Clinical Practice Guideline

Treating Tobacco Use and Dependence: 2008 Update

Guideline Panel

Michael C. Fiore, MD, MPH
(Panel Chair)
Carlos Roberto Jaén, MD, PhD, FAAFP
(PANEL Vice Chair)
Timothy B. Baker, PhD
(Senior Scientist)
William C. Bailey, MD, FACP, FCCP
Neal L. Benowitz, MD
Susan J. Curry, PhD
Sally Faith Dorfman, MD, MSHSA
Erika S. Froelicher, PhD, RN, MA, MPH
Michael G. Goldstein, MD
Cheryl G. Heaton, DrPH
Patricia Nez Henderson, MD, MPH

Richard B. Heyman, MD
Howard K. Koh, MD, MPH, FACP
Thomas E. Kottke, MD, MSPH
Harry A. Lando, PhD
Robert E. Mecklenburg, DDS, MPH
Robin J. Mermelstein, PhD
Patricia Dolan Mullen, DrPH
C. Tracy Orleans, PhD
Lawrence Robinson, MD, MPH
Maxine L. Stitzer, PhD
Anthony C. Tommasello, PhD, MS
Louise Villejo, MPH, CHES
Mary Ellen Wewers, PhD, MPH, RN

Guideline Liaisons

Ernestine W. Murray, RN, BSN, MAS, (Project Officer), Agency for Healthcare Research and Quality
Glenn Bennett, MPH, CHES, National Heart, Lung, and Blood Institute
Stephen Heishman, PhD, National Institute on Drug Abuse
Corinne Husten, MD, MPH, Centers for Disease Control and Prevention
Glen Morgan, PhD, National Cancer Institute
Christine Williams, MEd, Agency for Healthcare Research and Quality

Guideline Staff

Bruce A. Christiansen, PhD (Project Director)
Megan E. Piper, PhD (Project Scientist)
Victor Hasselblad, PhD (Project Statistician)
David Fraser, MS (Project Coordinator)
Wendy Theobald, PhD (Editorial Associate)
Michael Connell, BS (Database Manager)
Cathlyn Leitzke, MSN, RN-C (Project Researcher)

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Chapter 7  Specific Populations and Other Topics

Background

Many factors could affect the acceptability, use, and effectiveness of tobacco dependence treatments. This raises the question of whether interventions should be tailored or modified on the basis of personal characteristics or contextual factors such as gender, race/ethnicity, age, comorbidity, or hospitalization status. Should pregnant smokers receive tobacco dependence medication? Do tobacco dependence interventions interfere with nontobacco chemical dependency treatments? These and other specific populations and issues are considered in this chapter. The answers to these questions are relevant to a range of clinicians who routinely deal with specific populations of smokers (e.g., obstetricians, gynecologists, pediatricians, psychiatrists, internists, cardiologists, nurses, pharmacists, dentists, and dental hygienists).

Recommendation: 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)

Effective Treatments for Specific Populations

The above recommendation applies to the broad population of smokers, including HIV-positive smokers; hospitalized smokers; lesbian/gay/bisexual/transgender smokers; those with low socioeconomic status (SES)/limited formal education; smokers with medical comorbidities; older smokers; smokers with psychiatric disorders, including substance use disorders; racial and ethnic minorities; and women smokers. It does not apply to adolescents, pregnant smokers, light smokers, and smokeless tobacco users (see below).
The recommendation that tobacco dependence treatments be used with broad populations of tobacco users arises from several considerations. One is that many of the randomized trials that generated the treatment recommendations comprised diverse samples. A second consideration is that the studies that tested interventions in homogeneous, specific populations show that interventions that are effective in one population tend to be effective in other populations. Finally, the relative safety of the tobacco dependence treatments versus the hazards of continued tobacco use supports some extrapolation from extant data. Table 7.1 reviews the randomized clinical trial (RCT) evidence of effectiveness of various treatments in different populations. Unless specifically stated, this table presents evidence from individual, screened RCTs rather than from meta-analyses. It is not intended to provide a comprehensive review of the relevant literature, but rather to provide some key findings from that review. Importantly, adolescents, pregnant smokers, light smokers, and smokeless tobacco users each have their own sections of this Guideline update, given that they usually are excluded from the RCTs used to evaluate the effectiveness of interventions presented in this Guideline and may have other special issues (e.g., safety).

Table 7.1. Evidence of effectiveness of tobacco dependence interventions in specific populations

<table>
<thead>
<tr>
<th>Population of Smokers</th>
<th>Review of Evidence</th>
</tr>
</thead>
</table>
| HIV-positive          | No long-term RCTs have examined the effectiveness of interventions in this population. More research is needed.  
  • One study with 3-month followup indicated that telephone counseling is promising.418  
  • Pilot data indicate that effective treatments work with this population.419 |
| Hospitalized patients | 2007 Cochrane analyses420 revealed that intensive intervention (inpatient contact plus followup for at least 1 month) was associated with a significantly higher quit rate compared to control conditions (OR = 1.65; 95% CI = 1.44–1.90, 17 trials). Specific additional Cochrane findings:  
  • Posthospitalization followup appears to be a key component of effective interventions.  
  • No significant effect of medication was seen in this population. However, the effect sizes were comparable to those obtained in other clinical trials, suggesting that nicotine replacement therapy (NRT) and bupropion SR may be effective in this population. |
### Table 7.1. Evidence of effectiveness of tobacco dependence interventions in specific populations (continued)

<table>
<thead>
<tr>
<th>Population of Smokers</th>
<th>Review of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalized patients (continued)</td>
<td>• Intervention is effective regardless of the patient’s reason for admission. There was no strong evidence that clinical diagnosis of the medically comorbid condition affected the likelihood of quitting. Interventions that have been shown to be effective in individual studies are: counseling and medication(^{57,355,421-423}) and other psychosocial interventions, including self-help via brochure or audio/ videotape; chart prompt reminding physician to advise smoking cessation; hospital counseling; and postdischarge counseling telephone calls.(^{424,425}) Some data suggest NRT might not be appropriate in intensive care patients.(^{358})</td>
</tr>
<tr>
<td>Lesbian, gay, bisexual, transgender</td>
<td>No long-term RCTs have examined the effectiveness of interventions specifically in this population.</td>
</tr>
<tr>
<td>Low SES/limited formal education(^a)</td>
<td>• Meta-analysis (2008): 5 studies met selection criteria and contributed to a 2008 Guideline meta-analysis comparing counseling vs. usual care or no counseling among individuals with low SES/limited formal education. Meta-analytic results showed that counseling is effective in treating smokers with low SES/limited formal education (OR = 1.42; 95% C.I. = 1.04–1.92) (Abstinence rate without counseling = 13.2%; with counseling, abstinence rate = 17.7% [95% C.I. = 13.7%–22.6%]) • Interventions included in the meta-analysis were motivational messages with and without telephone counseling for low-income mothers and low-income African Americans,(^{172,426}) proactive telephone counseling in addition to nicotine patches,(^{427,428}) tailored bedside counseling and followup for hospitalized African-American patients.(^{429})</td>
</tr>
<tr>
<td>Medical co-morbidities</td>
<td>Tobacco use treatments have been shown to be effective among smokers with a variety of comorbid medical conditions. The comorbid conditions and effective interventions include: • Cardiovascular disease: psychosocial interventions,(^{430-439}) exercise,(^{440,441}) bupropion SR,(^{439,442}) but one study did not find significant long-term effects,(^{443}) nicotine patch, gum, or inhaler.(^{439}) • Lung/COPD patients: intensive cessation counseling,(^{444}) intensive behavioral (relapse prevention) program combined with nicotine replacement therapy,(^{445}) bupropion SR,(^{446,447}) nortriptyline,(^{447}) nicotine patch or inhaler.(^{448}) • Cancer: counseling and medication,(^{251,449,450}) motivational counseling.(^{451})</td>
</tr>
</tbody>
</table>
Treating Tobacco Use and Dependence: 2008 Update

Population of Smokers

Older smokers

- Research has demonstrated the effectiveness of the “4 A’s” (ask, advise, assist, and arrange followup) in patients ages 50 and older. Counseling interventions, physician advice, buddy support programs, age-tailored self-help materials, telephone counseling, and the nicotine patch all have been shown to be effective in treating tobacco use in adults 50 and older.

Psychiatric disorders, including substance use disorders

- Meta-analysis (2008): Four studies met selection criteria and were relevant to a 2008 Guideline meta-analysis comparing antidepressants (bupropion SR and nortriptyline) vs. placebo for individuals with a past history of depression. Meta-analytic results showed that antidepressants, specifically bupropion SR and nortriptyline, are effective in increasing long-term cessation rates in smokers with a past history of depression (OR = 3.42; 95% C.I. = 1.70–6.84; abstinence rates = 29.9%, 95% C.I. = 17.5%–46.1%). Note that these studies typically included intensive psychosocial interventions for all participants.

- Although psychiatric disorders may place smokers at increased risk for relapse, such smokers can be helped by tobacco dependence treatments.

- Some data suggest that bupropion SR and NRT may be effective for treating smoking in individuals with schizophrenia and may improve negative symptoms of schizophrenia and depressive symptoms. Data suggest that individuals on atypical antipsychotics may be more responsive to bupropion SR for treatment of tobacco dependence than those taking standard antipsychotics.

- Current evidence is insufficient to determine whether smokers with psychiatric disorders benefit more from tobacco use treatments tailored to psychiatric disorder/symptoms than from standard treatments.

- Evidence indicates that tobacco use interventions, both counseling and medication, are effective in treating smokers who are receiving treatment for chemical dependency.

- There is little evidence that tobacco dependence interventions interfere with recovery from nontobacco chemical dependencies among patients who are in treatment for such dependencies. One study suggests that delivery of smoking cessation interventions concurrent with alcohol dependence interventions may compromise alcohol abstinence outcomes, although there was no difference in smoking abstinence rates.
Psychiatric disorders, including substance use disorders (continued)

- The use of varenicline has been associated with depressed mood, agitation, suicidal ideation, and suicide. The FDA recommends that patients tell their health care provider about any history of psychiatric illness prior to starting varenicline and that clinicians monitor for changes in mood and behavior when prescribing this medication. In light of these FDA recommendations, clinicians should consider eliciting information on their patients’ psychiatric history. For more information, see the FDA package insert.

Racial/ethnic minorities

RCTs have examined the effectiveness of interventions in specific racial/ethnic minority populations:

- African Americans
  - Bupropion SR, nicotine patch, clinician advice, counseling, biomedical feedback, tailored self-help manuals and materials, and telephone counseling have been shown to be effective with African-American smokers.

- Asian and Pacific Islanders
  - No long-term RCTs have examined the effectiveness of interventions specifically in this population.

- Hispanics
  - Nicotine patch, telephone counseling, self-help materials, including a mood management component, and tailoring have been shown to be effective with Hispanic smokers.

- American Indians and Alaska Natives
  - Screening for tobacco use, clinician advice, clinic staff reinforcement, and followup materials have been shown to be effective for American Indian and Alaska Native populations.

Women

- Evidence shows that both men and women benefit from bupropion SR, NRT, and varenicline. Evidence is mixed as to whether women show as great a benefit from NRT as do men.
- Psychosocial interventions, including proactive phone counseling, individually tailored followup, and advice to quit geared toward children’s health, are effective with women. There is some evidence that exercise is effective for women, however, these findings are not consistent.

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*Go to [www.surgeongeneral.gov/tobacco/gdlhrefs.htm](http://www.surgeongeneral.gov/tobacco/gdlhrefs.htm) for the articles used in this meta-analysis.
Clinical Issues for Specific Populations

There are population-specific concerns and clinical issues regarding prevalence and treatment of tobacco dependence (see Table 7.2).

Table 7.2. Clinical issues for treating specific populations

<table>
<thead>
<tr>
<th>Issue</th>
<th>Approach</th>
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</table>
| Language            | • Ensure that interventions are provided in a language the patient understands. Most quitlines provide counseling in Spanish, and some provide counseling in other languages.503  
                      • All textual materials used (e.g., self-help brochures) should be written at an appropriate reading level. This is particularly important given epidemiological data showing that tobacco use rates are markedly higher among individuals of lower educational attainment.504,505 |
| Culture             | • Interventions should be culturally appropriate to be relevant and acceptable to the patient.506 The extent to which cultural tailoring enhances intervention effectiveness requires further research.490  
                      • Clinicians should remain sensitive to individual differences and spiritual and health beliefs that may affect treatment acceptance, use, and success in all populations (see Chapter 6A, Specialized Assessment). |
| Medical comorbidity | • Examine the possibility of medication interactions (See Chapter 6B, Interactions of First-Line Tobacco Use Medications With Other Drugs).308  
                      • Address how exposure to tobacco can alter the liver’s ability to metabolize different medications (HIV-positive patients). |

**HIV-Positive Smokers**

HIV-positive individuals are more likely to smoke than the general population.507-510 Currently, HIV-positive individuals are living longer, due to treatment advances, making the issue of cigarette smoking in this population a significant clinical concern.511,512 HIV-positive smokers have higher mortality rates and report lower quality of life than HIV-positive nonsmokers.513,516 In addition, HIV-positive smokers appear to be at greater risk for developing invasive pneumococcal diseases and CNS infections compared with non-HIV infected individuals.514,517 Also, compared to nonsmoking HIV-positive individuals, smoking among HIV-positive persons is associated with increased risk of several opportunistic infections518-520 and spontaneous pneumothorax.521 Data suggest that HIV-positive smokers underestimate the effects of smoking on their health, and some state that
they will not live long enough for the health effects of smoking to matter.\textsuperscript{507,522} In addition, some HIV-positive smokers report that smoking is an effective way to cope with the stress of their illness.\textsuperscript{522}

**Future Research**

The following topics regarding HIV-positive smokers require additional research:

- Effectiveness of medications and counseling/behavioral interventions, including tailored interventions
- Effectiveness of motivational interviewing and educational approaches in increasing motivation to quit
- Effectiveness of community and social support networks in bolstering quitting motivation and improving treatment outcomes

**Hospitalized Smokers**

It is vital that hospitalized patients attempt to quit using tobacco because tobacco use may interfere with their recovery and overall health. Among cardiac patients, second heart attacks are more common in those who continue to smoke.\textsuperscript{9,523} Lung, head, and neck cancer patients who are successfully treated for their cancer but who continue to smoke are at elevated risk for a second cancer.\textsuperscript{524-531} Additionally, smoking negatively affects COPD as well as bone and wound healing.\textsuperscript{531-538}

Hospitalized patients may be particularly motivated to make a quit attempt for two reasons. First, the illness resulting in hospitalization may have been caused or exacerbated by tobacco use, highlighting the patient’s perceived vulnerability to the health risks of smoking\textsuperscript{539} and making the hospitalization a “teachable moment.” Second, every hospital in the United States must now be smoke-free if it is to be accredited by The Joint Commission. As a result, every hospitalized smoker is temporarily housed in a smoke-free environment. In addition, more hospitals are adopting policies establishing tobacco-free campuses, thus extending smoke-free space from indoor facilities to surrounding outdoor environments.\textsuperscript{540-542} For these reasons, clinicians should use hospitalization as an opportunity to promote smoking cessation.\textsuperscript{11,543,544} This also is an opportunity for clinicians to
prescribe medications to alleviate withdrawal symptoms. If patients have positive experiences with the alleviation of their withdrawal symptoms, they may be more likely to use intensive treatments in a future quit attempt or maintain their hospital-enforced abstinence. Patients in long-term care facilities also should receive tobacco dependence interventions identified as effective in this Guideline. Suggested interventions for hospitalized patients can be found in Table 7.3.

Table 7.3. Suggested interventions for hospitalized patients

<table>
<thead>
<tr>
<th>For every hospitalized patient, the following steps should be taken:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ask each patient on admission if he or she uses tobacco and document tobacco use status.</td>
</tr>
<tr>
<td>• For current tobacco users, list tobacco use status on the admission problem list and as a discharge diagnosis.</td>
</tr>
<tr>
<td>• Use counseling and medications to help all tobacco users maintain abstinence and to treat withdrawal symptoms.</td>
</tr>
<tr>
<td>• Provide advice and assistance on how to quit during hospitalization and remain abstinent after discharge.</td>
</tr>
<tr>
<td>• Arrange for followup regarding smoking status. Supportive contact should be provided for at least a month after discharge.</td>
</tr>
</tbody>
</table>

The importance of posthospitalization followup has been demonstrated by research. However, there are systems-level issues that may complicate the ability of hospital-based clinicians to follow up with smoking patients. The development of fax-to-quit links with quitline services may be an effective and efficient way for hospitals to refer patients for smoking cessation followup.

Future Research

The following topics regarding hospitalized patients require additional research:

- Effectiveness of interventions provided by different hospital personnel, including nurses and respiratory therapists

- Effectiveness of counseling and medications with hospitalized patients

- Relapse prevention once the patient leaves the hospital, including use of fax-to-quit programs
Lesbian/Gay/Bisexual/Transgender (LGBT) Smokers

LGBT individuals, both adolescents and adults, are more likely to smoke than the general population, and tobacco marketing is targeted at these communities. LGBT individuals are more likely to have other risk factors for smoking, including daily stress related to prejudice and stigma.

Future Research

The following topics regarding LGBT smokers require additional research:

- Accessibility and acceptability of tobacco dependence interventions
- Rates of intervention use and effectiveness of both medications and counseling treatments, including quitlines
- Effectiveness of tailored interventions

Low SES/Limited Formal Education

Individuals with low SES and/or limited formal education, including the homeless, bear a disproportionate burden from tobacco. Addressing this particular disparity is an important part of improving the overall health of the American public. These patients are more likely to: smoke, have limited access to effective treatment, be misinformed about smoking cessation medications, be exposed to more permissive environmental and workplace smoking policies, and be targeted by tobacco companies. They are less likely to receive cessation assistance. Moreover, smokers with low SES/limited formal education are more likely to be uninsured or on Medicaid than are other smokers. Only 25 percent of smokers on Medicaid reported receiving any practical assistance with quitting. However, low SES smokers or those with limited formal education express significant interest in quitting and appear to benefit from treatment. Due to the prevalence of smoking in this population, it is vital that clinicians intervene with such individuals. It is important that interventions, particularly written materials, be delivered in a manner that is understandable to the patient.
Future Research

The following topics regarding low SES/limited formal education smokers require additional research:

- Effectiveness of and compliance with medications shown to be effective with general populations of smokers
- Effectiveness and utilization of novel treatment delivery settings (e.g., pharmacy-based, community-based, worksite)
- Effectiveness of quitlines, including ability of this population to access services using this modality
- Strategies for addressing misconceptions about effective cessation treatment that may be more common in these populations
- Cost-effectiveness of cessation interventions delivered as part of chronic disease management programs

Medical Comorbid Conditions, Including Cancer, Cardiac Disease, COPD, Diabetes, and Asthma

Smokers with comorbid medical conditions such as cancer, cardiac disease, COPD, diabetes, and asthma are important to target for tobacco use treatments, given the role that smoking plays in exacerbating these conditions. Clinicians treating smokers with these conditions have an ideal “teachable moment” in that they are treating a disease that may have been caused or exacerbated by smoking and that can be ameliorated by quitting but not by cutting down. Using chronic disease management programs to integrate tobacco dependence interventions into treatment may be an effective and efficient way to deliver tobacco use interventions to these populations.

Future Research

The following topics regarding smokers with comorbid medical conditions require additional research:

- Effectiveness of counseling and cessation medications among individuals with diabetes and asthma
• Impact and effectiveness of specialized assessment and tailored interventions in these populations

Older Smokers

It is estimated that more than 18 million Americans age 45 and older smoke cigarettes, accounting for 41 percent of all adult smokers in the United States;\textsuperscript{589} 4.5 million adults over age 65 smoke cigarettes.\textsuperscript{590} Even smokers over the age of 65 can benefit greatly from abstinence.\textsuperscript{9,405,523,591} Older smokers who quit can reduce their risk of death from coronary heart disease, COPD, and lung cancer and decrease their risk of osteoporosis.\textsuperscript{544,592,593} Moreover, abstinence can promote more rapid recovery from illnesses that are exacerbated by smoking and can improve cerebral circulation.\textsuperscript{453,594,595} In fact, age does not appear to diminish the desire to quit\textsuperscript{596} or the benefits of quitting smoking,\textsuperscript{166,597} and treatments shown to be effective in this Guideline have been shown to be effective in older smokers (see Table 7.1). However, smokers over the age of 65 may be less likely to receive smoking cessation medications identified as effective in this Guideline.\textsuperscript{598} Issues particular to this population (e.g., mobility, medications) make the use of proactive telephone counseling appear particularly promising. Importantly, Medicare has expanded benefits for tobacco cessation counseling and prescription medications (through Medicare Part D) for tobacco dependence treatment.\textsuperscript{219}

Future Research

The following topics regarding older smokers require additional research:

• Effectiveness of tailored as well as general counseling interventions for older smokers in promoting tobacco abstinence

• Effectiveness and side effects of medications

• Effective methods to motivate older smokers to make a quit attempt

Psychiatric Disorders, Including Substance Use Disorders

Psychiatric disorders are more common among smokers than in the general population. For instance, as many as 30 to 60 percent of patients seeking
tobacco dependence treatment may have a past history of depression, and 20 percent or more may have a past history of alcohol abuse or dependence. Smoking occurs at rates well above the population average among abusers of alcohol and drugs (i.e., greater than 70 percent), and one study found that these individuals have increased mortality from tobacco-related diseases. These individuals may present themselves less frequently for tobacco dependence treatment. However, such treatments could be conveniently delivered within the context of chemical dependence or mental health clinics.

As noted in the Specialized Assessment section in Chapter 6A, smokers currently experiencing a psychiatric disorder are at heightened risk for relapse to smoking after a cessation attempt. All smokers with psychiatric disorders, including substance use disorders, should be offered tobacco dependence treatment, and clinicians must overcome their reluctance to treat this population. However, the clinician may wish to offer the tobacco dependence treatment when psychiatric symptoms are not severe. Although patients in inpatient psychiatric units are able to stop smoking with few adverse effects (e.g., little increase in aggression), stopping smoking or nicotine withdrawal may exacerbate a patient’s comorbid condition. For instance, stopping smoking may elicit or exacerbate depression among patients with a prior history of affective disorder. One study suggests that alcohol treatment should precede tobacco dependence treatment to maximize the effect of the alcohol treatment. Considerable research, however, also indicates that tobacco dependence treatment does not interfere with patients’ recovery from the abuse of other substances. Treating tobacco dependence in individuals with psychiatric disorders is made more complex by the potential for multiple psychiatric diagnoses and multiple psychiatric medications. Stopping tobacco use may affect the pharmacokinetics of certain psychiatric medications. Therefore, clinicians should closely monitor the level or effects of psychiatric medications in smokers making a quit attempt.

**Future Research**

The following topics regarding psychiatric disorders, including substance use disorders, require additional research:
• Relative effectiveness and reach of different tobacco dependence medications and counseling strategies in patients with psychiatric comorbidity, including depression

• Effectiveness and impact of tobacco dependence treatments within the context of nontobacco chemical dependency treatments

• Importance and effectiveness of specialized assessment and tailored interventions in these populations

• Impact of stopping tobacco use on psychiatric disorders and their management

Racial and Ethnic Minority Populations

Some racial and ethnic minority populations in the United States—African Americans, American Indians and Alaska Natives, Asians and Pacific Islanders, Hispanics—experience higher mortality in a number of disease categories compared with others. For example, African Americans experience substantial excess mortality from cancer, cardiovascular disease, and infant death, all of which are directly affected by tobacco use. Moreover, they experience greater exposure to tobacco advertising. American Indian and Alaska Natives have some of the highest documented rates of infant mortality caused by SIDS, which also is affected by tobacco use and exposure to secondhand smoke. Therefore, the need to deliver effective tobacco dependence interventions to ethnic and racial minority smokers is critical. Unfortunately, evidence indicates that large proportions of some racial/ethnic groups lack adequate access to primary care providers and are more likely to have low SES. These populations may be less aware of Medicaid or other available benefits and more likely to harbor misconceptions about tobacco dependence treatments. Finally, these populations may be less likely to receive advice to stop smoking or use tobacco dependence treatment than are other individuals. This suggests that special efforts and resources should be provided to meet the treatment needs of these underserved populations.

The differences between racial and ethnic minorities and whites in smoking prevalence, smoking patterns, pharmacokinetics of nicotine, and quitting behavior in the United States are well documented. In addition, smoking prevalence and patterns vary substantially across and
within minority subgroups (e.g., gender, level of acculturation, tribal communities). Racial and ethnic minority groups also differ from whites in awareness of the health effects of smoking and awareness of the benefits of proven treatments, and some racial and ethnic minority populations report a greater sense of fatalism that may affect disease prevention efforts. On the other hand, both tobacco dependence and desire to quit appear to be prevalent across varied racial and ethnic groups. In fact, smokers in several racial and ethnic groups attempt to quit as often as or more often than nonminority smokers, but use effective treatments less often and have lower success rates.

## Future Research

The following topics regarding racial and ethnic minorities require additional research:

- Effectiveness of specific tobacco dependence interventions, including medications and quitlines, in these populations (e.g., American Indian and Alaska Native smokers)

- Effectiveness of culturally adapted versus generic interventions for different racial and ethnic minority populations

- Identification and development of interventions to address the specific barriers or impediments to treatment delivery, use, or success (e.g., SES, inadequate access to medical care, treatment misconceptions, not viewing tobacco use as problematic)

- Identification of motivators of cessation that are especially effective with members of racial and ethnic minority populations (e.g., fear of illness requiring long-term care and disability)

## Women

Data suggest that women are more likely to seek assistance in their quit attempts than are men. Research suggests that women benefit from the same interventions as do men, although the data are mixed on whether they benefit as much as men. Women may face different stressors and barriers to quitting that may be addressed in treatment. These include greater likelihood of depression, greater weight control concerns, hormon-
al cycles, greater nonpharmacologic motives for smoking (e.g., for socialization), educational differences, and others. This suggests that women may benefit from tobacco dependence treatments that address these issues, although few studies have examined programs targeted at one gender.

Future Research

The following topics regarding gender differences require additional research:

- Gender differences in the effectiveness of tobacco dependence treatments found to be effective in this Guideline, including counseling and the effectiveness of varenicline and combination medications

- Impact of gender-specific motives that may increase quit attempts and success (e.g., quitting to improve fertility and reproductive health, pregnancy outcomes, physical appearance, and osteoporosis)

Other Specific Populations and Topics

Children and Adolescents

Recommendation: 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)

Recommendation: 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)

Recommendation: 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)
Background

Tobacco use is a pediatric concern. In the United States, about 4,000 children and adolescents under age 18 smoke their first cigarette each day, and an estimated 1,200 children and adolescents become daily cigarette smokers each day.44,674 Among adults who ever smoked daily, 90 percent tried their first cigarette before age 21.675 It is estimated that in 2006, 3.3 million U.S. adolescents aged 12 to 17 were current (past month) users of tobacco products and 2.6 million were current cigarette smokers.43 Although use of cigarettes and cigars declined slightly from 2005 among this age group, the use of smokeless tobacco increased.43 If current patterns persist, an estimated 6.4 million youth will die prematurely from a smoking-related disease.675 Young people experiment with or begin regular use of tobacco for a variety of reasons, including social and parental norms, advertising, movies and popular media, peer influence, parental smoking, weight control, and curiosity.676-685 Nicotine dependence, however, is established rapidly even among adolescents.686-689 Because of the importance of primary prevention, clinicians should ensure that they deliver tobacco prevention and cessation messages to pediatric patients and their parents. Because tobacco use often begins during preadolescence,690 clinicians should routinely assess and intervene with this population. Intervention research remains a priority for this population. Current reviews of smoking prevention and cessation interventions for adolescents have, so far, demonstrated limited evidence of effectiveness.691,692 A 2007 national survey of youth tobacco cessation programs showed a lack of such programs in communities most in need—those in which youth smoking prevalence is increasing.693 Prevention strategies useful in more general settings can be found in the Institute of Medicine report Growing Up Tobacco Free694 and in the 2000 Surgeon General’s Report Reducing Tobacco Use6 and recently have been addressed by several authors.695,696

Young people vastly underestimate the addictive potential of nicotine. Adolescent smokers, both occasional and daily smokers, are more likely than nonsmokers to think they can quit at any time.697 However, only about 4 percent of smokers aged 12 to 19 successfully quit smoking each year,698,699 and the rate of failed adolescent quit attempts exceeds that of adult smokers.32 Adolescents are very interested in quitting; 82 percent of 11- to 19-year-olds who smoke are thinking about quitting.700 and 77 percent have made a serious quit attempt in the past year.701,702 Adolescent quit attempts are rarely planned, and adolescents tend to choose unassisted
rather than assisted quit methods,\textsuperscript{32} even though young people who enroll in a tobacco cessation program are twice as likely to succeed in their quit attempt.\textsuperscript{703,704}

\section*{Tobacco Use Treatments in Children and Adolescents}

\textbf{Counseling}. Seven studies met selection criteria and were included in a new 2008 analysis comparing counseling to usual care among adolescent smokers. Results of this analysis are shown in Table 7.4. As can be seen from this analysis, the use of counseling approximately doubles long-term abstinence rates when compared to usual care or no treatment. In these studies usual care may have included brief advice, self-help pamphlets, reading materials, or a referral. Note that although counseling does significantly boost abstinence rates, absolute abstinence rates were quite low, attesting to the need for improved counseling interventions for adolescents. An inspection of the included studies revealed significant heterogeneity among analyzed articles. Thus, the Panel decided to make a “B” level recommendation rather than “A” level recommendation. A recent Cochrane meta-analysis produced mixed findings for counseling as a tobacco use treatment for youth.\textsuperscript{705}

\begin{table}[h]
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\begin{tabular}{|l|l|l|l|}
\hline
Adolescent smokers & Number of arms & Estimated odds ratio (95\% C.I.) & Estimated abstinence rate (95\% C.I.) \\
\hline
Usual care & 7 & 1.0 & 6.7 \\
Counseling & 7 & 1.8 (1.1–3.0) & 11.6 (7.5–17.5) \\
\hline
\end{tabular}
\caption{Meta-analysis (2008): Effectiveness of and estimated abstinence rates for counseling interventions with adolescent smokers (n = 7 studies)\textsuperscript{a}}
\end{table}

\textsuperscript{a} Go to www.surgeongeneral.gov/tobacco/gdlnrefs.htm for the articles used in this meta-analysis.

There were too few studies to perform meta-analyses on specific counseling techniques (e.g., motivational interviewing). The adolescent intervention studies that yielded significant effects used interventions that varied in intensity, format, and content. One study used an intervention that had one in-person counseling session and one telephone call; the other two interventions comprised six and eight sessions of counseling delivered in a group format. The counseling content of these interventions involved efforts to enhance motivation, establish rapport, set goals, promote problem-solving and skill training, and prevent relapse.\textsuperscript{482,706,707} One recent meta-analysis found significant effects for studies that employed cognitive-
behavioral strategies (self-monitoring and coping skills), social influence strategies (addressing social influences that serve to promote or maintain smoking), and motivational strategies (techniques to clarify desire for change and reduce ambivalence toward change).704

A series of studies comparing intensive group sessions based on social/cognitive therapy to a 10- to 20-minute brief intervention produced promising results, at least when measured at the end of treatment, across diverse adolescent populations.708-716 Interventions should be developmentally appropriate across the adolescent age span (e.g., appropriate for a 12-year-old vs. an 18-year-old). Additionally, counseling and other interventions have been recommended for young adults ages 18 to 24 years old.717

Recent studies indicate that adolescent smokers are identified and counseled to quit in about 33 to 55 percent of physician visits120,718,719 and about 20 percent of dental visits.120 Receipt of assistance in quitting was reported by 42 percent of adolescents and followup by only 16 percent of adolescents.719 Yet, in a survey of 5,000 adolescents (all of the 11th graders in the Memphis City Schools), more than 79 percent reported they would acknowledge their smoking if asked.718 Therefore, clinicians need to assess adolescent tobacco use, offer counseling, and follow up with these patients. Asking about tobacco use and advising adolescents to quit are the entry points for providing effective interventions. Clinicians may use motivational interventions such as those listed in Chapter 3B, which can be adapted for use with adolescents.173,706,720,721 It is important for clinicians to intervene with adolescents in a manner that respects confidentiality and privacy (e.g., interviewing adolescents without parents present).

Counseling Provided to Parents During the Pediatric Visit. Recent research suggests that tobacco use interventions provided to parents in pediatric clinics or during child hospitalizations increase parents’ interest in stopping smoking,198,722 parents’ quit attempts198,199 and parents’ quit rates,172,723,724 although one study failed to find such an effect.428

Children and adolescents also benefit if parents are given information on secondhand smoke exposure. A review of the studies conducted by the expert Panel showed that giving parents information on the harms of secondhand smoke reduces childhood exposure to such smoke and may reduce parental smoking rates.198,725
Questions have been raised about whether and how clinicians caring for children and adolescents might offer treatment for tobacco dependence to their parents who smoke. Would such treatment interfere with the doctor-patient relationship that parents might have with their physicians? In response to this concern, the American Medical Association adopted a policy statement in 2005 supporting the practice of pediatricians addressing parental smoking.726

**Tobacco Use Medications.** Although nicotine replacement has been shown to be safe in adolescents, there is little evidence that these medications and bupropion SR are effective in promoting long-term smoking abstinence among adolescent smokers.727-731 As a result, they are not recommended as a component of pediatric tobacco use interventions. One small pilot study (N = 22) found some positive initial effects for bupropion SR.730 However, other studies have found no difference between placebo and patch at 10 or 12 weeks postquit727 or between placebo versus gum or patch at 6 months postquit.729,732 The majority of these studies also included an intensive counseling component (6 or more sessions).

**Future Research**

The following topics regarding adolescents and children require additional research:

- Effectiveness of using the 5 A’s in pediatric clinics to treat both adolescents and parents

- Safety and effectiveness of medications in adolescents, including bupropion SR, NRT, varenicline, and a nicotine vaccine

- Effectiveness of counseling interventions designed specifically to motivate youth to stop using tobacco

- Effectiveness of child-focused versus family-focused or peer-focused interventions as well as interventions accessed via the Internet, quit-lines, and school-based programs

- Strategies for increasing the efficacy, appeal, and reach of counseling treatments for adolescent smokers
Light Smokers

Recommendation: Light smokers should be identified, strongly urged to quit, and provided counseling cessation interventions. (Strength of Evidence = B)

The field of tobacco dependence research has not achieved consensus regarding the definition of a light smoker. For the purposes of this Guideline, the Panel considered a light smoker to be anyone who smokes fewer than 10 cigarettes per day, given that these individuals frequently are excluded from the RCTs that are the basis of some of the treatment recommendations. This definition includes individuals who may not smoke daily. Light smoking does not refer to smoking low-tar/low-nicotine cigarettes. Despite lower consumption levels, light smokers are at risk for developing smoking-related diseases. A large, longitudinal study in Norway (N = 42,722) found an increase in risk of death from ischemic heart disease and other tobacco-related causes for both men and women who smoked one to four cigarettes per day. Similar results were found in a Finnish cohort, in which men who reported being “occasional smokers” demonstrated increased cardiovascular morbidity and mortality.

Light smoking is becoming more common, perhaps due to smoking restrictions and increases in the price of cigarettes. A recent National Health Interview Survey (NHIS) survey found that among adult smokers in the United States, approximately 25.4 percent report smoking 10 or fewer cigarettes per day, and 11.6 percent smoke 5 or fewer cigarettes per day. Many light smokers want to quit but have difficulty doing so. This is consistent with evidence that many light smokers are dependent, even though they smoke relatively few cigarettes. Light smokers also are less likely to receive treatment than are heavier smokers.

Light smokers should be provided counseling treatments identified as effective in this Guideline. One study found that health education was more effective than motivational interviewing for African-American light smokers (≤ 10 cigarettes per day).

Tobacco Use Medications. Two studies examined the effectiveness of medications with light smokers. One study found that use of the nicotine lozenge significantly increased 12-month abstinence rates among light smok-
ers (≤ 15 cigarettes per day) compared to placebo. Another study found no difference in effectiveness of 2-mg gum versus placebo.

**Future Research**

The following topic regarding light smokers requires additional research:

- Effectiveness of specific counseling and medication interventions with lighter smokers

**Noncigarette Tobacco Users**

Recommendation: Smokeless tobacco users should be identified, strongly urged to quit, and provided counseling cessation interventions. (Strength of Evidence = A)

Recommendation: Clinicians delivering dental health services should provide brief counseling interventions to all smokeless tobacco users. (Strength of Evidence = A)

Recommendation: 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)

Like cigarette smoking, the use of smokeless tobacco, such as chewing tobacco, snuff, or moist snuff, produces addiction to nicotine and has serious health consequences. Smokeless tobacco use was reported among 4 percent of adult men, but less than 1 percent of women in 2005. Health risks from these products include abrasion of teeth, gingival recession, periodontal bone loss, leukoplakia, and oral and pancreatic cancer. Thus, the use of smokeless tobacco is not a safe alternative to smoking, nor is there evidence to suggest that it is effective in helping smokers quit.

Evidence shows that counseling treatments are effective in treating smokeless tobacco users. Therefore, clinicians should offer quitting advice and assistance to their patients who use tobacco, regardless of the formulation of the tobacco product. Some information may be particularly relevant
in the treatment of smokeless tobacco use. For instance, a large majority of moist snuff users have identifiable oral lesions, and emphasizing this information during an oral exam may be useful in motivating a quit attempt. A close review of the literature showed that dental health clinicians (e.g., dental hygienists) delivering brief advice to quit using smokeless tobacco, in the context of oral hygiene feedback, can increase abstinence rates.250,751

Cigar smokers are at increased risk for coronary heart disease; COPD; periodontitis; and oral, esophageal, laryngeal, lung, and other cancers; with evidence of dose-response effects.752-756 The prevalence of cigar smoking was 5 percent for men and less than 1 percent for women.590 Although cigarette sales have declined over the last decade, cigar sales have increased in the United States, increasing 15.3 percent in 2005,757 and sales of “little cigars” were at an all-time high in 2006.758 Cigar smokers are known to discount the health effects of cigar smoking, believing it to be less detrimental than cigarettes.752,759

Clinicians should be aware of and address the use of other noncigarette tobacco products, including pipes, water pipes (also known as hookahs and narghile), cigarillos, loose tobacco, bidis, and betel quid. The use of cigars, pipes, and bidis is associated with cancers of the lung, stomach, oral cavity, larynx, and esophagus.760 Further, the evidence is mixed as to whether or not individuals who use noncigarette tobacco products, either alone or in addition to cigarettes, find it more or less difficult, in comparison to cigarette smokers, to become abstinent from tobacco.761,762

**Tobacco Use Medications.** Current evidence is insufficient to suggest that the use of tobacco cessation medications increases long-term abstinence among users of smokeless tobacco. Studies conducted to date with various medications have not shown that they increase abstinence rates in this population.750,751,763,764

**Future Research**

The following topics regarding noncigarette tobacco products require additional research:

- Effectiveness of advice and counseling treatments in promoting abstinence among users of noncigarette tobacco products, especially among users of pipes, cigars, and hookahs
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- Effectiveness of medications to promote abstinence among users of noncigarette tobacco products, including users of smokeless tobacco, pipes, cigars, and hookahs

- Effectiveness of combined medications and counseling and behavioral therapies with users of noncigarette tobacco products

- Effectiveness of medication and counseling interventions with individuals who both smoke cigarettes and use noncigarette tobacco products (“dual users”)

**Pregnant Smokers**

Recommendation: 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)

Recommendation: 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)

**Psychosocial Interventions.** The selection criteria for the pregnancy meta-analysis were adjusted to be appropriate for this unique population. Abstinence data were included only if they were biochemically confirmed, due to reports of deception regarding smoking status among pregnant women. Two different followup time periods were analyzed: prebirth abstinence (> 24 weeks gestation) and greater than 5 months postpartum abstinence. For the meta-analysis, either minimal interventions (< 3 minutes) or interventions labeled as “usual care” constituted the reference condition. Eight studies met the criteria and were included in the analysis comparing person-to-person psychosocial smoking cessation interventions with usual care in pregnant women. A “usual care” intervention with pregnant smokers typically consists of a recommendation to stop smoking, often supplemented by provision of self-help material or referral to a stop-smoking program or brief counseling. Person-to-person psychosocial interventions typically involved these treatment components as well as more intensive...
counseling than minimal advice. One study included 12 telephone counseling sessions after an initial in-person counseling session, and the remainder of the studies had at least two in-person counseling sessions. One study used a group intervention, and all of the other studies provided individual counseling. Six of the studies provided counseling only during pregnancy, one provided counseling in the hospital, and one provided counseling postdelivery. As Table 7.5 shows, psychosocial interventions are significantly more effective than usual care in getting pregnant women to quit while they are pregnant. These findings are consistent with other independent reviews. A meta-analysis also was conducted to examine the effects of psychosocial interventions on postpartum abstinence. The odds ratio for psychosocial intervention was consistent with a positive effect of counseling on postpartum abstinence; however, the results were not statistically significant (OR = 1.6, 95 percent C.I. = 0.7–3.5). Studies using telephone counseling as the only format that compared biochemically verified outcomes to a minimal intervention suggest a possible differential effect on light versus heavy smokers and underscore the need for further research about this format.

Table 7.5. Meta-analysis (2008): Effectiveness of and estimated preparturition abstinence rates for psychosocial interventions with pregnant smokers (n = 8 studies)

<table>
<thead>
<tr>
<th>Pregnant smokers</th>
<th>Number of arms</th>
<th>Estimated odds ratio (95% C.I.)</th>
<th>Estimated abstinence rate (95% C.I.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usual care</td>
<td>8</td>
<td>1.0</td>
<td>7.6</td>
</tr>
<tr>
<td>Psychosocial intervention (abstinence preparturition)</td>
<td>9</td>
<td>1.8 (1.4–2.3)</td>
<td>13.3 (9.0–19.4)</td>
</tr>
</tbody>
</table>

a Go to www.surgeongeneral.gov/tobacco/gdlnrefs.htm for the articles used in this meta-analysis.

Components of some person-to-person psychosocial interventions are listed in Table 7.6. These interventions were selected from articles included in the Table 7.5 meta-analysis and should guide clinicians when treating pregnant smokers.
Table 7.6. Examples of effective psychosocial interventions with pregnant patients

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician advice regarding smoking-related risks (2–3 minutes); videotape</td>
<td>Many pregnant women deny smoking, and the multiple-choice question format</td>
</tr>
<tr>
<td>with information on risks, barriers, and tips for quitting; midwife counseling in one 10-minute session; self-help manual; and followup letters.</td>
<td>improves disclosure. For example: Which of the following statements best describes your cigarette smoking?</td>
</tr>
<tr>
<td>Pregnancy-specific self-help materials (Pregnant Woman’s Self-Help Guide To Quit Smoking) and one 10-minute counseling session with a health educator.</td>
<td>• I smoke regularly now; about the same as before finding out I was pregnant.</td>
</tr>
<tr>
<td>Counselor provided one 90-minute counseling session plus bimonthly telephone followup calls during pregnancy and monthly telephone calls after delivery.</td>
<td>• I smoke regularly now, but I’ve cut down since I found out I was pregnant.</td>
</tr>
</tbody>
</table>

Smoking in pregnancy imparts risks to both the woman and the fetus. Cigarette smoking 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, and sudden infant death syndrome (SIDS); and has been linked to cognitive, emotional, and behavioral problems in children. 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.

The first step in intervention is assessment of tobacco use status. This is especially important in a population in which a stronger stigma against smoking increases the potential for deception. Research has shown that the use of multiple choice questions (see Table 7.7), as opposed to a simple yes/no question, can increase disclosure among pregnant women by as much as 40 percent.
Table 7.7. Clinical practice suggestions for assisting a pregnant patient in stopping smoking (continued)

<table>
<thead>
<tr>
<th>Clinical practice</th>
<th>Rationale</th>
</tr>
</thead>
</table>
| Assess pregnant woman’s tobacco use status using a multiple-choice question to   | • I have quit smoking since finding out I was pregnant.  
| improve disclosure.                                                              | • I wasn’t smoking around the time I found out I was pregnant, and I don’t currently smoke cigarettes.                                         |
| Congratulate those smokers who have quit on their own.                           | To encourage continued abstinence.                                                                                                               |
| Motivate quit attempts by providing educational messages about the impact of     | These are associated with higher quit rates.                                                                                                    |
| smoking on both maternal and fetal health.                                       |                                                                                                                                                  |
| Give clear, strong advice to quit as soon as possible.                           | Quitting early in pregnancy provides the greatest benefit to the fetus.                                                                          |
| Use problem-solving counseling methods and provide social support and pregnancy- | Reinforces pregnancy-specific benefits and increases cessation rates.                                                                           |
| specific self-help materials.                                                    |                                                                                                                                                  |
| Arrange for followup assessments throughout pregnancy, including further        | The woman and her fetus will benefit even when quitting occurs late in pregnancy.                                                               |
| encouragement of cessation.                                                       |                                                                                                                                                  |
| In the early postpartum period, assess for relapse and be prepared to continue   | Postpartum relapse rates are high, even if a woman maintains abstinence throughout pregnancy.                                                     |
| or reapply tobacco cessation interventions, recognizing that patients may        |                                                                                                                                                  |
| minimize or deny smoking.                                                        |                                                                                                                                                  |

Quitting smoking prior to conception or early in the pregnancy is most beneficial, but health benefits result from abstinence at any time. It is estimated that 20 percent or more of low birth-weight births could be prevented by eliminating smoking during pregnancy. Therefore, a pregnant smoker should receive encouragement and assistance in quitting throughout her pregnancy. Women attending preconception or other medical visits also should be offered tobacco use interventions, as smoking may decrease fertility and some adverse effects occur early in the pregnancy. In addition, treating tobacco dependence prior to conception...
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offers more options to the clinician, including medication options, as fetal health concerns are not present.

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.\textsuperscript{787,791,792} Postpartum relapse may be decreased by continued emphasis on the relationship between maternal smoking and poor health outcomes in infants and children (e.g., SIDS, respiratory infections, asthma, and middle ear disease).\textsuperscript{793-798} One pilot study found that a relapse prevention intervention was effective;\textsuperscript{799} however, two reviews of relapse prevention trials (both pre- and postdelivery) found no significant reduction in relapse.\textsuperscript{185,770} There is a great need for research on the prevention of postpartum relapse. Table 7.7 outlines clinical factors to address when counseling pregnant women about smoking.

Meta-analytic results support the effectiveness of self-help materials compared to either basic information sheets or no intervention in assisting women to quit during pregnancy (see Table 7.8). Pamphlets and quitting guides were used as the self-help intervention in both studies analyzed. Other studies document favorable outcomes when self-help materials, with or without brief discussion/counseling, are added to standard advice to quit smoking.\textsuperscript{774,800}

Table 7.8. Meta-analysis (2008): Effectiveness of and estimated preparturition abstinence rates for self-help interventions with pregnant smokers (n = 2 studies)\textsuperscript{a}

<table>
<thead>
<tr>
<th>Pregnant smokers</th>
<th>Number of arms</th>
<th>Estimated odds ratio (95% C.I.)</th>
<th>Estimated abstinence rate (95% C.I.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usual care</td>
<td>2</td>
<td>1.0</td>
<td>8.6</td>
</tr>
<tr>
<td>Self-help materials (preparturition)</td>
<td>2</td>
<td>1.9 (1.2–2.9)</td>
<td>15.0 (10.1–21.6)</td>
</tr>
</tbody>
</table>

\textsuperscript{a} Go to www.surgeongeneral.gov/tobacco/gdlnrefs.htm for the articles used in this meta-analysis.

**Tobacco use medication and pregnant smokers—Effectiveness.** The data on the effectiveness of nicotine replacement therapy with pregnant smokers include three randomized, controlled nicotine patch studies. One study randomly assigned 250 pregnant women who still were smoking after the first trimester to either a 15-mg, 16-hour active patch for 8 weeks and a 10-mg, 16-hour patch for 3 additional weeks or to a placebo. No significant
differences were seen in smoking abstinence rates, number of cigarettes smoked, birthweight, or number of preterm deliveries. A similar study of the nicotine patch with 30 pregnant women who still were smoking 15 or more cigarettes a day after the first trimester found moderate but nonsignificant differences in abstinence rates (23% in the active patch and counseling condition vs. 0% in the placebo patch and counseling condition). A recent study randomized 181 pregnant women to cognitive behavioral therapy (CBT) and NRT or CBT alone. Women in the CBT plus NRT group were significantly more likely to be abstinent at 7 weeks post-randomization (29% vs. 10%) and at 38 weeks gestation (22% vs. 7%). This study was stopped prior to completion (see safety section below). Based on these data, the Panel did not make a recommendation regarding medication use during pregnancy.

Tobacco use medication and pregnant smokers—Safety. Cigarette smoking during pregnancy is the greatest modifiable risk factor for pregnancy-related morbidity and mortality in the United States. Adverse effects of smoking during and after pregnancy include increased risks of spontaneous abortion, premature labor and delivery, placental abruption, fetal growth retardation, SIDS, and many health risks for the woman and her child.

Cigarette smoke contains thousands of chemicals, many of which may contribute to reproductive toxicity. Of particular concern are carbon monoxide, nicotine, and oxidizing chemicals. High levels of carbon monoxide exert neuroteratogenic effects. Oxidizing chemicals are likely to contribute to an increased risk of thrombotic complications and, by reducing nitric oxide availability, contribute to placental vasoconstriction and premature labor.

Nicotine may contribute to adverse effects of cigarette smoking during pregnancy and result in injury to the fetus. Nicotine has been postulated to cause uteroplacental insufficiency via vasoconstriction, to produce fetal neurotoxicity resulting in delayed or impaired brain development, to inhibit the maturation of pulmonary cells and to increase the risk of SIDS. These concerns are based primarily on animal studies. Relatively little human research with pure nicotine has been done in pregnant smokers.

Several studies of brief exposure to nicotine patches or nicotine gum have demonstrated small hemodynamic effects in the mother and fetus, gener-
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ally less than those seen with cigarette smoking. The three clinical trials of NRT in pregnant women have yielded information relative to safety. The Wisborg trial of 250 women randomized to nicotine patch (15 mg) or placebo for 11 weeks found no evidence of serious adverse effects of nicotine. To the contrary, birth weight was significantly higher in the NRT group, possibly due to reduced cigarette smoking in the NRT group. The Kapur study included 30 women randomized to nicotine patches (15 mg) or placebo, and reported no serious adverse effects of NRT. One placebo-treated woman experienced extreme nicotine withdrawal, associated with increased fetal movements, prompting discontinuation of the trial. The Pollack study included 181 women, 122 randomized to CBT plus NRT, and 59 to CBT alone. The NRT group could select nicotine patches, gum, or lozenge, or no NRT. More than half the women selected nicotine patches, the dose of which was adjusted according to the number of cigarettes smoked per day on study entry. As described in the “effectiveness” section above, women treated with NRT had significantly higher quit rates during pregnancy than did women receiving CBT alone. However, the study was terminated early by the Data Safety Monitoring Board (DSMB) due to a higher incidence of adverse events. Serious adverse events occurred in 30 percent of the NRT group compared to 17 percent of the CBT-alone group. The most frequent cause of serious adverse events was preterm labor. There was evidence that this difference in preterm labor was due to a difference between groups in history of preterm labor that predated study entry. The DSMB indicated that the study had to be terminated due to a priori stopping rules; however, they did not believe that the serious adverse events were related to NRT use. The authors concluded that this study cannot support or negate published literature about the harm of NRT during pregnancy.

Morales-Suarez-Varela et al. reported data from a retrospective cohort study suggesting that the use of NRT in women who quit smoking but who used nicotine substitutes during the first 12 weeks of pregnancy was associated with a small but significant increase in congenital malformations compared to mothers who smoked during the first trimester. This study suffers from multiple, substantial methodological problems, however, making its findings difficult to interpret. Also, the number of malformation cases in the NRT group was quite small, and the relative prevalence rate ratios for malformations in cases compared to controls were of borderline significance. Further, concerns exist about possible undetected spontaneous abortion among continuing smokers. In addition, most women who
use NRT do so in the second or third trimester, and no adverse event data were reported in these women.

Safety is not categorical. A designation of “safe” reflects a conclusion that a drug’s benefits outweigh its risks. Nicotine most likely does have adverse effects on the fetus during pregnancy. Although the use of NRT exposes pregnant women to nicotine, smoking exposes them to nicotine plus numerous other chemicals that are injurious to the woman and fetus. These concerns must be considered in the context of inconclusive evidence that cessation medications boost abstinence rates in pregnant smokers.

## Future Research

The following topics regarding smoking and pregnancy require additional research:

- Relapse prevention with pregnant women and women who have recently given birth

- Effectiveness of psychosocial treatment provided via nonface-to-face modalities, such as quitlines or Web-based programs

- The safety and effectiveness of tobacco dependence medications (bupropion SR, NRTs, and varenicline) during pregnancy for the woman and the fetus, including: the relative risks and benefits of medication use as a function of dependence, and the appropriate formulation and timing of medication use

- Safety and effectiveness of tobacco dependence medications, especially varenicline and bupropion SR as well as various forms of NRT, to the woman and child during nursing

- Effectiveness of economic incentives to promote quitting and sustained abstinence

- Effects of smoking during fertility treatment and the effects and effectiveness of cessation interventions on the infertile population, both men and women
• Effects of reporting smoking status and the provision of cessation interventions as part of the national database for assisted reproductive technology treatments (the Center for Disease Control and Prevention’s Assisted Reproductive Technology [ART] database, www.cdc.gov/art)

• Effectiveness of relapse prevention programs for spontaneous “self-quitters amongst pregnant women”

• Effectiveness of different types of counseling, behavioral therapies, and motivational interventions (e.g., physiological feedback of adverse impacts, quitting benefits) for pregnant women in general and in high-prevalence populations (e.g., American Indian and Alaska Native women, especially)

• Strategies for linking preconception, pregnancy, and postpartum (including pediatric) interventions

**Weight Gain After Stopping Smoking**

**Recommendation:** 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)

The majority of smokers who quit smoking gain weight. Most will gain fewer than 10 pounds, but there is a broad range of weight gain, with as many as 10 percent of quitters gaining as much as 30 pounds. However, weight gain that follows stopping smoking is a modest health threat compared with the risks of continued smoking.

Women tend to gain slightly more weight than men do. For both sexes, African Americans, people under age 55, and heavy smokers (those smoking more than 25 cigarettes per day) are at elevated risk for major weight gain.

For some smokers, especially women, concerns about weight or fears about weight gain are motivators to start smoking or continue smoking.
Adolescents, even as young as middle-school age, who are concerned about their weight initiate smoking more often than do other adolescents.\textsuperscript{683,837-838}

Concern about weight varies substantially by ethnicity. For example, adolescent African-American females are much less likely to report that they smoke to control weight than are white European Americans.\textsuperscript{683,839} This is an important area for further study, as little tobacco research focuses on women in racial/ethnic minority groups.\textsuperscript{683}

There is no convincing evidence that counseling interventions specifically designed to mitigate weight gain during attempts to stop smoking result in reduced weight gain.\textsuperscript{165,499,840} It also is unclear that such interventions affect cessation success; specifically, these interventions do not appear to adversely affect cessation.\textsuperscript{499,840-842}

Nicotine replacement—in particular, 4-mg nicotine gum and 4-mg nicotine lozenge—appears to be effective in delaying postcessation weight gain. Moreover, there appears to be a dose-response relation between gum use and weight suppression (i.e., the greater the gum use, the less weight gain occurs). Bupropion SR also appears to be effective in delaying postcessation weight gain.\textsuperscript{484,843-845} Once either nicotine gum or bupropion SR therapy is stopped, however, the quitting smoker, on average, gains an amount of weight that is about the same as if she or he had not used these medications.\textsuperscript{843,846-848}

Postcessation weight gain appears to be caused both by increased intake (e.g., eating, including high-caloric foods, and alcohol consumption) and by decreased metabolism. The involvement of metabolic mechanisms suggests that even if smokers do not increase their caloric intake upon quitting, they will, on average, gain some weight.\textsuperscript{849-852} Once an individual relapses and begins smoking at precessation levels, he or she usually will lose some or all of the weight gained during the quit attempt.

The research evidence reviewed above shows why concerns about weight gain can be barriers to smoking abstinence. Many smokers (especially women) are concerned about their weight and fear that quitting will produce weight gain. Many also believe that they can do little to prevent postcessation weight gain except return to smoking. These beliefs are difficult to address clinically because smoking does appear to affect weight.
Recommendations to Clinicians When Addressing Weight Gain

How should the clinician deal with concerns about weight gain? First, the clinician should neither deny the likelihood of weight gain nor minimize its significance to the patient. Rather, the clinician should inform the patient about the likelihood of weight gain and prepare the patient for its occurrence. The clinician also should counter exaggerated fears about weight gain given the relatively moderate weight gain that typically occurs. Certain types of information may help prepare the patient for postcessation weight gain (see Table 7.9). Clinicians also should inform the patient that smoking presents a much greater health risk than the negligible health risk involved in the modest weight gain associated with smoking abstinence.

Second, during the quit attempt, the clinician should offer to help the patient address weight gain (either personally or via referral) once the patient has successfully quit smoking. The patient should be encouraged to maintain or adopt a healthy lifestyle, including engaging in moderate exercise, eating plenty of fruits and vegetables, and limiting alcohol consumption.502,853

Exercise

Available research does not show that interventions to increase exercise reliably boost smoking abstinence rates.842,854 One recent study, however, showed that an exercise program occurring in three 45-minute sessions per week increases long-term smoking abstinence in women and delays weight gain when it is combined with a cognitive-behavioral smoking cessation program.853 As was the case for weight loss interventions, there is no evidence that exercise interventions undermine success in stopping smoking. Some evidence suggests that weight gain is reduced if smoking abstinence is accompanied by a moderate increase in physical activity.855 Vigorous exercise programs should not be implemented without consulting a physician. Although it may be difficult to get smokers to adhere to a vigorous exercise program, smokers should be encouraged to engage in moderate exercise and physical activity as part of a healthy lifestyle.856
Table 7.9. Clinician statements to help a patient prepare for and cope with post-cessation weight gain

<table>
<thead>
<tr>
<th>Clinician statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>The great majority of smokers gain weight once they quit smoking. However, even without special attempts at dieting or exercise, weight gain is usually 10 lbs. or less.</td>
</tr>
<tr>
<td>Some medications, including bupropion SR and nicotine replacement medicines, may delay weight gain.</td>
</tr>
<tr>
<td>There is evidence that smokers often gain weight once they quit smoking, even if they do not eat more. However, there are medications that will help you quit smoking and limit or delay weight gain. I can recommend one for you.</td>
</tr>
<tr>
<td>The amount of weight you will likely gain from quitting will be a minor health risk compared with the risks of continued smoking.</td>
</tr>
<tr>
<td>I know that you don’t want to gain a lot of weight. However, let’s focus on strategies to get you healthy rather than on weight. Think about eating plenty of fruits and vegetables, getting regular exercise, getting enough sleep, and avoiding high-calorie foods and beverages. Right now, this is probably the best thing you can do for both your weight and your health.</td>
</tr>
<tr>
<td>Although you may gain some weight after quitting smoking, compare the importance of this with the added years of healthy living you will gain, your better appearance (less wrinkled skin, whiter teeth, fresher breath), and good feelings about quitting.</td>
</tr>
</tbody>
</table>

Future Research

The following topics regarding weight gain during tobacco dependence treatment require additional research:

- Effectiveness of weight control measures during quit attempts and their effect on tobacco abstinence and weight, including issues of timing of weight control interventions

- Effectiveness of medications to control weight gain during quit attempts

- Effectiveness of the use of exercise to control weight gain during a quit attempt, including the optimal “dose” of exercise to minimize weight gain and not jeopardize cessation outcome

- Impact of weight gain concerns on specific populations, including adolescents who smoke and ethnic/minority women

- Strategies to increase adherence to exercise protocols as part of cessation interventions that include efforts to decrease weight gain