NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC)
GUIDELINE SYNTHESIS

TOBACCO USE CESSATION AND PREVENTION

Guidelines

1. U.S. Preventive Services Task Force (USPSTF). Counseling to prevent tobacco use and tobacco-caused disease: recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2003 Nov. 13 p. [22 references]
2. 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.
3. University of Michigan Health System (UMHS). Smoking cessation. Ann Arbor (Michigan): University of Michigan Health System, 2006. 12 p. [1 reference]

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INTRODUCTION:

A direct comparison of the United Stated Preventive Services Task Force (USPSTF), Department of Veteran Affairs, Department of Defense (VA/DoD), and

University of Michigan Health System (UMHS) recommendations for tobacco use cessation and prevention is provided in the tables below. Table 1 provides the scope of the guidelines, Table 2 compares the major recommendations, and Table 3 compares the potential benefits and harms of implementing the recommendations. Definitions for the levels of evidence used to support the guideline recommendations are given in Table 4.

The comparison in Table 2 is restricted to recommendations for interventions to be carried out by physicians and/or other health care professionals.

Following the tables and discussion of content comparison, the areas of agreement and differences among the guidelines are identified. In general, the timing of guideline development with respect to available data is an important factor to consider when evaluating areas of differences among the guidelines. Interpretation of available data is also considered.

Related Guidelines

- Registered Nurses Association of Ontario (RNAO). Integrating smoking cessation into daily nursing practice. Toronto (ON): Registered Nurses Association of Ontario (RNAO); 2003 Oct. 80 p. [59 references].
- New York State Department of Health. Smoking cessation in HIV-infected patients. New York (NY): New York State Department of Health; 2005 Jun. 8 p. [17 references].

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

- AHRQ, Agency for Healthcare Research and Quality
- DoD, Department of Defense
- FDA, Food and Drug Administration
- NRT, Nicotine replacement therapy
- UMHS, University of Michigan Health System
- U.S., United States
- USPSTF, United States Preventive Services Task Force
- VA, Veterans Affairs

TABLE 1: SCOPE	
Objectives	
USPSTF (2003)	• To summarize the USPSTF recommendations on counseling to prevent tobacco use and tobacco-caused disease and the supporting scientific evidence • To update the 1996 recommendations contained in the *Guide to Clinical Preventive Services*, Second Edition
VA/DoD	• To assist providers and tobacco specialists in delivering more

(2004)	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
UMHS (2006)	• To provide a systematic framework for care providers to assist patients in smoking cessation
Target Population	
USPSTF (2003)	• United States • General population, including adults, pregnant women, and children, seen in primary care settings
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)
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).
Intended Users	
USPSTF (2003)	Advanced Practice Nurses, Nurses, Physician Assistants, Physicians, Public Health Departments
VA/DoD (2004)	Advanced Practice Nurses, Allied Health Personnel, Physician Assistants, Physicians, Psychologists/Non-physician Behavioral Health Clinicians, Students
UMHS (2006)	Health Care Providers, Physicians
Interventions And Practices Considered	
USPSTF (2003)	Screening to identify and document tobacco use status

	Counseling and patient education, including: • "5-A" behavioral counseling framework (ask, advise, assess, assist, arrange) • 5 R's used to treat tobacco use (relevance, risk, rewards, roadblocks, repetition) • Telephone quitlines • Augmented pregnancy-tailored counseling • Self-help materials Pharmacotherapy, including: • Nicotine replacement therapy (i.e., nicotine gum, nicotine transdermal patches, nicotine inhaler, and nicotine nasal spray) • Sustained-release bupropion • Clonidine • Nortriptyline • Combination therapy

VA/DoD (2004)	Screening to identify and document tobacco use status
	
	Counseling and patient education, including:
	
	• "5-A" behavioral counseling framework (ask, advise, assess, assist, arrange)
	• 5 R's used to treat tobacco use (relevance, risk, rewards, roadblocks, repetition)
	• Telephone quit lines
	• Self-help materials
	
	Pharmacotherapy:
	
	• Firstline NRT:
	  • Transdermal delivery system (patches, e.g., Nicoderm CQ)
	  • Polacrilex resin (gum)
	  • Polacrilex resin (lozenge)
	  • Nasal spray (Nicotrol NS)
	  • Oral vapor inhaler (Nicotrol Inhaler)
	• Non-nicotine replacement products:
	  • First line: Bupropion SR (sustained release) and bupropion IR (immediate release)
	  • Second Line: Clonidine and nortriptyline
	• Combination Therapy
	
	Prevention strategies
	
	• Relapse prevention treatment (counseling and pharmacologic)
	• Encouraging children and adolescents to stay abstinent

	Tailoring of treatments to special populations (children/adolescents, pregnant women, hospitalized patients, older individuals, military personnel, psychiatric/mental health patients)

UMHS (2006)	Screening to identify and document tobacco use status
	
	Counseling and patient education, including:
	
	• "3A's and Refer" behavioral counseling framework (ask, advise, assess, and refer)
	• "5 R's" (relevance, risks, rewards, roadblocks, repetition) motivational intervention for users not ready to quit
	
	Pharmacotherapy:
	
	• First-line:
	  • Bupropion SR (sustained-release bupropion) or generic bupropion hydrochloride
	  • Varenicline
	  • Nicotine lozenge
	  • Nicotine gum
	  • Nicotine inhaler
	  • Nicotine nasal spray
	  • Transdermal nicotine patch
	• Second-line:
	  • Clonidine
	  • Nortriptyline
	• Combination Therapy
	
	Follow-up to prevent relapse
	
	Tailoring of treatments to special populations
	
	Advice on weight gain after smoking cessation
	
	Advice on non-cigarette tobacco products

TABLE 2: RECOMMENDATIONS FOR TOBACCO USE CESSATION AND PREVENTION	
SCREENING AND ASSESSMENT	
Screening for Tobacco Use	
USPSTF (2003)	The USPSTF strongly recommends that clinicians screen all adults for tobacco use and provide tobacco cessation interventions for those who

	use tobacco products (**A recommendation**). Clinics that implement screening systems designed to regularly identify and document a patient's tobacco use status increased their rates of clinician intervention, although there is limited evidence for the impact of screening systems on tobacco cessation rates.
VA/DoD (2004)	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.
UMHS (2006)	Ask all patients about smoking status and assess smoker's readiness to quit. Smoking status should be documented in the medical record. 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.
Willingness to Quit and Motivational Strategies	
USPSTF (2003)	Helpful aspects of counseling include providing problem-solving guidance for smokers to develop a plan to quit and to overcome common barriers to quitting and providing social support within and outside of treatment. Common practices that complement this framework include motivational interviewing, the 5 R's used to treat tobacco use (relevance, risks, rewards, roadblocks, repetition), assessing readiness to change, and more intensive counseling and/or referrals for quitters needing extra help. Telephone "quit lines" have also been found to be an effective adjunct to counseling or medical therapy.
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]**
UMHS (2006)	Assess whether the patient is "ready to attempt to quit." If "no," offer motivational interventions using the 5 "R's" • Relevance of quitting: impact of smoking on current health/illness and/or on children and others in household; social and economic costs of tobacco use • Risks of tobacco use: potential negative consequences of smoking • Rewards of quitting: improved health, improved taste, money saved, healthier children, freedom from addiction • Roadblocks to quitting: patient-identified barriers to quitting smoking • Repetition: above strategies are repeated every time an

	unmotivated patient has a visit
TREATMENT STRUCTURE AND INTENSITY	
Advise Tobacco Users to Quit	
USPSTF (2003)	Advise smokers to quit through clear personalized messages.
VA/DoD (2004)	Tobacco users should be advised to quit at every visit because there is a dose-response relationship between number of contacts and abstinence. **[A]** *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.
UMHS (2006)	Advise all smokers to seriously consider making a quit attempt using a clear, strong, and personalized message.
Intensity of Clinical Interventions	
USPSTF (2003)	Brief tobacco cessation counseling interventions, including screening, brief counseling (3 minutes or less), and/or pharmacotherapy, have proven to increase tobacco abstinence rates, although there is a dose-response relationship between quit rates and the intensity of counseling. Effective interventions may be delivered by a variety of primary care clinicians.
VA/DoD (2004)	• 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*. 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]").
UMHS (2006)	Advice as brief as 3 minutes is effective in smoking cessation *[**A**]*. 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 and ability to pay *[**C**]*.

Follow-up Assessment and Procedures (Prevention of Relapse)	
USPSTF (2003)	Arrange follow-up and support (after assisting in quitting).
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]** *Background*. Tobacco dependence is a chronic disease that often requires repeated interventions. Tobacco addiction is a chronic disorder that carries with it the vulnerability to relapse persisting for weeks, months, and perhaps even years. Therefore, consistent follow-up is necessary to ensure optimal care. **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]**
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.
TREATMENT ELEMENTS	
Counseling and Behavioral Therapies	
USPSTF (2003)	Helpful aspects of counseling include providing problem-solving guidance for smokers to develop a plan to quit and to overcome common barriers to quitting and providing social support within and outside of treatment. Common practices that complement this framework include motivational interviewing, the 5 R's used to treat tobacco use (relevance, risks, rewards, roadblocks, repetition), assessing readiness to change, and more intensive counseling and/or referrals for quitters needing extra help. Telephone "quitlines" have also been found to be an effective adjunct to counseling or medical therapy.
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 **[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. **Note**: 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.

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:
	
	• Help the patient with a quit plan:
	  • Set a quit date and record this on patient's chart. Ask the patient to mark this on his/her calendar. Quit date abstinence is a strong predictor of long-term success *[**C**]*.
	  • Patient should inform family, friends, co-workers of quit plan and request support.
	  • Have patient remove cigarettes from home, car, and

	workplace environments. • Review previous quit attempts • Anticipate challenges, particularly during the first critical few weeks (i.e., nicotine withdrawal symptoms). • 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.
Adjunctive Pharmacotherapy	
USPSTF (2003)	FDA-approved pharmacotherapy that has been identified as safe and effective for treating tobacco dependence includes several forms of NRT (i.e., nicotine gum, nicotine transdermal patches, nicotine inhaler, and nicotine nasal spray) and sustained-release bupropion. Other medications, including clonidine and nortriptyline, have been found to be efficacious and may be considered. <u>Combination Therapy</u> There are fair quality studies showing that combining the nicotine patch with either the gum or nasal spray is more efficacious than using a single form of nicotine replacement therapy alone.
VA/DoD (2004)	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. <u>Combination Therapy</u> 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]** **Note**: • Pharmacotherapies NOT recommended for tobacco cessation: antidepressants other than bupropion SR and nortriptyline; anxiolytics/benzodiazepines/beta-blockers; silver acetate; and mecamylamine. • 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]**
UMHS (2006)	Nicotine replacement therapies (NRTs), 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**]*.

	Combination Therapy 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**]*.
CONSIDERATIONS IN SPECIAL POPULATIONS	
Pregnancy and Second-hand Smoke Exposure in Infants and Children	
USPSTF (2003)	The USPSTF strongly recommends that clinicians screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke (**A recommendation**). The USPSTF found good evidence that extended or augmented smoking cessation counseling (5-15 minutes) using messages and self-help materials tailored for pregnant smokers, compared with brief generic counseling interventions alone, substantially increases abstinence rates during pregnancy, and leads to increased birth weights. Although relapse rates are high in the post-partum period, the USPSTF concluded that reducing smoking during pregnancy is likely to have substantial health benefits both for the baby and the expectant mother. The USPSTF concluded that the benefits of smoking cessation counseling outweigh any potential harms. There is little evidence on the safety and efficacy of tobacco cessation pharmacotherapy for the pregnant woman, the fetus, or the nursing mother and child. Therefore, pharmacotherapy for pregnant women may be considered when the likelihood of quitting and its potential benefits outweighs the risks of the therapy and continued smoking.
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).
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.
Children and Adolescents: Screening and Prevention of Initiation of Smoking	
USPSTF (2003)	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for tobacco use or interventions to prevent and treat tobacco use and dependence among children or adolescents (**I recommendation**). The USPSTF found limited evidence that screening and counseling children and adolescents in the primary care setting are effective in either preventing initiation or promoting cessation of tobacco use.
VA/DoD (2004)	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]**
UMHS (2006)	No recommendations offered.
Children and Adolescents: Counseling and Treatment of Tobacco-dependence	
USPSTF (2003)	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for tobacco use or interventions to prevent and treat tobacco use and dependence among children or adolescents (**I recommendation**). The USPSTF found limited evidence that screening and counseling children and adolescents in the primary care setting are effective in either preventing initiation or promoting cessation of tobacco use. The USPSTF found that school- and classroom-based smoking cessation programs may be more effective than no intervention among tobacco users who attend these programs. As with tobacco cessation programs for adults in the community setting, programs with a greater number of counseling sessions and increasing intensity of follow-up had higher quit rates. There is little evidence on the safety and efficacy of tobacco cessation pharmacotherapy in children or adolescents.
VA/DoD (2004)	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]**
UMHS (2006)	NRT or bupropion may be considered for use in adolescent smokers *[**D**]*. While the evidence indicates that these therapies are safe, they seem to be more effective when coupled with counseling.

	Some studies demonstrate that smoking cessation counseling in the primary care setting can improve adolescent smokers' quit rates *[**A**]*.
Gender Concerns, Racial/Ethnic Minorities, Patients with Psychiatric Cofactors, Older Smokers, and Hospitalized Patients	
USPSTF (2003)	No recommendations offered.
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]**
UMHS (2006)	*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**]*. *Racial/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. *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.

TABLE 3: BENEFITS AND HARMS	
Benefits	
USPSTF (2003)	**Smoking Cessation Benefits** There is good quality evidence that smoking cessation lowers the risk for heart disease, stroke, and lung disease. **Effectiveness of Counseling** The USPSTF found good quality evidence examining the efficacy of various levels of intensity of tobacco cessation counseling by clinicians based on a meta-analysis of 43 studies. Compared with no intervention, minimal counseling, lasting less than 3 minutes, has been shown to increase overall tobacco abstinence rates. Increasing session length and frequency increased efficacy in a dose-response manner. There is limited evidence to determine the optimal duration and periodicity of tobacco counseling interventions. *Pregnancy-tailored Counseling* A meta-analysis of 7 studies found that abstinence rates were higher (16.8% vs. 6.6%) for pregnant smokers receiving pregnancy-tailored counseling and self-help materials compared with pregnant smokers receiving brief counseling or "usual care." *Counseling for Children/Adolescents* The USPSTF found limited evidence of the efficacy of counseling children or adolescents in the clinical primary care setting, but found

	that school- and classroom-based smoking cessation programs may be more effective than no intervention among tobacco users who attend these programs. As with tobacco cessation programs for adults in the community setting, programs with a greater number of counseling sessions and increasing intensity of follow-up had higher quit rates. **Effectiveness of Pharmacotherapy** Several FDA-approved pharmacotherapies have been identified as safe and effective in helping adults to quit smoking. • Nicotine products, including nicotine gum, transdermal patch, nicotine nasal spray, and nicotine inhaler, have all been studied in comparison with placebo. There are good quality studies to support the abstinence rates among people who use these products compared with those who do not: 18 to 31% versus 10 to 17%. There are fair quality studies showing that combining the nicotine patch with either the gum or nasal spray is more efficacious than using a single form of nicotine replacement therapy alone. • Sustained-release bupropion has been shown to be efficacious compared with placebo, with an estimated cessation rate of 23 to 38% compared with 17%. • Other pharmacotherapies, including clonidine and nortriptyline, have been shown to result in higher smoking cessation rates when compared with placebo, although their use may be limited by side effects.
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.
UMHS (2006)	Effective interventions and strategies for health care providers to assist patients in smoking cessation
Harms	
USPSTF (2003)	There is little evidence on the safety and efficacy of tobacco cessation pharmacotherapy for the pregnant woman, the fetus, or the nursing mother and child. Therefore, pharmacotherapy for pregnant women may be considered when the likelihood of quitting and its potential benefits outweighs the risks of the therapy and continued smoking. Likewise, there is little evidence on the safety and efficacy of tobacco cessation pharmacotherapy in children or adolescents.
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.
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.

TABLE 4. EVIDENCE RATING SCHEMES AND REFERENCES	
USPSTF (2003)	**Definitions**

	The Task Force grades its **recommendations** according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms): **A** The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms. **B** The USPSTF recommends that clinicians provide [this service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms. **C** The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation. **D** The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits. **I** The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined. The USPSTF grades the **quality of the overall evidence** for a service on a 3-point scale (good, fair, poor): **Good** Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

	Fair Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes. **Poor** Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.
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
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

GUIDELINE CONTENT COMPARISON

The United States Preventive Services Task Force (USPSTF), Department of Veterans Affairs, Department of Defense (VA/DoD), and University of Michigan Health System (UMHS), present recommendations for tobacco use cessation and prevention. The organizations provide explicit reasoning behind their judgments and rate the evidence upon which their recommendations are based.

All of the guidelines included in this synthesis utilized to some degree, evidence and recommendations released in 2000 by the U.S Public Health Service (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. USPSTF likewise based its recommendations on the evidence provided in the 2000 PHS document including more recently published literature. The VA/DoD guideline refers often to the PHS guideline but has also based its recommendations on an extensive review of more recent literature.

Although all groups provide recommendations on identification of tobacco users and the benefits of counseling and adjunctive pharmacologic treatment for tobacco use, VA/DoD provides the most extensive and comprehensive review, presenting detailed outlines for both brief and intensive strategies to be used by clinicians for tobacco use intervention. VA/DoD also emphasizes a "Population Health" strategy that promotes primary-care based treatment and prevention.

Areas of Agreement

The recommendations for tobacco use cessation and prevention are in almost total concurrence for all three guideline groups. 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 is universally recommended. UMHS includes a referral in their framework, indicating that if 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.

Identification and Documentation of Tobacco Users

The guidelines are in general agreement regarding the need to identify tobacco users during routine clinic visits. Most groups recommend the use of a chart or sticker system to label a patient as a user or former user of tobacco.

Benefits of Counseling

All of the guidelines agree on the effectiveness of counseling as a means for clinicians to modify behavior and address tobacco dependence in their patients. All guidelines agree that advice to patients 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. 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). The importance of frequent and/or intensive counseling is also stressed by all of the organizations. In particular, the dose-response relationship between treatment intensity and abstinence from tobacco use is emphasized.

Adjunctive Pharmacologic Therapy

The use of nicotine replacement therapy (NRT) as an adjunct to counseling is endorsed by all three guideline groups, except in special circumstances. Bupropion is also recommended by all groups as either first-line or second-line medication. Nortriptyline is recognized as a second-line treatment by all three groups. UMHS recommends clonidine as a second-line treatment in patients unwilling or unable to use NRT or bupropion or who fail on first-line therapy. VA/DoD likewise state that clonidine may be considered on a case-by-case basis after first-line treatments have been used or considered, and should only be used under the supervision of a physician. USPSTF states that clonidine may be considered as pharmacotherapy because it results in higher smoking cessation rates when compared with placebo, although its use may be limited by side effects.

There is also general agreement between the groups with respect to the efficacy of combination NRT. All three groups note that studies with combination NRT suggest improved efficacy compared with single forms of NRT. 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.

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.

Prevention Strategies

The need for follow-up to prevent and treat relapses is acknowledged by UMHS and VA/DoD (USPSTF does not provide any specific recommendations in this area).

VA/DoD also emphasizes the need for clinicians to help prevent the initiation of tobacco use in children and adolescents through direct counseling or by participation in school-based or community programs.

Passive Smoke Exposure

VA/DoD offers specific recommendations on counseling to parents on the need to limit children's exposure to second-hand smoke. UMHS and VA/DoD state that the negative effects of passive smoking should be emphasized in trying to motivate smokers to quit.

Gender Concerns, Racial/Ethnic Minorities, Patients with Psychiatric Cofactors, Older Smokers, and Hospitalized Patients

UHMS and VA/DoD address special populations in their guidelines. Both groups 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.

Areas of Differences

Counseling and Treatment of Children and Adolescents

The three groups that provide specific recommendations on counseling and treatment of child and adolescent tobacco users differ somewhat in their approach. 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 note however that interventions shown to be effective with adults may also be considered with adolescents.

VA/DoD recommends adjunctive pharmacotherapy but only when the clinician has evidence that the adolescent is nicotine dependent and is willing to quit. UMHS states that the same counseling and treatment strategies used in adults can be applied to adolescents; however, they admit that there is limited evidence regarding the efficacy of brief clinician interventions in treating tobacco use in adolescence. They concede that in many cases, "expert opinion rather than empirical data is used to guide clinical interventions for young smokers." USPSTF also states that there is no evidence for the efficacy of cessation programs in young people. USPSTF therefore does not recommend for or against any routine interventions in the primary care setting for screening or treatment of children or adolescents for tobacco use.

Treatment During Pregnancy

Although all of the groups strongly endorse smoking cessation interventions in pregnant women who smoke, they differ in their recommendations concerning use of pharmacologic therapy. VA/DoD (through DoD/VA Clinical Practice Guideline for Management of Uncomplicated Pregnancy) makes no recommendations either for or against drug therapy during pregnancy. UMHS notes that, while few studies have addressed NRTR or bupropion in pregnancy directly, research has shown that less nicotine and fewer metabolites cross the placenta with NRT than with smoking. Therefore, they advise cautious use of bupropion with NRT (especially nicotine gum) after reviewing risks and benefits with the patient. For breastfeeding mothers, UMHS states that data supports the use of bupropion plus NRT in nursing mothers, with increased cessation rates. They note that it is not known whether varenicline is excreted in human milk.

USPSTF also cites the lack of evidence on the safety and efficacy of pharmacotherapy for the pregnant woman, the fetus, or the nursing mother and child. Therefore, USPSTF makes no recommendations for or against pharmacotherapy during pregnancy, but advises that "pharmacotherapy for pregnant women may be considered when the likelihood of quitting and its potential benefits outweigh the risks of the therapy and continued smoking."

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