NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC) GUIDELINE SYNTHESIS

TOBACCO USE CESSATION

Guidelines

1. **Public Health Service (PHS)**. Treating tobacco use and dependence: 2008 update. Rockville (MD): 2008 May. 257 p.
2. **University of Michigan Health System (UMHS)**. Smoking cessation. Ann Arbor (Michigan): University of Michigan Health System, 2006. 12 p. [1 reference]
3. **Veterans Affairs, Department of Defense (VA/DoD)**. VA/DoD clinical practice guideline for the management of tobacco use. Washington (DC): Department of Veteran Affairs; 2004 Jun. 81 p.

INTRODUCTION

A direct comparison of the Public Health Service (PHS), University of Michigan Health System (UMHS), and Department of Veteran Affairs, Department of Defense (VA/DoD) recommendations for tobacco use cessation is provided in the tables below.

- Table 1 provides a quick-view glance at the primary interventions considered by each group.
- Table 2 provides a comparison of the overall scope of the guidelines.
- Table 3 provides a more detailed comparison of the specific recommendations offered by each group for the topics under consideration in this synthesis, including:
    - Initial Interventions
        - Screening for Tobacco Use
        - Advise Tobacco Users to Quit
        - Assess Willingness to Quit and Provide Motivational Strategies
    - Treatment
        - Referral and/or Determination of Treatment Plan
        - Counseling and Behavioral Therapies
        - Pharmacotherapy
        - Combined Behavioral and Pharmacological Interventions
    - Considerations in Special Populations
        - Pregnant Women
        - Children and Adolescents
        - Other Special Populations
    - Follow-Up
    - Patient Education
- Table 4 lists the potential benefits and harms associated with the implementation of each guideline as stated in the original guidelines.

- Table 5 presents the rating schemes used by the guideline groups to rate the level of evidence and/or the strength of the recommendations.

Following the tables and discussion of content comparison, the areas of agreement and areas of differences among the guidelines are identified.

Related Guideline

- New York State Department of Health. Smoking cessation in HIV-infected patients. New York (NY): New York State Department of Health; 2008 Feb. 5 p. [19 references].

Listed below are common abbreviations used within the tables and discussions:

- AHRQ, Agency for Healthcare Research and Quality
- DoD, Department of Defense
- ETS, environmental tobacco smoke
- FDA, Food and Drug Administration
- NRT, Nicotine replacement therapy
- PHS, Public Health Service
- SR, sustained release
- TTS, tobacco treatment specialist
- UMHS, University of Michigan Health System
- VA, Veterans Affairs

TABLE 1: COMPARISON OF INTERVENTIONS AND PRACTICES CONSIDERED
("✓" indicates topic is addressed)

	PHS (2008)	UMHS (2006)	VA/DoD (2004)
INITIAL INTERVENTIONS			
Screening for Tobacco Use	✓	✓	✓
Advise to Quit	✓	✓	✓
Assess Willingness to Quit and Provide Motivational Strategies	✓	✓	✓
TREATMENT			
Referral and/or Determination of Treatment Plan	✓	✓	✓
Counseling and Behavioral Therapies	✓	✓	✓

Pharmacotherapy	✓	✓	✓
Combined Counseling and Pharmacological Interventions	✓	✓	✓
CONSIDERATIONS IN SPECIAL POPULATIONS			
Pregnant Smokers	✓	✓	✓
Children and Adolescents	✓	✓	✓
Other Special Populations	✓	✓	✓
FOLLOW-UP	✓	✓	✓
PATIENT EDUCATION	✓	✓	✓

TABLE 2: SCOPE	
Objectives	
PHS (2008)	• To provide evidence-based recommendations along with a simple and flexible set of strategies that ensure that all patients who use tobacco are offered motivational interventions and effective treatments to overcome tobacco addiction • To include new effective clinical treatments for tobacco dependence that have become available since the 2000 guideline was published
UMHS (2006)	• To provide a systematic framework for care providers to assist patients in smoking cessation
VA/DoD (2004)	• To assist providers and tobacco specialists in delivering more effective treatments that reduce the prevalence of tobacco use among the beneficiaries of the Veterans Health Administration and the Department of Defense • To assist patients to quit using tobacco and, therefore, improve clinical outcomes
Target Population	
PHS	• United States

(2008)	• Tobacco users
UMHS (2006)	• United States • The guideline focuses on adult and adolescent smokers with consideration for special populations (e.g., pregnant and breastfeeding patients, racial and ethnic minorities, patients with psychiatric co-factors, non-cigarette tobacco users, gender concerns, older smokers, hospitalized smokers).
VA/DoD (2004)	• United States • Any person (age greater than 12 years) who is eligible for care in the Veterans Health Administration or the Department of Defense health care delivery system (including adults, and students in elementary and middle schools)
Intended Users	
PHS (2008)	Advanced Practice Nurses Allied Health Personnel Dentists Health Plans Hospitals Managed Care Organizations Nurses Pharmacists Physical Therapists Physician Assistants Physicians Psychologists/Non-physician Behavioral Health Clinicians Public Health Departments Respiratory Care Practitioners Substance Use Disorders Treatment Providers
UMHS (2006)	Health Care Providers Physicians
VA/DoD (2004)	Advanced Practice Nurses Allied Health Personnel Physician Assistants Physicians Psychologists/Non-physician Behavioral Health Clinicians Students

TABLE 3: RECOMMENDATIONS FOR TOBACCO USE CESSATION AND PREVENTION	
INITIAL INTERVENTIONS	
Screening for Tobacco Use	
PHS (2008)	*Screen for Tobacco Use* All patients should be asked if they use tobacco and should have their tobacco-use status documented on a regular basis. Evidence has shown that clinic screening systems, such as expanding the vital signs to include tobacco use status or the use of other reminder systems such as chart stickers or computer prompts, significantly increase rates of clinician intervention. **(Strength of Evidence = A)**
UMHS (2006)	**Key Points** **ASK** all patients about smoking status and assess smoker's readiness to quit. Smoking status should be documented in the medical record. **Rationale for Recommendations** All patients should be asked about their smoking status and assessed for their willingness to quit (see Table 1 in the original guideline document). If a patient smokes, this should be documented in the medical record so that intervention can be offered. Techniques to remind the physician of a patient's smoking status include smoking status stickers, listing tobacco use on active problem list of tobacco status as part of vital signs.
VA/DoD (2004)	**Ask About Tobacco Use** Patients should be asked about tobacco use at most visits, as repeated screening increases rates of clinical intervention. **[A]** • Screening for tobacco use in primary care should occur at least three times/year. **[Expert Consensus]** • Screening for tobacco use by other specialties or disciplines should be done at least once per year. **[Expert Consensus]** • Screening adolescents should include assessment of environmental tobacco exposure. *Background*. In order to assess tobacco use status, all patients should be asked about their use of tobacco (including the use of tobacco in any form) upon visiting any provider. This may be accomplished when the patient's vital signs are taken. The tobacco use status should be

	noted in the patient's record. If the medical record indicates that the patient has never used tobacco or has not used it for many years, repeated assessment is not necessary.
Advise Tobacco Users to Quit	
PHS (2008)	*Advice to Quit Smoking* All physicians should strongly advise every patient who smokes to quit because evidence shows that physician advice to quit smoking increases abstinence rates. **(Strength of Evidence = A)**
UMHS (2006)	**Key Points** **ADVISE** all smokers to seriously consider making a quit attempt using a clear, strong, and personalized message. Advice as brief as 3 minutes is effective in smoking cessation ***[A]***. **Rationale for Recommendations** Brief clinician advice should be offered to the patient, including a personalized message as to why it is important to quit smoking now. Patients should then be asked about their willingness to quit smoking in the next month.
VA/DoD (2004)	**Advise to Quit** • Tobacco users should be advised to quit at every visit because there is a dose-response relationship between number of contacts and abstinence. **[A]** • Physicians should strongly advise tobacco users to quit, as physician advice increases abstinence rates. **[A]** • Health care team members should strongly advise all tobacco users to quit. **[B]** *Background*. Every health care team member should urge every tobacco user to quit. Repeated messages on the importance of quitting made over time have an accumulated effect on encouraging patients to quit. This message should be delivered in the brief "advice" format such that it is clear, (e.g., "I think it is important for you to quit tobacco use now and I can help you."), concise, strong, (e.g., "As your clinician I want you to know that quitting tobacco use is the most important thing you could do to protect your health.") and personalized (e.g., "Quitting your tobacco use will help improve your [health symptom or specific disease]").
Assess Willingness to Quit and Provide Motivational Strategies	

PHS (2008)	*Specialized Assessment* Once a tobacco user is identified and advised to quit, the clinician should assess the patient's willingness to quit at this time. **(Strength of Evidence = C)** • If the patient is willing to make a quit attempt at this time, interventions identified as effective in this Guideline should be initiated. (see Chapter 3A and 4 in the original guideline document) • If the patient is unwilling to quit at this time, an intervention designed to increase future quit attempts should be provided. (see Chapter 3B in the original guideline document) Tobacco dependence treatment is effective and should be delivered even if specialized assessments are not used or available. **(Strength of Evidence = A)** *For Smokers Not Willing To Make a Quit Attempt At This Time* Motivational intervention techniques appear to be effective in increasing a patient's likelihood of making a future quit attempt. Therefore, clinicians should use motivational techniques to encourage smokers who are not currently willing to quit to consider making a quit attempt in the future. **(Strength of Evidence = B)**
UMHS (2006)	**ASSESS** all smokers' willingness to make a quit attempt. If not yet ready to quit, offer motivational intervention using the 5 "R's": • **R**elevance of quitting: impact of smoking on current health/illness and/or on children and others in household; social and economic costs of tobacco use • **R**isks of tobacco use: potential negative consequences of smoking • **R**ewards of quitting: improved health, improved taste, money saved, healthier children, freedom from addiction • **R**oadblocks to quitting: patient-identified barriers to quitting smoking • **R**epetition: above strategies are repeated every time an unmotivated patient has a visit
VA/DoD (2004)	**Assess Willingness to Quit** Tobacco users should be assessed for willingness to quit at every visit. **[C]** • Willingness to quit should be assessed at least three times/year. **[Expert Consensus]** *Background*. Tobacco users should be given advice appropriate to

	their level of interest in quitting. Approximately 70 percent of tobacco users want to quit. The patient's level of interest will determine subsequent steps to be taken. By knowing the person's stage of willingness to quit tobacco use, the health care provider can decide whether to provide motivational material to quit tobacco use or, alternatively, specific instructions to help the person quit. **Promote Motivation to Quit** Tobacco users who are not willing to quit at this time should receive brief, non-judgmental motivational counseling designed to increase their motivation to quit, to include discussion about **[Expert Consensus]:** • **R**elevance: connection between tobacco use and current symptoms, disease, and medical history • **R**isks: risks of continued tobacco use and tailor the message to individual risk/relevance of cardiovascular disease or exacerbation of preexisting disease • **R**ewards: potential benefits for quitting tobacco use to their medical, financial, and psychosocial well-being • **R**oadblocks: barriers to quitting and discuss options and strategies to address patient's barriers • **R**epetition: Reassess willingness to quit at subsequent visits; repeat intervention for unmotivated patients at every visit. Use of motivational intervention should be considered. This technique has been shown to be beneficial in motivating and changing behaviors of individuals with other substance use dependencies, including some evidence in cessation of smoking. **[B]**
TREATMENT	
Referral and/or Determination of Treatment Plan	
PHS (2008)	No specific recommendations offered.

UMHS (2006)	**REFER** patients interested in quitting within 30 days to a tobacco treatment specialist or other appropriate tobacco cessation program. Alternatively, health care providers can directly provide the following treatment:
	
	Treatment Options
	
	• **ASSIST** those ready to make a quit attempt:
	  • Set a quit date. Quit date abstinence is a strong predictor of long-term success ***[C]***.
	  • Give advice on quitting and provide supplementary materials.

	• Prescribe pharmacologic therapy as appropriate. Nicotine replacement therapies, bupropion hydrochloride, and varenicline have been proven effective ***[A]***. • **ARRANGE** follow-up either with phone call or office visit. • Prevent relapse by congratulating successes and reinforcing reasons for quitting. • Assess any difficulties with pharmacologic therapy. **Rationale for Recommendations** <u>Refer</u> If patients are willing to make a quit attempt, the clinician has two options. The first option is to refer the patient to a Tobacco Treatment Specialist (TTS) or other appropriate tobacco cessation program. A TTS is a trained health professional who specializes in the treatment of tobacco dependence as part of his or her professional role. The TTS demonstrates the knowledge and skills to provide effective and evidence-based treatment for tobacco dependence. The TTS also serves as a resource and consultant to other healthcare professionals. The TTS can also provide the most effective and appropriate treatment to special populations (e.g. patients with a variety of co-morbidities, chemical dependency, or pregnancy). Many health care organizations have a TTS on staff. Local tobacco treatment specialists can be identified by state tobacco control agencies or through the Association for Treatment of Tobacco Use and Dependence (www.attud.org). Many national organizations such as the American Cancer Society and American Lung Association offer tobacco cessation programs. Listings of local programs can often be obtained through state and local health departments. The second option is to treat the patient. Several factors make health care settings ideal for delivery of smoking cessation interventions. As stated above, at least 70% of smokers see a physician each year. As many as 70% of these smokers report a desire to quit and have made at least one serious quit attempt. Smokers also report that advice from a clinician is an important motivator to quit.
VA/DoD (2004)	**Educate about Treatment Options; Arrive at Shared Decision for Choice of Treatment; Determine and Document Treatment Plan** Providers and patients should discuss the range of available treatment options and arrive at a mutually agreeable treatment plan. Discussion should address **[Expert Consensus]**: • Individually relevant information regarding effectiveness, availability, suitability, and contraindications of different treatment options • Patient's individual preferences and concerns about the treatment

options/combinations
- Tailoring treatment for patients with special needs (pregnancy, adolescents, comorbid conditions)
- Choosing the most intensive treatment option that the patient is willing to use/attend

Patient education and a treatment plan should be documented in the patient's record. **[Expert Consensus]**

Assist Tobacco User to Quit

All tobacco users who are willing to quit should be offered an effective tobacco cessation intervention, including:

- Pharmacotherapy
- Counseling
- Follow-up

All tobacco users must have reasonable access to minimal counseling and to either an intermediate or intensive cessation program. **[A]**

Cessation treatment may include the following components:

- Tobacco use cessation pharmacotherapy **[A]**
- Counseling techniques that have been shown to be effective (problem solving, skill training, intra and extra treatment support) **[A]**
- Multiple treatment sessions **[A]**
- Multiple formats, proactive telephone counseling, and group or individual counseling **[A]**
- Multiple types of counselors (e.g., physicians, psychologists, nurses, pharmacists, health educators) **[B]**

Aversive smoking interventions (rapid smoking, rapid puffing, other aversive smoking techniques) increase abstinence rates and may be used with smokers who desire such treatment or who have been unsuccessful using other interventions. **[B]** Although aversive smoking has been demonstrated to be effective, it is rarely used due to the availability of medication.

There is insufficient evidence to recommend for or against the use of the following interventions:

- Acupuncture **[C]**
- Hypnosis **[C]**
- Physiological feedback and restricted environmental stimulation therapy **[C]**
- "Harm reduction" products **[C]**

There is insufficient evidence to support the following strategies:

	relaxation/breathing, contingency contracting, weight/diet, cigarette fading, exercise, and negative effect. Exercise may be considered to help prevent the weight gain associated with tobacco cessation. **[I]**
Counseling and Behavioral Therapies	
PHS (2008)	**Treatment Structure and Intensity** *Intensity of Clinical Interventions* Minimal interventions lasting less than 3 minutes increase overall tobacco abstinence rates. Every tobacco user should be offered at least a minimal intervention, whether or not he or she is referred to an intensive intervention. **(Strength of Evidence = A)** There is a strong dose-response relation between the session length of person-to-person contact and successful treatment outcomes. Intensive interventions are more effective than less intensive interventions and should be used whenever possible. **(Strength of Evidence = A)** Person-to-person treatment delivered for four or more sessions appears especially effective in increasing abstinence rates. Therefore, if feasible, clinicians should strive to meet four or more times with individuals quitting tobacco use. **(Strength of Evidence = A)** *Type of Clinician* Treatment delivered by a variety of clinician types increases abstinence rates. Therefore, all clinicians should provide smoking cessation interventions. **(Strength of Evidence = A)** Treatments delivered by multiple types of clinicians are more effective than interventions delivered by a single type of clinician. Therefore, the delivery of interventions by more than one type of clinician is encouraged. **(Strength of Evidence = C)** *Formats of Psychosocial Treatments* Proactive telephone counseling, group counseling, and individual counseling formats are effective and should be used in smoking cessation interventions. **(Strength of Evidence = A)** Smoking cessation interventions that are delivered in multiple formats increase abstinence rates and should be encouraged. **(Strength of Evidence = A)** **Treatment Elements**

	Types of Counseling and Behavioral Therapies Two types of counseling and behavioral therapies result in higher abstinence rates: (1) providing smokers with practical counseling (problem solving skills/skills training), and (2) providing support and encouragement as part of treatment. These types of counseling elements should be included in smoking cessation interventions. **(Strength of Evidence = B)**

UMHS (2006)	Refer patients interested in quitting within 30 days to a tobacco treatment specialist or other appropriate tobacco cessation program.
	
	Alternatively, health care providers can directly provide the following treatment:
	
	• Consider referral to intensive counseling (multi-session, group or individual). Referral considerations include:
	  • Multiple, unsuccessful quit attempts initiated by brief intervention
	  • Increased need for skill building (coping strategies/problem solving), social support, and relapse prevention
	  • Psychiatric cofactors such as depression, eating disorder, anxiety disorder, attention deficit disorder, or alcohol abuse
	• Give key advice on successful quitting.
	  • **Abstinence**. Total abstinence is essential ***[D]***, not even a single puff after quit date.
	  • **Alcohol**. Drinking alcohol is strongly associated with relapse ***[C]***.
	  • **Other smokers in the household**. The presence of other smokers in the household, particularly a spouse, is associated with lower success rates ***[C]***.
	• Provide supplemental educational materials.
	
	Rationale for Recommendations
	
	<u>Treatment — Counseling</u>
	
	There is a strong dose response relationship between the intensity of person-to-person contact and successful outcomes ***[A]***. When providing counseling, health care providers should be aware that barriers to smoking cessation include, but are not limited to, severe withdrawal during previous quit attempts, the presence of other smokers in the home or workplace, stressful life circumstances, psychiatric co-morbidities (i.e. depression, alcoholism), multiple quit attempts, and low motivation. Identifying these barriers during initial assessment will help to provide a tailored approach during counseling.
	
	In addition to clinician counseling in the office, intensive counseling

	(frequently defined as a minimum of weekly meeting for the first 4 to 7 weeks of cessation) significantly enhances cessation rates. However, participation in intensive counseling is based largely on patients' motivation to quit ***[C]***. In some locations, if physicians formally refer patients to a tobacco cessation program, a third party may cover the fee with patients paying a reduced or no fee.
VA/DoD (2004)	**Initiate Counseling** *Counseling in the Clinic* Tobacco users who are willing to quit should receive some form of counseling. There is a dose-response relationship in counseling and rate of abstinence. **[A]** • Minimal counseling (lasting <3 minutes) increases overall tobacco abstinence rates. **[A]** • Intensive counseling (>10 minutes) increases abstinence rates. **[A]** • Multiple counseling sessions increase abstinence rates. **[A]** Effective counseling can be delivered in multiple formats (e.g., group counseling, proactive telephone counseling, and individual counseling) and may be more effective when combined. **[A]** Counseling should be provided by a variety of clinician types (physicians or nonphysician clinicians, such as nurses, dentists, dental hygienists, psychologists, pharmacists, and health educators) to increase quit rates. **[A]** All patients who are willing to quit should have access to intensive counseling (Quitlines or intensive cessation program). *Quitlines* Tobacco users who are willing to quit may receive counseling via telephone Quitlines, as proactive telephone counseling has been demonstrated to be effective. Pharmacotherapy still needs to be coordinated by the primary care provider. **[A]** *Background*. There is strong evidence that behavioral interventions work. More intense interventions, as defined by face-to-face contact, using a multidisciplinary approach and multiple formats, result in better cessation outcomes. However, even brief counseling increases overall abstinence rates. Effective counseling can also be provided by a wide variety of health care professionals, in addition to the patient's primary care physician. Tobacco use counseling and treatment can be provided in a variety of settings. It is crucial that the provider ensures that the tobacco user receives counseling and medication to assist him/her in quitting, regardless of the setting. Counseling tobacco

	users should start with having the patient set a quit date. Counseling and behavioral tobacco use cessation interventions should include: (1) providing practical counseling (problem-solving skills/skills training), (2) providing social support as part of treatment, and (3) helping tobacco users obtain social support outside of treatment. These three types of counseling and behavior therapies result in higher abstinence rates. Proactive telephone counseling, such as that provided by a Quitline, is another effective option for providing counseling to tobacco users.
Pharmacotherapy	
PHS (2008)	**Medication Evidence** Clinicians should encourage all patients attempting to quit to use effective medications for tobacco dependence treatment, except where contraindicated or for specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). **(Strength of Evidence = A)** **Recommendations Regarding Individual Medications: First-Line Medications** First-line medications are those that have been found to be safe and effective for tobacco dependence treatment and that have been approved by the FDA for this use, except in the presence of contraindications or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). These first-line medications have an established empirical record of effectiveness, and clinicians should consider these agents first in choosing a medication. For the 2008 update, the first-line medications are listed in Table 6.26 in the original guideline document by size of the odds ratio and in the text alphabetically by generic name. *Bupropion SR* Bupropion SR is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = A)** *NRT* <u>Nicotine Gum</u> Nicotine gum is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = A)** Clinicians should offer 4 mg rather than 2 mg nicotine gum to highly

dependent smokers. **(Strength of Evidence = B)**

Nicotine Inhaler

The nicotine inhaler is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = A)**

Nicotine Lozenge

The nicotine lozenge is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = B)**

Nicotine Nasal Spray

Nicotine nasal spray is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = A)**

Nicotine Patch

The nicotine patch is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = A)**

Varenicline

Varenicline is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = A)**

Recommendations Regarding Second-Line Medications

Second-line medications are medications for which there is evidence of effectiveness for treating tobacco dependence, but they have a more limited role than first-line medications because: (1) the FDA has not approved them for a tobacco dependence treatment indication; and (2) there are more concerns about potential side effects than exist with first-line medications. Second-line medications should be considered for use on a case-by-case basis after first line treatments (either alone or in combination) have been used without success or are contraindicated. The listing of the second-line medications is alphabetical by generic name.

Clonidine

Clonidine is an effective smoking cessation treatment. It may be used under a physician's supervision as a second-line agent to treat tobacco dependence. **(Strength of Evidence = A)**

Nortriptyline

Nortriptyline is an effective smoking cessation treatment. It may be

used under a physician's supervision as a second-line agent to treat tobacco dependence. **(Strength of Evidence = A)**

Combination Medications

Certain combinations of first-line medications have been shown to be effective smoking cessation treatments. Therefore, clinicians should consider using these combinations of medications with their patients who are willing to quit. Effective combination medications are:

- Long-term (>14 weeks) nicotine patch + other NRT (gum and spray)
- The nicotine patch + the nicotine inhaler
- The nicotine patch + bupropion SR **(Strength of Evidence = A)**

The number and variety of analyzable articles was sufficient to assess the effectiveness of five combinations of medications relative to placebo. Only the patch + bupropion combination has been approved by the FDA for smoking cessation. See the original guideline document for evidence regarding the following combinations:

- Nicotine patch + bupropion SR
- Nicotine patch + nicotine inhaler
- Long-term nicotine patch use + *ad libitum* NRT
- Nicotine patch + nortriptyline
- Nicotine patch + second generation antidepressants

Medications Not Recommended by the Guideline Panel

- Antidepressants other than bupropion SR and nortriptyline
- Selective serotonin re-uptake inhibitors (SSRIs)
- Anxiolytics/benzodiazepines/beta-blockers
- Opioid antagonists/naltrexone
- Silver acetate
- Mecamylamine
- Extended use of medications
- Use of NRT in cardiovascular patients

Use of Over-the-Counter Medications

Over-the-counter nicotine patch therapy is more effective than placebo, and its use should be encouraged. **(Strength of Evidence = B)**

Other Specific Populations and Topics

Weight Gain After Smoking Cessation

For smokers who are greatly concerned about weight gain, it may be most appropriate to prescribe or recommend bupropion SR or NRT (in

	particular nicotine gum and nicotine lozenge), which have been shown to delay weight gain after quitting. **(Strength of Evidence = B)**
UMHS (2006)	**Treatment — Pharmacologic Therapies** NRT, bupropion hydrochloride (Zyban), and varenicline (Chantix®) have been shown to significantly improve cessation rates ***[A]***. Therefore, pharmacologic therapy should be recommended to all patients except in the presence of specific contraindications. Bupropion and varenicline are the two non-nicotine products with FDA approval for smoking cessation. Non-FDA approved agents with potential benefit in smoking cessation include nortriptyline and clonidine. These drugs may best be used as second-line agents when patients cannot take or do not wish to take either NRT, bupropion, or varenicline ***[D]***. **NRT** The various NRTs significantly decrease symptoms of the withdrawal syndrome as smokers abruptly stop smoking ***[A]***. In very highly dependent smokers, 4 mg gum is superior to 2 mg and most effective with counseling ***[A]***. High dose patch therapy (i.e., 44 mg/24 hr = two patches) is safe and decreases withdrawal symptoms in highly dependent smokers, but does not increase long term cessation rates ***[A]***. Those smoking 5 or fewer cigarettes per day have been shown to have few symptoms of nicotine withdrawal when they quit ***[C]*** and may not require NRT ***[D]***. For those using nicotine gum, spray or inhaler, it is important that they are instructed in technique and dosing frequency so that underdosing does not occur. See Table 4 in the original guideline document for dosing and administration recommendations. The patient should also be provided with the educational handout, "How to Use Your Nicotine Product." <u>Combining NRTs</u> Given the additional cost of dual therapies (e.g., patch plus gum; patch plus inhaler; patch plus nasal spray) and limited benefit, combining NRT is best reserved for highly addicted smokers with several previous failed quit attempts ***[D]***. <u>Patients with Cardiovascular Disease</u> The patch and nasal spray have demonstrated safety in patients with stable coronary artery disease ***[A]***. While patients should be reminded not to smoke while using these products, studies have shown no increase in cardiac event rates when patients smoke while wearing the

	patch ***[C]***. **Choosing between Bupropion Hydrochloride or Nicotine Replacement** A single trial sponsored by the manufacturer of Zyban suggests that bupropion may be superior to nicotine patch therapy ***[A]***. Given this single study, it remains reasonable to consider patient preferences, previous quit attempt experiences and cost when choosing among pharmacologic therapies ***[D]***. For smokers who have previously been unsuccessful, one randomized study showed higher success rates for both bupropion alone or in combination with the nicotine patch, compared to nicotine patch alone ***[A]***.
VA/DoD (2004)	**Initiate Pharmacotherapy to Assist Quit** Tobacco users attempting to quit should be prescribed one or more effective first-line pharmacotherapies for tobacco use cessation. **[A]** • First-line therapies include five NRTs (transdermal patch, gum, nasal spray, lozenges, or vapor inhaler) and non-nicotine replacement (bupropion immediate release [IR] or sustained release [SR]). **[A]** • Pharmacotherapy should be combined with minimal counseling (less than 3 minutes). **[A]** • Patient should be strongly advised not to use tobacco while using NRT. • Selection of an agent should be based on patient characteristics, relative contraindications, and patient preferences. **[Expert Consensus]** • Typical duration for NRT is 8 to 12 weeks, and for bupropion 7 to 12 weeks **[Expert Consensus]** Tobacco users who do not respond to first-line therapies should: • Continue the same agent for a longer duration • Switch to a different first-line agent or • Consider combination of two agents. Combination therapy may be effective for patients unable to quit with a single first-line agent. **[B]** • Combining the nicotine patch with a self-administered form of NRT (gum or nasal spray) is more efficacious than a single form of NRT. **[B]** • There is some suggestive evidence for combining bupropion SR with NRT, but it is inconclusive. **[B]**

If patient has not responded after 2 courses of treatment, re-evaluate to assess the need of referral to intensive cessation program.

Pharmacotherapies NOT recommended for tobacco cessation: antidepressants other than bupropion SR and nortriptyline; anxiolytics/benzodiazepines/beta-blockers; silver acetate; and mecamylamine.

Special consideration should be given to the potential risks versus benefits in the presence of special circumstances (e.g., adolescents, pregnant women, mental health comorbidity, and populations with special military duties). **[Expert Consensus]**

Patient who responded to therapy and successfully quit the use of tobacco and then relapsed should be treated in same manner as the initial therapy.

Insufficient evidence exists to recommend the use of extended pharmacotherapy for relapse prevention. **[I]**

First Line NRT

Treatment of nicotine dependence with NRT should adhere to the three guiding principles of substance use disorder pharmacotherapy:

- Dose to effect: The initial dose should be sufficient to provide the patient with a nicotine dose similar to that seen prior to cessation of tobacco. Providers should always assess the patient's nicotine dependence before prescribing cessation aids.
- Treat withdrawal symptoms: The nicotine replacement dose should be sufficient to prevent or minimize craving for tobacco products.
- Avoid adverse reactions: The nicotine replacement dose should be small enough that signs and symptoms of over medication (i.e., headache, nausea, and palpitations) do not occur.

Five types of NRT products are available in the U.S. for pharmacological treatment of tobacco dependence.

- Transdermal delivery system (patches)
- Polacrilex resin (gum)
- Polacrilex resin (lozenge)
- Nasal spray
- Oral vapor inhaler

First Line Non-NRT

There are a number of factors to be considered when determining whether a person desiring help in tobacco cessation would be a

	candidate for bupropion SR, including: • Nicotine dependence • Motivation to quit • Inability or disinclination to use nicotine replacement • Contraindicated drugs or disease states [e.g., seizures, alcohol dependency]
Combined Psychosocial and Pharmacological Interventions	
PHS (2008)	*Combining Counseling and Medication* The combination of counseling and medication is more effective for smoking cessation than either medication or counseling alone. Therefore, whenever feasible and appropriate, both counseling and medication should be provided to patients trying to quit smoking. **(Strength of Evidence = A)** There is a strong relation between the number of sessions of counseling, when it is combined with medication, and the likelihood of successful smoking cessation. Therefore, to the extent possible, clinicians should provide multiple counseling sessions, in addition to medication, to their patients who are trying to quit smoking. **(Strength of Evidence = A)**
UMHS (2006)	The efficacy of all forms of NRT is improved with concomitant counseling, but there is evidence for the effectiveness of NRT, even in the absence of counseling. In very highly dependent smokers, 4 mg gum is superior to 2 mg and most effective with counseling ***[A]***.
VA/DoD (2004)	Pharmacotherapy should be combined with minimal counseling (less than 3 minutes). **[A]**
CONSIDERATIONS IN SPECIAL POPULATIONS	
Pregnant Women	
PHS (2008)	**Other Specific Populations and Topics** *Pregnant Smokers* Because of the serious risks of smoking to the pregnant smoker and the fetus, whenever possible pregnant smokers should be offered person-to-person psychosocial interventions that exceed minimal advice to quit. **(Strength of Evidence = A)**

	Although abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in pregnancy can yield benefits. Therefore, clinicians should offer effective tobacco dependence interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy. (Strength of Evidence = B)
UMHS (2006)	**Pregnant Patients** Intensive counseling interventions increase quit rates during pregnancy *[**A**]*. If intensive counseling is not possible, brief in-office counseling still has a beneficial effect and should be offered. Few studies have addressed the safety of NRT or bupropion in pregnancy directly; however, studies show that less nicotine and fewer metabolites cross the placenta with the use of NRT than with smoking itself. Therefore cautious use of bupropion with NRT (especially nicotine gum) may be considered after reviewing risks and benefits with the patient. **Breastfeeding Women** Smoking leads to a significant reduction in breast milk volume and increases the likelihood of early discontinuation *[**A**]*. Data support the use of bupropion plus NRT in nursing mothers, with increased cessation rates. The safety profile is favorable, as less nicotine and fewer metabolites are found in breast milk with NRT, compared to smoking more than a half a pack per day. Additionally, eliminating environmental exposure to the infant is a favorable outcome. It is not known whether varenicline is excreted in human milk.
VA/DoD (2004)	The guideline refers to recommendations offered in DoD/VA Clinical Practice Guideline for Management of Uncomplicated Pregnancy regarding smoking cessation and pregnancy. Specific recommendations from this guideline include: • Strongly recommend routine screening for tobacco use in pregnancy at the initial prenatal visit. For patients who smoke, recommend assessment of smoking status at each subsequent prenatal visit. • If the screening is positive, cessation should be strongly recommended. • There is insufficient data to recommend for or against pharmacologic therapy for tobacco cessation in pregnancy. *Background*. Smoking in pregnancy presents risks for both the woman and the fetus. Tobacco use by pregnant women has been shown to cause adverse fetal outcomes, including stillbirths, spontaneous abortions, decreased fetal growth, premature births, low birth weight, placental abruption, sudden infant death syndrome (SIDS), cleft palates and cleft lips, and childhood cancers. Many women are

	motivated to quit during pregnancy, and health care professionals can take advantage of this motivation by reinforcing the knowledge that cessation will reduce health risks to the fetus and that there are postpartum benefits for both the mother and child. Even women who have maintained total abstinence from tobacco for 6 or more months during pregnancy have a high rate of relapse in the postpartum period. Postpartum relapse may be decreased by continued emphasis on the relationship between maternal smoking and poor health outcomes in infants and children (i.e., SIDS, respiratory infections, asthma, and middle ear disease).
Children and Adolescents	
PHS (2008)	*Children and Adolescents* Clinicians should ask pediatric and adolescent patients about tobacco use and provide a strong message regarding the importance of totally abstaining from tobacco use. **(Strength of Evidence = C)** Counseling has been shown to be effective in treatment of adolescent smokers. Therefore, adolescent smokers should be provided with counseling interventions to aid them in quitting smoking. **(Strength of Evidence = B)** Secondhand smoke is harmful to children. Cessation counseling delivered in pediatric settings has been shown to be effective in increasing abstinence among parents who smoke. Therefore, to protect children from secondhand smoke, clinicians should ask parents about tobacco use and offer them cessation advice and assistance. **(Strength of Evidence = B)**
UMHS (2006)	**Treatment — Counseling** The evidence for the effectiveness of counseling in adolescent smokers is less robust. However, some studies demonstrate that smoking cessation counseling in the primary care setting can improve adolescent smokers' quit rates ***[A]***. There is little difference between the well infant, child respiratory illness, and other child illness settings as contexts for parental smoking cessation interventions ***[B]***. **Treatment — Pharmacologic Therapies** The utility of pharmacologic therapy for adolescents has been examined in a number of small studies. While the evidence indicates that these therapies are safe, they seem to be more effective when coupled with counseling. Additional, larger trials are ongoing to evaluate this issue. In the meantime, NRT or bupropion may be considered for use in adolescent smokers ***[D]***.

VA/DoD (2004)	**Children and Adolescents** Pediatric and adolescent patients and their parents should be screened by health care providers for tobacco use and provided a strong message regarding the importance of total abstinence from tobacco use. **[Expert Consensus]** Health care providers in a pediatric setting should advise parents to quit smoking to limit their children's exposure to second-hand smoke. **[A]** Health care providers in a pediatric setting should offer smoking cessation advice and interventions to parents to improve the parent's chance of quitting use of tobacco. **[C]** Adolescents who use tobacco and are interested in quitting should be offered counseling and behavioral interventions that were developed for adolescents. **[A]** Counseling and behavioral interventions shown to be effective with adults may be considered for use with adolescents. **[Expert Consensus]** When treating adolescents, providers may consider prescriptions for bupropion SR or NRT when there is evidence of nicotine dependence and desire to quit tobacco use. **[Expert Consensus]**
Other Special Populations	
PHS (2008)	**Special Populations and Other Topics** The interventions found to be effective in this Guideline have been shown to be effective in a variety of populations. In addition, many of the studies supporting these interventions comprised diverse samples of tobacco users. Therefore, interventions identified as effective in this Guideline are recommended for all individuals who use tobacco, except when medication use is contraindicated or with specific populations in which medication has not been shown to be effective (pregnant women, smokeless tobacco users, light smokers, and adolescents). **(Strength of Evidence = B)** See the original guideline document for a discussion of clinical issues for specific populations, including HIV-positive smokers; hospitalized smokers; lesbian/gay/bisexual/transgender (LGBT) smokers; smokers with low socioeconomic status (SES)/limited formal education; smokers with comorbid conditions, including cancer, cardiac disease, chronic obstructive pulmonary disease (COPD), diabetes, and asthma; older smokers; smokers with psychiatric disorders, including substance use disorders; racial and ethnic minority populations, and

	women. **Other Specific Populations and Topics** *Light Smokers* Light smokers should be identified, strongly urged to quit, and provided counseling cessation interventions. **(Strength of Evidence = B)** *Noncigarette Tobacco Users* Smokeless tobacco users should be identified, strongly urged to quit, and provided counseling cessation interventions. **(Strength of Evidence = A)** Clinicians delivering dental health services should provide brief counseling interventions to all smokeless tobacco users. **(Strength of Evidence = A)** Users of cigars, pipes, and other noncigarette forms of smoking tobacco should be identified, strongly urged to quit, and offered the same counseling interventions recommended for cigarette smokers. **(Strength of Evidence = C)**
UMHS (2006)	*Racial and Ethnic Minorities* Smoking cessation treatment has been shown to be effective across both racial and ethnic minorities ***[A]***. Little research has examined intervention specifically designed for a particular ethnic or racial group; however, it is recommended that, when possible, smoking cessation treatment should be tailored to the specific ethnic or racial population with which they are used ***[C]***. It is essential that counseling or self-help materials be conveyed in a language understood by the smoker. *Psychiatric Cofactors* If presence of psychiatric cofactors, such as depression, eating disorder, anxiety disorder, attention deficit disorder, or alcohol abuse, strongly consider referral to intensive counseling ***[B]***. Treatment of cofactors must be undertaken in preparation for smoking cessation. *Non-cigarette Tobacco Users* Spit tobacco users should be identified and strongly urged to quit tobacco use, using the same counseling interventions recommended for smokers ***[A]***. The clinicians should provide a clear message that the use of spit tobacco is not a safe alternative to smoking. Use of

	cigars, pipes, and other non-cigarette combustible forms of tobacco should be identified, strongly urged to quit, and offered the same counseling interventions recommended for smokers ***[C]***. *Gender Concerns* Smoking cessation treatments are shown to benefit both women and men ***[B]***. Two studies suggest that some treatments are less efficacious in women than in men. Women may face different stressors and barriers to quitting (e.g., greater likelihood of depression, greater weight control concerns, and hormonal cycles). This research suggests cessation programs that address these issues would be more effective in treating women ***[D]***. *Older Smokers* Smoking cessation treatment has been shown to be effective for older adults and should be provided, as cessation improves pulmonary function and cerebral circulation ***[A]***. Several studies have found cessation rates among motivated older adults similar to those for younger adults; however, supportive counseling and social support may be of more value to prevent relapse than education or skills training ***[A]***. *Hospitalized Smokers* Providing hospitalized patients with high-intensity behavioral counseling and follow-up of at least 30 days has been shown to increase cessation rates ***[A]***. NRT supplementation can also be useful in this population. Briefer interventions (<20 minutes, delivered only during the hospitalization) have not yet been shown to be helpful. Additional treatment can include self-help brochures or audio/video tapes, chart prompts reminding physicians to advise for cessation, pharmacologic therapy, hospital counseling, and post-discharge counseling telephone calls. Hospitalization should be used as a springboard to promote smoking cessation.
VA/DoD (2004)	**Military Recruits and Trainees** Prevent relapse of basic trainees who quit using tobacco as a result of their participation in basic military training. • Relapse prevention should be addressed with every former tobacco user. **[Expert Consensus]** **Hospitalized Patients** Encourage all health care team members to advise hospitalized tobacco users to quit and provide tobacco cessation treatment.

	• All patients admitted to hospitals should have tobacco use status identified in the medical record. **[A]** • Tobacco users who are hospitalized should be given advice to quit. **[B]** • Tobacco users who are hospitalized should be given tobacco cessation treatment including medication and counseling. **[B]** • Whenever possible, augmented smoking cessation treatment should be provided to tobacco users who are hospitalized. **[Expert Consensus]** • Tobacco users should be referred for continuing treatment and support upon discharge. **[Expert Consensus]** **Older Patients** Encourage all health care team members to advise older tobacco users to quit and provide tobacco cessation treatment. • Tobacco users who are older should be given advice to quit. **[A]** • Tobacco users who are older should be given tobacco cessation treatment, including medication and counseling. **[A]** • There are insufficient data to support or refute variations on smoking cessation interventions among the elderly. Assessment and treatment of tobacco users who are older should follow the recommendations included in the guideline. **[I]** **Psychiatric/Mental Health Patient** Provide effective tobacco cessation services to patients with psychiatric comorbidities • Tobacco users with comorbid psychiatric and substance abuse conditions should be provided tobacco cessation treatment. **[B]** • Tobacco users receiving treatment for chemical dependency should be provided tobacco cessation treatments to include counseling and pharmacotherapy. **[C]** • Tobacco users with other comorbidities may have a low rate of successful treatment. The optimal treatment for tobacco users with current/past depression is uncertain, but they may require longer and more intensive treatment. **[B]**
Follow-up and Prevention of Relapse	
PHS (2008)	*Follow-up Assessment and Procedures* All patients who receive a tobacco dependence intervention should be assessed for abstinence at the completion of treatment and during subsequent clinic contacts. (1) Abstinent patients should have their quitting success acknowledged, and the clinician should offer to assist the patient with problems associated with quitting (see Chapter 3C,

	For the Patient Who Has Recently Quit, in the original guideline document). (2) Patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt. **(Strength of Evidence = C)**: • If the patient is willing to make another quit attempt, provide or arrange additional treatment (see Chapter 3A, For the Patient Willing To Quit, in the original guideline document.) • If the patient is not willing to try to quit, provide or arrange an intervention designed to increase future quit attempts (see Chapter 3B, For the Patient Unwilling To Quit, in the original guideline document).
UMHS (2006)	Arrange follow-up either with phone call or office visit. Follow-up contact should occur soon after the quit date, preferably during the first week ***[C]***. Extending treatment contacts over a number of weeks appears to increase cessation rates ***[D]***. Further follow-up as needed. For abstinent patients, prevent relapse by • Congratulate successes and stress importance of remaining abstinent. • Review benefits to be derived from quitting. • Inquire regarding problems encountered and offer possible solutions to maintaining abstinence. For smoking patients: • Review circumstances and elicit re-commitment to total abstinence. • Remind patients that a lapse can be used as a learning experience. • Identify problems, suggest alternative behaviors and anticipate challenges in the immediate future. • Re-assess choice of pharmacologic interventions as needed. • Consider referral to a more intense or specialized program.
VA/DoD (2004)	**Arrange Follow-up** Tobacco users who receive a tobacco cessation intervention should be scheduled for ongoing follow-up for abstinence. **[B]** Follow-up should be documented and should: • Establish contact with the tobacco user 1 to 2 weeks after quitting date to assess abstinence **[B]** • Assess effectiveness of pharmacotherapy and appropriate use **[Expert Consensus]**

- Assess for abstinence at the completion of the treatment and during subsequent clinical contact for the duration of at least 6 months **[Expert Consensus]**
- Provide relapse prevention to tobacco users who remain abstinent

Tobacco users who relapse should be assessed for willingness to make another quit attempt and offered repeated interventions. **[B]**

Tobacco users should be tracked to increase the systematic delivery of interventions for tobacco cessation and increase the likelihood of long-term abstinence. **[B]**

Initiate/Reinforce Relapse Prevention

- Relapse prevention should be addressed with every former tobacco user. **[Expert Consensus]**
- Providers should address individual, environmental, and biopsychosocial factors associated with relapse. **[Expert Consensus]**
- Providers should address weight gain after quitting, as tobacco use cessation is often followed by weight gain. Consider bupropion SR (sustained release) or NRT, in particular, nicotine gum, which have been shown to delay weight gain after quitting.
- Patients with multiple relapses or who are having trouble in a current quit attempt in a clinical setting should be directed to more intense counseling programs or medication should be adjusted. **[B]**

Background. Tobacco use is characterized as a chronic relapsing disorder due to the high number of relapses after a single quit attempt. Studies have documented that smokers may make between 3 and 7 serious quit attempts before successfully quitting. Relapse frequently occurs within a few hours or up to 3 months after quitting, and may even occur after a year or more of abstinence. Addressing the issue of relapse before it occurs and identifying risk factors has been helpful in devising coping strategies to help the tobacco user to quit and prepare them to accept relapse as a learning experience and not a failure.

Assess Risk for Relapse

- Tobacco users who have been abstinent for less than three months should be assessed for relapse. **[B]**
- Tobacco users attempting to quit should be screened for a history of depression or a presentation of depressive symptoms predating the quit attempt as these factors strongly predict relapse. **[B]**
- Psychosocial and environmental risk factors for relapse should be assessed to include stress, depression, withdrawal symptoms, previous quit attempts, close presence of other tobacco users, history of substance use disorder, and/or other risky behaviors.

	[C] • Patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt. **[C]** **Relapse** • Patient who responded to therapy and successfully quit the use of tobacco and then relapsed should be treated in same manner as the initial therapy. • Insufficient evidence exists to recommend the use of extended pharmacotherapy for relapse prevention. **[I]** • Consider referral for intensive behavioral modification counseling for tobacco users with multiple relapses. **[Expert Consensus]**
Follow-up and Prevention of Relapse	
PHS (2008)	**Treatment Structure and Intensity** *Formats of Psychosocial Treatments* Tailored materials, both print and Web-based, appear to be effective in helping people quit. Therefore, clinicians may choose to provide tailored self-help materials to their patients who want to quit. **(Strength of Evidence = B)**
UMHS (2006)	**Information the Patient Needs to Know** **Supplementary materials**. The UMHS produces two useful patient education handouts: • How to use your nicotine product • Tips for quitting smoking Additionally, the National Cancer Institute produces the pamphlet "Clearing the Air" (NIH Pub. 03-1647). You may obtain 20 free copies at a time by calling 1-800-4-CANCER (1-800-422-6237). It is also available online at http://www.smokefree.gov/pubs/clearing_the_air.pdf. **Preparation and effects**. Review with patients the following additional information about preparing for quitting and related factors. • **Review handout(s)**. The handout(s) provide many useful tips to help you with your quit attempt. Read these and make plans before your quit attempt. • **NRT/bupropion/varenicline**. NRT, bupropion, and varenicline are most effective when used correctly. If you have any uncertainties about proper use, this should be clarified.

	• **Caffeine**. You are likely to perceive greater effects from your usual caffeine consumption after you quit smoking and may need to decrease your intake. • **Theophylline**. If you take theophylline, levels should be checked approximately 2 weeks after you quit smoking.
VA/DoD (2004)	**Offer Self-Help Material** Consider offering a variety of effective self-help educational materials to motivate and aid in the quitting process (e.g., pamphlets/booklets/mailings/manuals, videotapes, audiotapes, Internet Web pages, and computer programs). **[Expert Consensus]**

TABLE 4: BENEFITS AND HARMS	
Benefits	
PHS (2008)	Appropriate assessment and treatment of tobacco use and dependence
UMHS (2006)	Effective interventions and strategies for health care providers to assist patients in smoking cessation
VA/DoD (2004)	• Early detection of tobacco use • Decreased rates of tobacco use • Increased rates of smoking cessation • Prevention of tobacco use in students who have not starting using tobacco • Decreased rates of relapse in persons who have quit tobacco use • Flexibility to accommodate local policies or procedures, including those regarding staffing patterns and referral to or consultation with other health care providers • Appropriate management of tobacco use in target population • Improved patient education regarding abstinence from tobacco **Subgroups Most Likely to Benefit** There are special target populations of smokers who need to be identified and referred for intervention because of the high likelihood of adverse outcomes that accompany continued tobacco use. These include: • Pregnancy - Due to increased risk to the mother and potential fetal prematurity, all pregnant patients should be encouraged to stop smoking as early in pregnancy as possible.

	• Chronic tobacco related disease - Smokers who have developed a progressive, chronic tobacco related disease (emphysema, coronary artery disease, peripheral vascular disease) that will continue to deteriorate should be urged to make an attempt to quit tobacco during routine primary care for those disorders. • Complications of surgical anesthesia - Smoking cessation should be addressed with all pre-operative patients. If tobacco users will quit smoking 4 to 6 weeks prior to anesthesia, complications and postoperative recovery (infections, wound healing, cardiac procedures) can be reduced.
Harms	
PHS (2008)	• Weight gain related to cessation of tobacco use • Exacerbation of comorbid psychiatric conditions following cessation of tobacco use • Side effects of pharmacological agents approved by the U.S. Food and Drug Administration (FDA) for smoking cessation: *Bupropion SR*: The most common side effects reported were insomnia (35% to 40%) and dry mouth (10%). *Nicotine chewing gum*: Common side effects include mouth soreness, hiccups, dyspepsia, and jaw ache. These effects are generally mild and transient, and often can be alleviated by correcting the patient's chewing technique. *Nicotine inhaler*: Local irritation in the mouth and throat was observed in 40% of patients using the nicotine inhaler. Coughing (32%) and rhinitis (23%) also were common. Severity was generally rated as mild, and the frequency of such symptoms declined with continued use. *Nicotine lozenge*: The most common side effects are nausea, hiccups, and heartburn. Individuals on the 4-mg lozenge also had increased rates of headache and coughing (less than 10% of participants). *Nicotine nasal spray*: • Nasal/airway reactions. Some 94% of users report moderate to severe nasal irritation in the first 2 days of use; 81% still reported nasal irritation after 3 weeks, although rated severity was mild to moderate. Nasal congestion and transient changes in sense of smell and taste were also reported. Nicotine nasal spray should not be used in persons with severe reactive airway disease. • Dependency. Nicotine nasal spray has a dependence potential intermediate between other nicotine-based

	therapies and cigarettes. About 15% to 20% of patients report using the active spay for longer periods than recommended, and 5% used the spray at a higher dose than recommended. *Nicotine patch*: Up to 50% of patients using the nicotine patch will have a local skin reaction. Skin reactions are usually mild and self-limiting, but occasionally worsen over the course of therapy. Local treatment with hydrocortisone cream (1%) or triamcinolone cream (0.5%) and rotating patch sites may ameliorate such local reactions. In fewer than 5% of patients, such reactions require the discontinuation of nicotine patch treatment. Other side effects include insomnia and/or vivid dreams. *Varenicline*: Nausea, trouble sleeping, abnormal/vivid/strange dreams • Side effects of pharmacologic agents not FDA approved for smoking cessation: *Clonidine*: Most commonly reported side effects include dry mouth (40%), drowsiness (33%), dizziness (16%), sedation (10%), and constipation (10%). As an antihypertensive medication, clonidine can be expected to lower blood pressure in most patients. Therefore, clinicians may need to monitor blood pressure when using this medication. Rebound hypertension may occur if the dose is not gradually reduced over a period of 2 to 4 days (rapid increase in blood pressure, agitation, confusion, and/or tremor may occur). *Nortriptyline*: Most commonly reported side effects include sedation, dry mouth (64% to 78%), blurred vision (16%), urinary retention, lightheadedness (49%), and shaky hands (23%). See the tables in Chapter 3 of the original guideline documents for additional information, including precautions when using medications in pregnant smokers or those with cardiovascular disease. Also see Chapter 6 in the original guideline document for information about interactions of first-line tobacco use medications with other drugs.
UMHS (2006)	Side effects of medications may occur and include the following: • *Nicotine Lozenge* — Headache, diarrhea, flatulence, heartburn, hiccups, nausea, coughing, sore throat, and upper respiratory infection (occurring in >5% of patients) • *Transdermal Nicotine Patch* — Skin reactions such as pruritus, edema, rash; sleep disturbance • *Nicotine Gum (Polacrilex)* — Jaw fatigue, hiccups, belching, and nausea • *Nicotine Nasal Spray* — Nasal irritation/rhinorrhea (98% of

	patients), sneeze, cough • *Nicotine Inhaler* — Cough, mouth and throat irritation • *Bupropion Hydrochloride SR (Zyban®) and Bupropion Hydrochloride* — Insomnia, dry mouth, nausea, and seizures. It should be used with caution in patients with predisposition to seizure (i.e., head trauma, alcohol withdrawal, concomitant use with other medications that lower seizure threshold — antipsychotics, antidepressants, theophylline) • *Varenicline (Chantix®)* — Nausea, insomnia, and unusual dreams; should not be used in conjunction with NRT products • *Clonidine* — Dry mouth and sedation • *Nortriptyline* — Dry mouth Few studies have addressed the safety of nicotine replacement therapy or bupropion in pregnancy directly; however, studies show that less nicotine and fewer metabolites cross the placenta with the use of nicotine replacement therapy than with smoking itself. The U.S. Food and Drug Administration (FDA) pregnancy risk categories are: bupropion — category B, nicotine transdermal, spray and inhaler — category D, nicotine gum — category C, varenicline — category C. Most smokers who quit will gain weight, but the majority will gain less than 10 pounds.
VA/DoD (2004)	**Adverse Effects of Medication** • *Nicotine Transdermal (patch)*: sleep disturbance, local irritation, bone pain, headache, nausea • *Nicotine Polacrilex Resin (gum)*: local mouth irritation, jaw pain, rhinitis, nausea • *Nicotine Polacrilex Resin (lozenge)*: local mouth irritation, headache, nausea, diarrhea, flatulence, hiccup, heartburn, cough • *Nicotine Nasal Spray*: headache, nausea, confusion, palpitations, nasal irritation • *Nicotine Oral Vapor Inhaler*: local irritation, cough, rhinitis, headache, dyspepsia • *Bupropion Sustained Release (SR) and Bupropion Immediate Release (IR)*: anxiety, disturbed concentration, dizziness, insomnia, constipation, dry mouth, nausea • *Clonidine and nortriptyline* are associated with more severe adverse effects (significant drug-drug interactions) than either NRT or bupropion SR. Withdrawal effects from abrupt discontinuation can also be serious. These agents should be used only under the supervision of a physician. **Subgroups Most Likely to Be Harmed** • Use of NRT must be carefully assessed and monitored in persons with hyperthyroidism, peptic ulcer disease, insulin-dependent diabetes mellitus, temporomandibular joint (TMJ) syndrome (nicotine gum), severe renal impairment, and certain peripheral

	vascular diseases. • Nicotine from any NRT product may be harmful to children and pets if taken orally.

TABLE 5. EVIDENCE RATING SCHEMES AND REFERENCES	
PHS (2008)	**Strength of Evidence Grades** A. Multiple well-designed randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings. B. Some evidence from randomized clinical trials supported the recommendation, but the scientific support was not optimal. For instance, few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation. C. Reserved for important clinical situations in which the Panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.
UMHS (2006)	Levels of evidence reflect the best available literature in support of an intervention or test: A. Randomized controlled trials B. Controlled trials, no randomization C. Observational trials D. Opinion of expert panel
VA/DoD (2004)	**Quality of Evidence (QE)** **I**: Evidence obtained from at least one properly randomized controlled trial **II-1**: Evidence obtained from well-designed controlled trails without randomization **II-2**: Evidence obtained from well-designed cohort or case-control analytic studies **II-3**: Evidence obtained from multiple time series, dramatic results in uncontrolled experiments **III**: Opinions of respected authorities; case reports, and reports of

expert committees

Overall Quality

Good: High grade evidence (I or II-1) directly linked to health outcome

Fair: High grade evidence (I or II-1) linked to intermediate outcome or Moderate grade evidence (II-2 or II-3) directly linked to health outcome

Poor: Level III evidence or no linkage of evidence to health outcome

Net Effect of Intervention

Substantial:

- More than a small relative impact on a frequent condition with a substantial burden of suffering, or
- A large impact on an infrequent condition with a significant impact on the individual patient level

Moderate:

- A small relative impact on a frequent condition with a substantial burden of suffering, or
- A moderate impact on an infrequent condition with a significant impact on the individual patient level

Small:

- A negligible relative impact on a frequent condition with a substantial burden of suffering, or
- A small impact on an infrequent condition with a significant impact on the individual patient level

Zero or Negative:

- Negative impact on patients, or
- No relative impact on either a frequent condition with a substantial burden of suffering, or
- An infrequent condition with a significant impact on the individual patient level

Grade of Recommendation

A: A strong recommendation that the intervention is always indicated and acceptable

	B: A recommendation that the intervention may be useful/effective **C**: A recommendation that the intervention be considered **D**: A recommendation that a procedure may be considered not useful/effective, or may be harmful **I**: Insufficient evidence to recommend for or against; the clinician will use clinical judgment

GUIDELINE CONTENT COMPARISON

The Public Health Service (PHS), University of Michigan Health System (UMHS), and the Department of Veterans Affairs, Department of Defense (VA/DoD) present recommendations for tobacco use cessation. The organizations provide explicit reasoning behind their judgments and rate the evidence upon which their recommendations are based.

The 2008 PHS guideline included in this synthesis updates a previous version, published in 2000. The UMHS and the VA/DoD guidelines included in this synthesis utilized to some degree, evidence and recommendations released in 2000 by the U.S PHS. For instance, UMHS utilized evidence derived from literature searches of both the 1996 Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality [AHRQ]) guideline and the 2000 PHS guideline (both of which are now considered out of date). UMHS also supplemented the supporting evidence for their recommendations with subsequently published information. The VA/DoD guideline refers often to the 2000 PHS guideline, but also based its recommendations on an extensive review of more recent literature.

Areas of Agreement

Initial Interventions

All three guidelines recommend a variation of the "Five A" behavioral counseling framework of asking (identifying users), advising (urging users to quit), assessing (determining users' willingness to quit), assisting (through counseling or drug therapy), and arranging for follow-up. UMHS recommends an updated variation of this framework known as the "3-A's and Refer" model. This model recommends that if, during assessment, it is determined that the patient is interested in quitting within 30 days, he or she should be referred to a Tobacco Treatment Specialist or other tobacco cessation program. They do, however, also provide treatment recommendations for physicians who choose to treat the patient rather than refer him or her.

The guidelines agree that all patients should be asked if they use tobacco and should have their tobacco-use status documented on a regular basis. The groups recommend that physicians advise all tobacco users identified during screening to

seriously consider making a quit attempt and that advice should be "clear," "strong," and "personalized" and should include a discussion of the health benefits of quitting, self-help materials, and referral to community groups, if necessary. After being assessed for willingness to quit, each of the guidelines also agrees that patients who do not wish to quit should receive motivational interventions (e.g., the 5 R's: relevance, risks, rewards, roadblocks, and repetition).

Counseling and Behavioral Therapies

There is overall agreement that tobacco users who are willing to quit should have access to some form of counseling, including intensive counseling if desired. PHS and VA/DoD agree that counseling is most effective when delivered by a variety of clinician types and in multiple formats, and that proactive telephone counseling (quitlines), group counseling, and individual counseling are effective. They are also in agreement that specific types of counseling and behavioral therapies should be included in smoking cessation interventions. The two types recommended by both groups are practical counseling (problem solving/skills training) and the provision of support and encouragement as part of treatment. VA/DoD also recommends a third type of counseling, which is helping tobacco users obtain social support outside of treatment.

The dose-response relationship between treatment intensity and abstinence from tobacco use is emphasized by all three groups. They agree that counseling as brief as three minutes can be effective in smoking cessation, but that intensive interventions are more effective than less intensive interventions and should be used whenever possible. With regard to frequency, there is overall agreement that multiple counseling sessions increase abstinence rates. PHS notes that, if possible, clinicians should strive to meet four or more times with individuals quitting tobacco use. UMHS similarly notes that intensive counseling (frequently defined as a minimum of weekly meeting for the first 4 to 7 weeks of cessation) significantly enhances cessation rates.

Pharmacologic Therapy

Recommendations regarding pharmacologic therapy are similar. NRT (nicotine gum, patch, inhaler, nasal spray, and lozenge) and bupropion, are first-line pharmacologic therapies recommended by all three groups. The two most recently published guidelines, PHS (2008) and UMHS (2006) also cite varenicline (approved by the FDA in 2006) as an appropriate first-line agent. Nortriptyline and clonidine are recommended as second-line treatments by all three guideline groups.

All three groups also address combining NRTs for improved efficacy. PHS and VA/DoD agree that combining the nicotine patch (PHS specifies long-term [>14 weeks] patch) with a self-administered form of NRT (gum or nasal spray) is more efficacious than a single form of NRT. The combination of the nicotine patch and the nicotine inhaler is also cited as effective by PHS. UMHS, however, notes that, given the additional cost of dual therapies and limited benefit, combining NRT is best reserved for highly addicted smokers with several previous failed quit attempts.

With regard to combining NRT and non-nicotine medications, PHS recommends the combination of the nicotine patch and bupropion SR, noting that it is the only combination approved by the FDA for smoking cessation. VA/DoD in contrast notes that there is some suggestive evidence for combining these two agents, but it is inconclusive. The divergence between the two groups may be due to research studies published since the publication of the VA/DoD guideline (2004). UMHS does not provide a formal recommendation, but notes that for smokers who have previously been unsuccessful, one randomized study showed higher success rates for both bupropion alone or in combination with the nicotine patch, compared to nicotine patch alone.

There are some disagreements on the use of drug therapy in pregnant women and in children and adolescents, and these differences are also discussed below.

Pregnant Women

The guideline groups agree that pregnant women who smoke should be strongly urged to quit. UMHS and PHS recommend intensive counseling be offered to pregnant smokers, but note that brief counseling still has a beneficial effect and should be offered if intensive counseling is not possible.

Other Special Populations

All three guidelines address special populations and agree that these special populations can benefit from many of the same treatments as the general population, but that treatment can be improved by recognizing the problems or concerns of the individual.

Follow-Up (Prevention of Relapse)

There is overall agreement that all patients who receive a tobacco dependence intervention should be assessed for abstinence at the completion of treatment and during subsequent clinic contacts. The groups agree that abstinent patients should have their quitting success acknowledged, be offered assistance with problems associated with quitting, and be educated regarding relapse prevention. All three groups recommend that patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt and if so, offered repeated interventions.

Counseling of Children and Adolescents

All three groups agree that there is evidence to support the effectiveness of counseling interventions to promote smoking cessation in adolescents. VA/DoD states that adolescents who use tobacco and are interested in quitting should be offered counseling and behavioral interventions that were developed for adolescents. They add, however, that interventions shown to be effective with adults may also be considered for use with adolescents. UMHS states that the evidence for the effectiveness of counseling in adolescent smokers is less robust than for adults, but that some studies do demonstrate that smoking cessation counseling in the primary care setting can improve adolescent smokers' quit rates.

Recommendations regarding pharmacological interventions in adolescents differ. Refer to Areas of Differences below.

Areas of Differences

Pharmacological Treatment During Pregnancy

The groups differ in their recommendations concerning use of pharmacologic therapy for pregnant women. VA/DoD (through DoD/VA Clinical Practice Guideline for Management of Uncomplicated Pregnancy) makes no recommendations either for or against drug therapy during pregnancy. PHS states that there is insufficient evidence to recommend medications for pregnant women. UMHS, in contrast, notes that cautious use of bupropion with NRT (especially nicotine gum) may be considered after reviewing risks and benefits with the patient.

Environmental Tobacco Smoke (ETS)

While all three groups agree that ETS is harmful to children, there is disagreement regarding the effectiveness of counseling interventions aimed at parents who smoke to limit children's exposure to ETS. PHS and VA/DoD agree that in order to limit their children's exposure to secondhand smoke, clinicians should ask parents about tobacco use and offer them cessation advice and assistance. UMHS, in contrast, states that there is mixed evidence to support counseling to reduce ETS exposure in the home. They resume by noting that there is little difference between the well infant, child respiratory illness, and other child illness settings as contexts for parental smoking cessation interventions.

Pharmacological Treatment of Children and Adolescents

Recommendations regarding pharmacological treatment of tobacco dependence in adolescents differ. VA/DoD states that physicians may consider prescribing bupropion SR or NRT to adolescents when there is evidence of nicotine dependence and desire to quit. UMHS similarly notes that until ongoing larger studies addressing this topic are published, NRT or bupropion may be considered for use in adolescent smokers. PHS, in contrast to VA/DoD and UMHS, states that there is insufficient evidence to recommend medications for tobacco dependence treatment to adolescents.

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