groups comprise more than 30 individuals charged with the responsibility of identifying effective, experimentally validated tobacco dependence treatments and practices. This article summarizes the key recommendations of the updated guideline and highlights differences between the original and updated guidelines. This article is intended to serve as a primer for effective clinic-based tobacco intervention treatments. Readers interested in more details regarding the literature review, data analytic methods, and the consensus process may refer to the updated guideline,[6] which is also located on the Agency for Healthcare Research and Quality Web site (http://www.ahrq.gov). Both this article and the updated guideline target 3 principal audiences: the broad range of primary care clinicians for whom tobacco dependence treatment is just 1 of many activities; tobacco dependence treatment specialists for whom the treatment of tobacco use is a major professional activity; and health care administrators, insurers, and purchasers who have the capacity to implement systems changes that support and encourage tobacco dependence treatments, including reimbursing for these cost-effective treatments.

An overarching theme of the updated guideline is the need to coordinate care among the 3 audiences. Although some particular interventions may be more relevant for certain audiences, all audiences should be aware of and implement, where possible, the full range of effective treatments. Therefore, the updated guideline dissociates the intervention strategies from audience type. Major intervention categories outlined in the updated guideline are brief interventions, intensive interventions, and systems interventions.

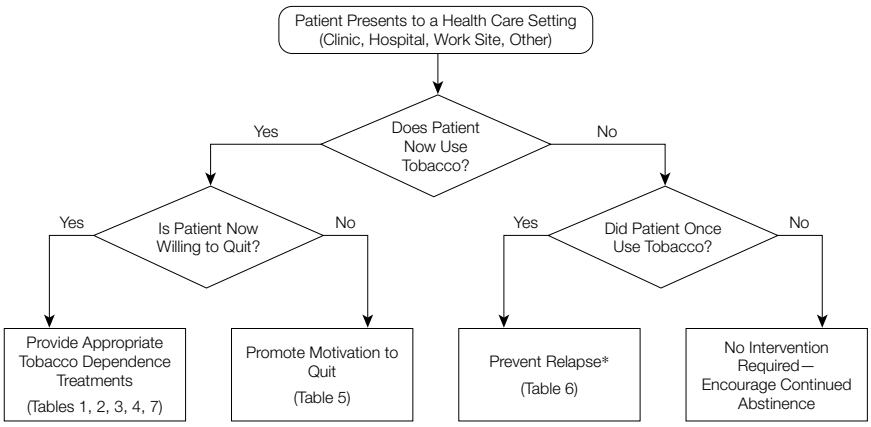
One notable change in the updated clinical practice guideline is that the new title, *Treating Tobacco Use and Dependence*, underscores 3 truths about tobacco use.[7] First, all tobacco products, not just cigarettes, exact devastating costs on the nation's health and welfare. Second, for most users, tobacco use results in true drug dependence, one comparable to the dependence caused by opiates, amphetamines, and cocaine. Third, chronic tobacco use warrants repeated clinical intervention just as do other addictive disorders.

Overview of Guideline Development Procedures

The updated guideline is intended to identify empirically based and validated assessments and treatments for tobacco dependence. The principal steps in the guideline development were similar for both the original and the updated guidelines.

The guideline panel, aided by additional experts in the field, formulated clinically significant questions to be addressed in literature reviews and analyses. Approximately 6000 research articles and abstracts, including 3000 from the original guideline, were reviewed to identify studies appropriate for evaluation. Articles that were relevant were coded for possible use in meta-analyses if they: (1) reported the results of a placebo/comparison-controlled trial evaluating a tobacco use assessment or treatment randomized on the patient level; (2) provided follow-up results at least 5 months after the quit date; (3) were published in a peer-reviewed journal; (4) were published between January 1, 1975, and January 1, 1999; and (5) were published in English. Three independent raters coded features of all articles accepted for possible use in the meta-analyses. Where possible, efficacy analyses used point-prevalence abstinence data that reflected the intent-to-treat principle. Except for pregnancy studies, all follow-up data reflected smoking status at least 5 months following the quit day and included both biochemically confirmed and self-reported data. Pregnancy analyses used preparturition outcomes and data that were exclusively biochemically confirmed. Random-effects logistic regression was used for meta-analysis. Between the original and updated guidelines, many analyses were repeated, but with updated data sets. New studies were added, and a careful application of screening criteria resulted in the exclusion of a small number of studies that had been included in the original guideline analyses. In general, meta-analytic findings were consistent

Figure. Algorithm for Treating Tobacco Use



*Relapse prevention interventions are not necessary in the case of the adult who has not used tobacco for many years.

across the original and updated guidelines. Overall, more than 50 separate meta-analyses were conducted in the preparation of the updated guideline. A listing of the articles used in the meta-analyses can be found on the Agency for Healthcare Research and Quality Web site.

The results of the new meta-analyses and other relevant data (eg, meta-analyses from the original guideline, other published meta-analyses, background, and review articles), were presented to the guideline panel, who examined the findings and made requests for additional data and analyses as needed. The guideline panel generated consensus recommendations from the findings and assigned strength-of-evidence ratings to each recommendation. Ratings reflected the quality and amount of evidence supporting a recommendation and can be found in the updated guideline.

A draft of the updated clinical practice guideline, *Treating Tobacco Use and Dependence,* was reviewed by more than 70 external experts in the field of tobacco research and treatment and was modified accordingly.

Tobacco Use as a Treatable Chronic Disease

Tobacco dependence has many features typical of a chronic disease. While a minority of tobacco users achieve permanent abstinence in an initial quit attempt, the majority persist in tobacco use for many years and typically cycle through multiple periods of relapse and remission. A failure to appreciate the chronic nature of tobacco dependence may undercut clinicians' motivation to treat tobacco use consistently. If tobacco dependence is recognized as a chronic condition, clinicians will better understand the relapsing nature of the ailment and the requirement for ongoing care. As with chronic diseases such as diabetes, hypertension, or hyperlipidemia, clinicians encountering a patient dependent on tobacco must provide that patient with simple counseling advice, support, and appropriate pharmacotherapy. Finally, clinicians should recognize that relapse is common and that it reflects the chronic nature of dependence, not their own or their patients' failure.

While tobacco use can be a chronic condition, the updated guideline analyses reveal that it can be treated effectively. Although only about 7% of smokers achieve long-term success when trying to quit on their own, updated guideline analyses revealed that success rates can be increased to 15% to 30% by using guideline-recommended treatments. The most effective treatments were intensive counseling and pharmacotherapies. However, even brief treatments such as physician advice to quit can increase abstinence rates significantly.

Moreover, the data document that the full range of interventions is cost-effective. Over time, people who successfully quit use fewer health care resources. In addition, many of the treatments are reimbursable, providing an additional incentive for individual physicians to provide treatment.

KEY GUIDELINE RECOMMENDATIONS

Assessing Tobacco Use

The first step in treating tobacco use and dependence is to identify tobacco users. At least 70% of smokers visit a physician each year, more than 50% visit a dentist, and many visit other clinicians.[2-4] Therefore, clinicians are well positioned to intervene with patients who use tobacco. Effective identification of tobacco use status not only opens the door for successful interventions (eg, physician advice), but it guides clinicians to identify appropriate interventions based on patients' tobacco use status and willingness to quit. Finally, smokers cite a physician's advice to quit as an important motivator for attempting to stop smoking. Screening methods along with brief interventions are presented in the FIGURE and in TABLE 1.

Brief Clinical Interventions

Brief interventions can be provided by any clinician but are most relevant to primary care clinicians who treat a wide variety of patients and face severe time constraints. The updated guideline analyses suggest that a wide variety of clinicians can effectively implement these strategies and that interventions as brief as 3 minutes can increase cessation rates significantly. In addition, the updated guideline recommends that these interventions be used with all populations, including adolescents, pregnant women, older smokers, and racial and ethnic minorities. However, special consideration should be given to the appropriateness of pharmacotherapy in certain populations (eg, those with medical contraindications, those smoking fewer than 10 ciga-

rettes per day, pregnant/breastfeeding women, and adolescent smokers). The goal is to ensure that every patient who uses tobacco is identified and offered at least a brief intervention at each clinical visit.

Brief interventions can be used with 3 types of patients: current tobacco users now willing to make a quit attempt; current tobacco users unwilling to make a quit attempt at this time; and former tobacco users who have recently quit.

Table 1. Brief Strategies to Help the Patient Willing to Quit Tobacco Use—The "5 As"

Action	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 vital signs to include tobacco use or use an alternative universal identification system. VITAL SIGNS Blood Pressure: _____ Pulse: _____ Weight: _____ Temperature: _____ Respiratory Rate: _____ Tobacco Use: Current Former Never (circle one) Alternatives to expanding the vital signs are to place tobacco-use status stickers on all patient charts or to indicate tobacco-use status using electronic medical records or computer reminder systems.
	Step 2: Advise—strongly urge all tobacco users to quit.
In a clear, strong, and personalized manner, urge every tobacco user to quit.	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 need 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/she is willing to make a quit attempt at this time (eg, within the next 30 days).	Assess patient's willingness to quit: If the patient is willing to make a quit attempt at this time, provide assistance. If the patient will participate in an intensive treatment, deliver such a treatment or refer to an intensive intervention. If the patient clearly states he/she is unwilling to make a quit attempt at this time, provide a motivational intervention. If the patient is a member of a special population (eg, adolescent, pregnant smoker, racial/ethnic minority), consider providing additional information.
	Step 4: Assist—aid the patient in quitting.
Help the patient with a quit plan.	A patient's preparations for quitting: *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 (eg, work, home, car).
Provide practical counseling (problem solving/skills training). (See Table 2)	*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 intratreatment social support. (See Table 2)	Provide a supportive clinical environment while encouraging the patient in his/her quit attempt. "My office staff and I are available to assist you."
Help patient obtain extratreatment social support. (See Table 2)	Help patient develop social support for his/her quit attempt in his/her environment 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. (See Tables 3 and 4)	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, nicotine gum, nicotine inhaler, nicotine nasal spray, and nicotine patch.
Provide supplementary materials.	*Sources*—Federal agencies, nonprofit agencies, or local/state health departments. *Type*—Culturally/racially/educationally/age-appropriate for the patient. *Location*—Readily available at every clinician's workstation.
	Step 5: Arrange—schedule follow-up contact.
Schedule follow-up contact, either in person or via telephone.	*Timing*—Follow-up contact should occur soon after the quit date, preferably during the first week. A second follow-up contact is recommended within the first month. Schedule further follow-up contacts as indicated. *Actions during follow-up 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 2. Common Elements of Effective Counseling and Behavioral Therapies for Smoking Cessation

Component	Examples
Practical Counseling (Problem Solving/Skills Training) Treatment	
Identify events, internal states, or activities that increase the risk of smoking or relapse.	Negative affect Being around other smokers Drinking alcohol Experiencing urges Being under time pressure
Identify and practice coping or problem-solving skills. Typically, these skills are intended to cope with dangerous situations.	Learning to anticipate and avoid temptation Learning cognitive strategies that will reduce negative moods Accomplishing lifestyle changes that reduce stress, improve quality of life, or produce pleasure Learning cognitive and behavioral activities to cope with smoking urges (eg, distracting attention)
Provide basic information about smoking and successful quitting.	The fact that any smoking (even a single puff) increases the likelihood of full relapse Withdrawal typically peaks within 1-3 weeks after quitting Withdrawal symptoms include negative mood, urges to smoke, and difficulty concentrating The addictive nature of smoking
Intratreatment Supportive Interventions	
Encourage the patient in the quit attempt.	Note that effective tobacco dependence treatments are now available Note that half of all people who have ever smoked have now quit Communicate belief in patient's ability to quit
Communicate caring and concern.	Ask how patient feels about quitting Directly express concern and willingness to help Be open to the patient's expression of fears of quitting, difficulties experienced, and ambivalent feelings
Encourage the patient to talk about the quitting process.	Ask about: Reasons the patient wants to quit Concerns or worries about quitting Success the patient has achieved Difficulties encountered while quitting
Extratreatment Supportive Interventions	
Train patient in support-solicitation skills.	Show videotapes that model support skills Practice requesting social support from family, friends, and coworkers Aid patient in establishing a smoke-free home
Prompt support seeking.	Help patient identify supportive others Call patient to remind him/her to seek support Inform patients of community resources such as hotlines/helplines
Clinician arranges outside support.	Mail letters to supportive others Call supportive others Invite others to cessation sessions Assign patients to be "buddies" for one another

Adults who have never used tobacco or who have been abstinent for an extended period do not require intervention.

For the Patient Willing to Quit. Given that so many tobacco users visit a primary care clinician each year, it is important that these clinicians be prepared to intervene with tobacco users who are willing to quit. The 5 major steps (the "5 As") to intervention in the primary care setting are: (1) *ask* the patient if he or she uses tobacco; (2) *advise* him or her to quit; (3) *assess* willingness to make a quit attempt; (4) *assist* those who are willing to make a quit attempt; and (5) *arrange* for follow-up contact to prevent relapse (Table 1). These strategies are designed to be brief, requiring 3 minutes or less of direct clinician time. Office systems that institutionalize tobacco use assessment and intervention will foster the adoption of these strategies. These strategies are consistent with those of the National Cancer Institute,[8,9] the American Medical Association,[10] and others.

The updated guideline urges clinicians to provide both counseling and pharmacotherapy for every patient making a quit attempt. The 3 recommended components of counseling (practical counseling, intratreatment social support, and extratreatment social support) are described in TABLE 2. In addition to counseling, all smokers making a quit attempt should receive pharmacotherapy, except in cases in which pharmacotherapy use requires special consideration (eg, those with medical contraindications, those smoking fewer than 10 cigarettes per day, pregnant/breastfeeding women, and adolescent smokers). TABLE 3 describes general pharmacotherapy guidelines for smoking cessation and TABLE 4 provides prescribing instructions for specific medications.

For the Patient Unwilling to Make a Quit Attempt at This Time. For patients not ready to make a quit attempt, clinicians should provide a brief intervention designed to promote the motivation to quit. Patients unwilling to make a quit attempt during a visit may lack information about the harmful effects of tobacco, may lack the required financial resources, may have fears or concerns about quitting, or may be demoralized because of previous relapse.[11] Such patients may respond to a motivational intervention designed to educate, reassure, and motivate. TABLE 5 outlines the components of such a motivational intervention built around the "5 Rs": *relevance*, *risks*, *rewards*, *roadblocks*, and *repetition*. Evidence suggests motivational interventions are most likely to be successful when the clinician is empathic, promotes patient autonomy (eg, choice among options), avoids arguments, and supports the patient's self-efficacy (eg, by identifying previous successes in efforts to change behavior).[12-14]

For the Patient Who Has Recently Quit. Because of the chronic relapsing nature of tobacco dependence, clinicians should provide brief relapse prevention treatment for recent quitters. When clinicians encounter such a patient, they should reinforce the patient's decision to quit, review the benefits of quitting, and assist the patient

in resolving any residual problems arising from quitting. Although most relapse occurs early in the quitting process,[15-17] some relapse occurs months or even years after the quit date.[18,19]

Relapse prevention interventions are especially important soon after quitting and can be delivered by means of either scheduled clinic visits, telephone calls, or any time the clinician encounters an ex–tobacco user. A systematic, institutionalized mechanism to identify recent quitters and contact them is essential to deliver relapse prevention messages effectively. Relapse prevention interventions can be divided into 2 categories: minimal practice for all quitters, and prescriptive interventions for patients with problems maintaining abstinence (TABLE 6).

Intensive Clinical Interventions

Intensive tobacco dependence treatment can be provided by any trained clinician who has the resources available to provide intensive interventions. There is substantial evidence that more intensive interventions produce higher success rates and are more cost-effective than less-intensive interventions. Therefore, intensive interventions are appropriate for any tobacco user willing to participate in them and should not be limited to any subpopulation of tobacco users (eg, heavily dependent smokers).[20] TABLE 7 lists components of an intensive intervention.

Systems Interventions

An increasing number of Americans receive their health care in managed care settings. As a consequence, agents such as health system administrators, insurers, and health care purchasers now play an expanded role in the delivery of health care to most Americans. For example, managed care organizations and other insurers influence medical care through restrictive formularies, performance feedback to clinicians, and marketing approaches that prompt patient demand for particular services.

Table 3. General Clinical Guidelines for Prescribing Pharmacotherapy for Smoking Cessation*

Who should receive pharmacotherapy for smoking cessation?	All smokers trying to quit except in the presence of special circumstances. Special consideration should be given before using pharmacotherapy with selected populations: those with medical contraindications, those smoking fewer than 10 cigarettes/day, pregnant/breastfeeding women, and adolescent smokers.
What are the first-line pharmacotherapies recommended in the updated guideline?	All 5 of the FDA-approved pharmacotherapies for smoking cessation are recommended, including sustained-release bupropion hydrochloride, nicotine gum, nicotine inhaler, nicotine nasal spray, and the nicotine patch.
What factors should a clinician consider when choosing among the 5 first-line pharmacotherapies?	Because of the lack of sufficient data to rank-order these 5 medications, choice of a specific first-line pharmacotherapy must be guided by factors such as clinician familiarity with the medications, contraindications for selected patients, patient preference, previous patient experience with a specific pharmacotherapy (positive or negative), and patient characteristics (eg, history of depression, concerns about weight gain).
Are pharmacotherapeutic treatments appropriate for lighter smokers (eg, 10-15 cigarettes/day)?	If pharmacotherapy is used with lighter smokers, clinicians should consider reducing the dose of first-line NRT pharmacotherapies. No adjustments are necessary when using sustained-release bupropion hydrochloride.
What second-line pharmacotherapies are recommended in the updated guideline?	Clonidine hydrochloride and nortriptyline hydrochloride
When should second-line agents be used for treating tobacco dependence?	Consider prescribing second-line agents for patients unable to use first-line medications because of contraindications or for patients for whom first-line medications are not helpful. Monitor patients for the known adverse effects of second-line agents.
Which pharmacotherapies should be considered with patients particularly concerned about weight gain?	Sustained-release bupropion hydrochloride and nicotine replacement therapies, in particular nicotine gum, have been shown to delay but not prevent weight gain.
Are there pharmacotherapies that should be especially considered in patients with a history of depression?	Sustained-release bupropion hydrochloride and nortriptyline hydrochloride appear to be effective with this population.
Should nicotine replacement therapies be avoided in patients with a history of cardiovascular disease?	No. The nicotine patch in particular is safe and has been shown not to cause adverse cardiovascular effects. However, the safety of these products has not been established for the immediate post-MI period or in patients with severe or unstable angina.
May tobacco dependence pharmacotherapies be used long-term (eg, 6 months or more)?	Yes. This approach may be helpful with smokers who report persistent withdrawal symptoms during the course of pharmacotherapy or who desire long-term therapy. A minority of individuals who successfully quit smoking use ad libitum NRT medications (gum, nasal spray, inhaler) long-term. The long-term use of these medications does not present a known health risk. Additionally, the FDA has approved the use of sustained-release bupropion hydrochloride for a long-term maintenance indication.
May pharmacotherapies ever be combined?	Yes. There is evidence that combining the nicotine patch with either nicotine gum or nicotine nasal spray increases long-term abstinence rates over those produced by a single form of NRT.†

*FDA indicates Food and Drug Administration; MI, myocardial infarction; and NRT, nicotine replacement therapy.
†This conclusion is based upon a meta-analysis in which each study compared a dual–NRT treatment condition with a single–NRT treatment condition.

These agents can also craft and implement systems, policies, and environmental prompts (eg, posters, clinician tear sheets, chart stickers, signs) that render tobacco use assessment and treatment an integral part of health care. Indeed, research has shown that systems-level change can increase utilization of tobacco dependence treatment and reduce smoking prevalence among enrollees of managed health care plans.[21]

Without supportive systems, policies, and environmental prompts, the individual clinician may not assess and treat tobacco use consistently. Therefore, just as clinicians must assume responsibility to treat their patients for tobacco use, so must health care administrators, insurers, and purchasers assume responsibility to craft policies, provide resources, and display leadership that results in consistent and effective tobacco use treatment. The updated guideline describes 6 strategies for systems-level interventions: (1) implement a tobacco user identifica-

Table 4. Suggestions for the Clinical Use of Pharmacotherapies for Smoking Cessation*

Pharmacotherapy	Precautions/ Contraindications	Adverse Effects	Dosage	Duration	Availability	Cost per Day
First-line						
Sustained-release bupropion hydrochloride	History of seizure History of eating disorders	Insomnia Dry mouth	150 mg every morning for 3 days then 150 mg twice daily (begin treatment 1-2 weeks prequit)	7-12 weeks maintenance up to 6 months	Prescription only	$3.33
Nicotine gum		Mouth soreness Dyspepsia	1-24 cigarettes/d: 2 mg gum (up to 24 pieces/d) ≥25 cigarettes/d: 4 mg gum (up to 24 pieces/d)	Up to 12 weeks	OTC only	$6.25 for 10 2-mg pieces $6.87 for 10 4-mg pieces
Nicotine inhaler		Local irritation of mouth and throat	6-16 cartridges/d	Up to 6 months	Prescription only	$10.94 for 10 cartridges
Nicotine nasal spray		Nasal irritation	8-40 doses/d	3-6 months	Prescription only	$5.40 for 12 doses
Nicotine patch		Local skin reaction Insomnia	21 mg/24 h 14 mg/24 h 7 mg/24 h	4 weeks then 2 weeks then 2 weeks	Prescription and OTC†	$4.22
			15 mg/16 h	8 weeks		$4.51
Second-line						
Clonidine	Rebound hypertension	Dry mouth Drowsiness Dizziness Sedation	0.15-0.75 mg/d	3-10 weeks	Prescription only (oral formulation) Prescription only (patch)	$0.24 for 0.2 mg $3.50
Nortriptyline	Risk of arrhythmias	Sedation Dry mouth	75-100 mg/d	12 weeks	Prescription only	$0.74 for 75 mg

*The information contained in this table is not comprehensive. Please see package inserts for additional information. Prices based on retail prices at a national chain pharmacy, located in Madison, Wis, April 2000. First-line pharmacotherapies have been approved for smoking cessation by the Food and Drug Administration; second-line pharmacotherapies have not. OTC indicates over the counter.
†Generic brands of the nicotine patch recently became available and may be less expensive.

Table 5. Enhancing Motivation to Quit Tobacco Use—The "5 Rs" for the Patient Unwilling to Quit at This Time

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 (eg, having children in the home), health concerns, age, sex, and other important patient characteristics (eg, 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. The clinician should emphasize that smoking low-tar/low-nicotine cigarettes or use of other forms of tobacco (eg, smokeless tobacco, cigars, and pipes) will not eliminate these risks. Examples of risks are: *Acute risks*: shortness of breath, exacerbation of asthma, harm to pregnancy, impotence, infertility, increased serum carbon monoxide levels *Long-term risks*: myocardial infarction and strokes, lung and other cancers (larynx, oral cavity, pharynx, esophagus, pancreas, bladder, cervix), chronic obstructive pulmonary diseases (chronic bronchitis and emphysema), long-term disability and need for extended care *Environmental risks*: increased risk of lung cancer and heart disease in spouses; higher rates of smoking by children of tobacco users; increased risk for low birth weight, sudden infant death syndrome, asthma, middle ear disease, and respiratory infections in children of smokers
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. Examples of rewards include: improved health; food will taste better; improved sense of smell; save money; feel better about yourself; home, car, clothing, and breath will smell better; can stop worrying about quitting; set a good example for children; have healthier babies and children; not worry about exposing others to smoke; feel better physically; perform better in physical activities; reduced wrinkling/aging of skin.
Roadblocks	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. Typical barriers might include: withdrawal symptoms, fear of failure, weight gain, lack of support, depression, enjoyment of tobacco.
Repetition	The motivational intervention should be repeated every time an unmotivated patient visits the clinical setting. Tobacco users who have failed in previous quit attempts should be told that most people make repeated quit attempts before they are successful.

tion system in every clinic (Table 1, Step 1); (2) provide education, resources, and feedback to promote provider intervention; (3) dedicate staff to provide tobacco dependence treatment and assess the delivery of this treatment in staff performance evaluations; (4) promote hospital policies that support and provide tobacco dependence services; (5) include tobacco dependence treatments (both counseling and pharmacotherapy) identified as effective in the updated guideline as paid or covered services for all subscribers or members of health insurance packages; and (6) reimburse clinicians and specialists for delivery of effective tobacco dependence treatments, and include these

Table 6. Components of Brief Strategies to Prevent Relapse to Tobacco Use

Minimal Practice Relapse Prevention	
These interventions should be part of every encounter with a patient who has recently quit.	Every ex–tobacco user undergoing relapse prevention should receive congratulations on any success and strong encouragement to remain abstinent. When encountering a recent quitter, use open-ended questions designed to initiate patient problem solving (eg, How has stopping tobacco use helped you?). The clinician should encourage the patient's *active* discussion of the topics below: The benefits, including potential health benefits, the patient may derive from cessation. Any success the patient has had in quitting (eg, duration of abstinence, reduction in withdrawal). The problems encountered or anticipated threats to maintaining abstinence (eg, depression, weight gain, alcohol, other tobacco users in the household).
Prescriptive Relapse Prevention	
Prescriptive relapse prevention components are individualized based on information obtained about problems the patient has encountered in maintaining abstinence. These more intensive relapse prevention interventions may be delivered during dedicated follow-up contact (in person or by telephone) or through a specialized clinic or program. Specific problems likely to be reported by patients and potential responses follow.	
Problem	**Responses**
Lack of support for cessation	Schedule follow-up visits or telephone calls with the patient. Help the patient identify sources of support within his/her environment. Refer the patient to an appropriate organization that offers cessation counseling or support.
Negative mood or depression	If significant, provide counseling, prescribe appropriate medications, or refer the patient to a specialist.
Strong or prolonged withdrawal symptoms	If the patient reports prolonged craving or other withdrawal symptoms, consider extending the use of an approved pharmacotherapy or adding/combining pharmacological medications to reduce strong withdrawal symptoms.
Weight gain	Recommend starting or increasing physical activity; discourage strict dieting. Reassure the patient that some weight gain after quitting is common and appears to be self-limiting. Emphasize the importance of a healthy diet. Maintain the patient on pharmacotherapy known to delay weight gain (eg, sustained-release bupropion hydrochloride and nicotine replacement therapies, particularly nicotine gum). Refer the patient to a specialist or program.
Flagging motivation/ feeling deprived	Reassure the patient that these feelings are common. Recommend rewarding activities. Probe to ensure that the patient is not engaged in periodic tobacco use. Emphasize that beginning to smoke (even a puff) will increase urges and make quitting more difficult.

Table 7. Components of an Intensive Smoking Cessation Intervention

Component	Strategy of Implementation
Assessment	Assessments should ensure that tobacco users are willing to make a quit attempt using an intensive treatment program. Other assessments can provide information useful in counseling (eg, stress level, presence of comorbidity).
Program clinicians	Multiple types of clinicians are effective and should be used. One counseling strategy would be to have a medical/health care clinician deliver messages about health risks and benefits and deliver pharmacotherapy and nonmedical clinicians deliver additional psychosocial or behavioral interventions.
Program intensity	Because of evidence of a strong dose-response relationship,* the program should consist of 4 or more sessions, with the longest session lasting longer than 10 minutes, for a total contact time longer than 30 minutes.
Program format	Either individual or group counseling may be used. Proactive telephone counseling is also effective. Use of adjuvant self-help material is optional. Follow-up assessment intervention procedures should be used.
Type of counseling and behavioral therapies	Counseling and behavioral therapies should involve practical counseling (problem solving/skills training) and intratreatment and extratreatment social support.
Pharmacotherapy	Every smoker should be encouraged to use pharmacotherapies endorsed in the updated guideline except in the presence of special circumstances. Special consideration should be given before using pharmacotherapy in selected populations (eg, pregnancy, adolescents) (see Table 3 for general clinical guidelines). The clinician should explain how these medications increase smoking cessation success and reduce withdrawal symptoms. The first-line pharmacotherapy agents include sustained-release bupropion hydrochloride, nicotine gum, nicotine inhaler, nicotine nasal spray, and the nicotine patch.
Population	Intensive intervention programs may be used with all tobacco users willing to participate in such efforts.

*This conclusion is based upon meta-analyses of studies in which subjects were randomly assigned to treatments of different intensities. Therefore, treatment intensity was not confounded with a subject's willingness/motivation to remain in treatment. Some studies in the meta-analyses compared active treatments of varying intensities while other studies compared only an active treatment with a control condition.

interventions among the defined duties of clinicians.

Clinician Training

Clinicians report the lack of relevant knowledge as a significant barrier to intervening with their patients who use tobacco.[22-25] The updated guideline, therefore, recommends that all clinicians and clinicians-in-training be trained in effective strategies to assist tobacco users to make a quit attempt and to motivate those who are unwilling to quit. A review of the published literature concluded that training appears to be most effective when coupled with other systems changes, such as clinic reminder systems and staff education. Training in tobacco use interventions should not only transmit essential treatment skills but also inculcate the belief that tobacco dependence treatment is a standard of good practice.[26]

Economic Aspects of Tobacco and Health Systems Interventions

Smoking cessation treatments ranging from brief clinician advice to specialist-delivered intensive programs are not only clinically effective but are also extremely cost-effective relative to other common disease prevention interventions and medical treatments, such as the treatment of hypertension and hypercholesterolemia, and preventive screening interventions, such as periodic mammography and Papanicolaou tests.[27-34] Treating tobacco dependence is particularly important economically, in that it can prevent a variety of costly chronic diseases and complications, such as heart disease, cancer, pulmonary disease, and delayed wound healing.

Smoking cessation treatments are also cost-effective in special populations such as hospitalized patients and pregnant women. For hospitalized patients, successful tobacco abstinence not only reduces general medical costs in the short-term but also reduces the number of future hospitalizations.[35] Smoking cessation interventions for pregnant women are especially favorable because they result in fewer low-birth-weight newborns and perinatal deaths; fewer physical, cognitive, and behavioral problems during infancy and childhood; and important health benefits for the woman.[36,37]

The failure of health plans or insurers to cover tobacco dependence treatment could reduce access to these services and reduce the number of people seeking these services. Moreover, the presence of prepaid or discounted prescription drug benefits increases patients' receipt of pharmacotherapy and smoking abstinence rates.[21,38-40] Therefore, the guideline suggests that those tobacco dependence treatments identified as effective in the updated guideline be a covered benefit of all insurance plans, both public and private.

Primary care clinicians frequently cite insufficient insurance reimbursement as a barrier to the provision of preventive services such as tobacco dependence treatment.[41] Therefore, the updated guideline suggests that sufficient resources should be allocated for clinician reimbursement and systems support to ensure the delivery of efficacious tobacco use treatments.

The provision of tobacco dependence treatment may also be increased by ensuring that health plan "report cards" (eg, the National Committee for Quality Assurance Health Plan Employer Data and Information Set)[42,43] support smoker identification and treatment and by mandating that the accreditation criteria used by Joint Commission on Accreditation of Healthcare Organizations and other accrediting bodies include an evaluation of the availability and utilization of effective tobacco assessment and intervention policies. To achieve this goal, interventions based on the updated guideline should be included in standard ratings and measures of overall health care quality (eg, the National Committee for Quality Assurance Health Plan Employer Data and Information Set and the Foundation for Accountability).

Guideline Recommendations Regarding Special Populations and Special Topics

The updated guideline addressed the treatment of tobacco use as it relates to special populations (such as women, pregnant smokers, racial and ethnic minorities, hospitalized smokers, smokers with comorbidity and/or chemical dependency, children and adolescents, and older smokers) and specific topics (such as weight gain after smoking cessation, and noncigarette tobacco products). Readers interested in a detailed discussion of these topics are referred to the updated guideline.

CONCLUSIONS

In summary, the updated Guideline Panel's major conclusions and recommendations are as follows:

1. Tobacco dependence is a chronic condition that often requires repeated intervention. However, effective treatments exist that can produce long-term or even permanent abstinence.

2. Because effective tobacco dependence treatments are available, every patient who uses tobacco should be offered at least one of these treatments: (a) Patients willing to try to quit tobacco use should be provided treatments identified as effective; (b) Patients unwilling to try to quit tobacco use should be provided a brief intervention designed to increase their motivation to quit.

3. It is essential that clinicians and health care delivery systems (including administrators, insurers, and purchasers) institutionalize the consistent identification, documentation, and treatment of every tobacco user seen in a health care setting.

4. Brief tobacco dependence treatment is effective, and every patient who uses tobacco should be offered at least brief treatment.

5. There is a strong dose-response relationship between the intensity of tobacco dependence counseling and its effectiveness. Treatments involving person-to-person contact (via individual, group, or proactive telephone counseling) are effective, and their effectiveness increases with treatment intensity (ie, session length, number of sessions, and total minutes of contact).

6. Three types of counseling and behavioral therapies were found to be es-

pecially effective and should be used with all patients attempting tobacco cessation: (a) provision of practical counseling (problem solving/skills training); (b) provision of social support as part of treatment (intratreatment social support); and (c) help in securing social support outside of treatment (extratreatment social support).

7. Numerous effective pharmacotherapies for smoking cessation now exist. Except in the presence of special circumstances, these should be used with all patients attempting to quit smoking. Special consideration should be given before using pharmacotherapy with selected populations: eg, those with medical contraindications, those smoking fewer than 10 cigarettes/day, pregnant/breastfeeding women, and adolescent smokers. Five first-line pharmacotherapies were identified that reliably increase long-term smoking abstinence rates: sustained-release bupropion hydrochloride, nicotine gum, nicotine inhaler, nicotine nasal spray, and the nicotine patch. Two second-line pharmacotherapies were identified as efficacious and may be considered by clinicians if first-line pharmacotherapies are not effective: clonidine hydrochloride and nortriptyline hydrochloride. Over-the-counter transdermal nicotine patches are effective relative to placebo, and their use should be encouraged.

8. Tobacco dependence treatments are both clinically effective and cost-effective relative to other medical and disease-prevention interventions. As such, insurers and purchasers should ensure that (a) all insurance plans include as a reimbursed benefit the counseling and pharmacotherapeutic treatments identified as effective in the updated guideline; and (b) clinicians are reimbursed for providing tobacco dependence treatment just as they are reimbursed for treating other chronic conditions.

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Research, though toilsome, is easy; imaginative vision, though delightful, is difficult.
—A. C. Bradley (1851-1935)