ASHP Therapeutic Position Statement on the Cessation of Tobacco Use

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Position

The American Society of Health-System Pharmacists (ASHP) discourages all use of tobacco products and supports evidence-based tobacco-control policies and activities that reduce the prevalence of tobacco use. ASHP strongly encourages health care providers to take an active role in promoting the health of their patients by systematically integrating into routine patient care (a) the identification of tobacco users and (b) the delivery of evidence-based tobacco-cessation interventions. ASHP recommends behavioral and pharmacologic therapies for cessation, advocates their use for all patients attempting to quit smoking (except when medically contraindicated or in specific populations for which there is insufficient evidence of effectiveness), and advises that these therapeutic interventions be reimbursed under health insurance plans.

To enable more effective and consistent identification of tobacco use and drug interactions with smoking, ASHP urges that all patient records, including those in electronic medical records and pharmacy information technology systems, include a designated field for the collection of tobacco-use data and that this field be integrated within the system such that clinically significant drug interactions with tobacco products are identified. Schools that offer health professional degree programs are encouraged to integrate comprehensive tobacco-cessation training as part of their core curricula, and licensed clinicians are advised to participate in continuing-education programs as necessary to acquire and maintain tobacco-cessation counseling skills. Given the established dangers of secondhand smoke exposure, ASHP supports legislation promoting smoke-free environments for the employees and patrons of all workplaces and public venues. Furthermore, because the sale of tobacco products contradicts the clinician's role in promoting health, ASHP strongly opposes the sale or distribution of tobacco products in all establishments where health care services are rendered.

Epidemiology of tobacco use

As the former U.S. Surgeon General C. Everett Koop stated in 1982, "Cigarette smoking is the chief single, avoidable cause of death in our society and the most important public health issue of our time."[1] This statement remains true today, nearly three decades later. The Centers for Disease Control and Prevention (CDC) estimates that nearly 438,000 Americans die each year from smoking,[2] and approximately 50,000 persons die annually due to involuntary exposure to tobacco smoke.[3]

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Cigarettes are the only marketed consumable product that, when used as intended, will contribute to the death of half or more of its users.[4]

While cigarettes are, by far, the most frequently used form of tobacco in the United States, other forms of smoked tobacco (e.g., cigars, clove cigarettes [kreteks], pipe tobacco, bidis, hookah) and smokeless tobacco (e.g., chewing tobacco, snuff) can also lead to dependence and should be addressed by clinicians. Despite the proven negative health consequences of tobacco use and the fact that approximately 70% of smokers want to quit,[5] 20.8% of the U.S. adult population continues to smoke either every day (16.7%) or some days (4.1%).[6] In 2006, more men (23.9%) than women (18.0%) were smokers.[6] The prevalence of smoking also varied by race or ethnicity (non-Hispanic American Indian/Alaska Native, 32.4%; non-Hispanic white, 21.9%; non-Hispanic black, 23.0%; Hispanic, 15.2%; non-Hispanic Asian, 10.4%), education level (higher education is associated with a lower prevalence), and poverty level (20.4% of individuals living at or above the federal poverty level; 30.6% of individuals living below the poverty level).[6] An estimated 44.3% of cigarettes smoked in the United States are by persons with mental illness.[7]

Smoking prevalence varies across the nation. In 2006, the highest median prevalence of smoking was evident in Kentucky (28.6%) and the lowest was in Utah (9.8%).[8] Because most teens who smoke at least monthly continue to smoke in adulthood,[9] tobacco-use trends among youth are viewed as a key indicator of future national health trends.[10] In 2007, an estimated 21.6% of 12th graders (23.1% of males and 19.6% of females) had smoked one or more cigarettes in the past 30 days.[11] The prevalence of smoking has declined among adolescents over the past decade; however, the downward trend has largely diminished among 12th graders in recent years.

In the past decade, the prevalence of cigarette smoking has decreased while the per-capita consumption of cigars has increased.[12] However, beginning in 2005, there has been a slight trend toward decreased cigar use. In 2007, the prevalence of cigar smoking (one or more cigars in the past month) among persons 12 years or older was 5.4%.[13] Cigar weight and nicotine content vary widely, with most cigars ranging in weight from 1 to 22 g. In comparison, a typical U.S. cigarette weighs <1 g. The nicotine content in 10 commercially available cigars studied in 1996 ranged from 10 to 444 mg.[14] Cigarette brands sold by major manufacturers in the United States have a lower and less-variable total nicotine content, ranging from 11.9 to 14.5 mg of nicotine per cigarette.[15] As such, it is possible for one large cigar to contain as much tobacco as an entire pack of cigarettes and to deliver enough nicotine to establish and maintain dependence.[14]

In 2007, an estimated 8.1 million Americans 12 years of age or older (3.2%) had used smokeless tobacco in the past month; men (6.3%) were more likely than were women (0.4%) to be users.[13] The prevalence of smokeless tobacco use is highest among individuals ages 18–25 years and is substantially higher among American Indians, Alaskan Natives, and residents of the southern United States and rural areas.[13,16] While sales of most forms of smokeless tobacco (e.g., looseleaf, plug, twist) have declined since the mid-1980s, moist snuff sales have increased steadily since the late 1980s.[12]

An enormous economic burden accompanies tobacco use. Each pack of cigarettes smoked costs society $7.18 ($3.45 for associated medical care and $3.73 for productivity losses), for a total of $157 billion in annual health-related economic losses.[17] The lifelong smoker (e.g., one pack per day for 50 years) spends more than $100,000 on his or her smoking habit in addition to the associated medical care costs of tobacco use.

Extensive evidence implicates tobacco as the primary known preventable cause of death in the United States. As such, ASHP strongly supports evidence-based tobacco-control initiatives that aim to reduce the prevalence of tobacco use by (a) preventing the initiation of tobacco use and (b) promoting and maintaining cessation. Tobacco-control initiatives (e.g., those described in each state's comprehensive cancer control plan) should comply with recommendations set forth by CDC as delineated in the "Best Practices for Comprehensive Tobacco Control Programs"[18] and the "Guide to Community Preventive Services: Tobacco Use Prevention and Control."[19]

Nicotine pharmacology

Tobacco products are carefully engineered formulations that optimize the delivery of nicotine, a chemical that meets established criteria for an addictive substance.[20] Once absorbed, nicotine induces a variety of central nervous system, cardiovascular, and metabolic effects. Within seconds after inhalation, nicotine reaches the brain and stimulates the release of various neurotransmitters including dopamine, which induces nearly immediate feelings of pleasure and relieves nicotine-withdrawal symptoms. This rapid dose response reinforces the need to repeat the administration of nicotine, thereby perpetuating smoking behavior.[21] The short half-life ($t_{½}$ = 2 hours) of nicotine generally necessitates frequent dosing throughout the day, and tobacco users become adept at titrating nicotine intake to maintain pleasure and arousal, modulate mood, and avoid withdrawal symptoms.[21]

When nicotine is discontinued, the following withdrawal symptoms may develop: irritability, impatience,

anxiety, difficulty concentrating, restlessness, hunger, depression, insomnia, and cravings.[22-24] Most physical withdrawal symptoms generally manifest within 24–48 hours after quitting and gradually dissipate over two to four weeks[23]; however, strong cravings for tobacco can persist for months or even years.[25] The nicotine levels generated by smokeless tobacco are similar to those of smoking, although their onset of action is less rapid. Upon quitting, smokeless tobacco users experience withdrawal symptoms similar to those of smokers.[26] Although nicotine is the dependence-causing component of tobacco, it is not directly responsible for the myriad of negative health consequences of tobacco use.

Health consequences of tobacco use and exposure to secondhand smoke

Smoking. According to the 2004 Surgeon General's report on the health consequences of smoking,[27] smoking harms nearly every organ of the body, is causally associated with numerous diseases (Table 1), and reduces the health of smokers in general. In addition to contributing to the development of disease, smoking also can lead to exacerbation or reduced control of existing conditions such as hypertension, diabetes mellitus, and asthma. On average, men and women lose 13.2 and 14.5 years of life because of smoking, respectively.[17] Between 1997 and 2001, an estimated 437,902 annual U.S. deaths were attributable to smoking. Of these deaths, 158,529 (36.2%) were due to cancer, 137,979 (31.5%) to cardiovascular disease, and 101,454 (23.2%) to respiratory disease.[2]

Table 1.
Diseases and Other Adverse Health Effects Caused by Smoking[27]

Cancers
Acute myeloid leukemia
Bladder
Cervical
Esophageal
Gastric
Kidney
Laryngeal
Lung
Oral cavity and pharyngeal
Pancreatic
Cardiovascular diseases
Abdominal aortic aneurysm
Coronary heart disease (angina pectoris, ischemic heart disease, myocardial infarction)
Cerebrovascular disease (transient ischemic attacks, stroke)
Peripheral arterial disease
Pulmonary diseases
Acute respiratory illnesses
Upper respiratory tract (rhinitis, sinusitis, laryngitis, pharyngitis)
Lower respiratory tract (bronchitis, pneumonia)
Chronic respiratory illnesses
Chronic obstructive pulmonary disease
Respiratory symptoms: cough, phlegm, wheezing, dyspnea
Poor asthma control
Reduced lung function in infants exposed in utero to maternal smoking
Reproductive effects
Reduced fertility in women
Pregnancy and pregnancy outcomes
Preterm or premature rupture of membranes
Placenta previa
Placental abruption
Preterm delivery
Low infant birth weight
Infant mortality (sudden infant death syndrome)
Other effects
Cataract
Osteoporosis (reduced bone density in postmenopausal women, increased risk of hip fracture)
Periodontitis
Peptic ulcer disease (in patients who are infected with *Helicobacter pylori*)
Adverse surgical outcomes
Poor wound healing
Respiratory complications

Smokeless tobacco. Users of smokeless forms of tobacco are often under the mistaken impression that these formulations are a "safe" alternative to smoking cigarettes. In addition to cosmetic effects such as halitosis and staining of the teeth, smokeless tobacco use is associated with serious health effects, including cancer, soft tissue alterations (e.g., leukoplakia), and periodontal effects.[16] Smokeless tobacco contains high concentrations of carcinogens, which have direct contact with mucosal tissues over prolonged periods of time. The most serious consequence of smokeless tobacco use is an increased risk of developing oral and pharyngeal cancers, and the risk appears to be dose related, in that heavy, longtime users are more likely to develop oral cancer than are nonusers. The health effects of smokeless tobacco with regard to

cardiovascular disease are not well understood, and published data are conflicting.[28-30] Although smokeless tobacco products do not confer many of the risks associated with the inhalation of combusted tobacco (e.g., pulmonary disease, lung cancer), these products do impose harm and should not be recommended as aids for smoking cessation, because safer, effective products (i.e., medications with FDA-approved labeling for use in smoking cessation) are available.[31]

Secondhand smoke exposure. Exposure to secondhand smoke results in an estimated 50,000 deaths annually, in addition to contributing to numerous diseases among nonsmoking children and adults.[3] Major conclusions of the Surgeon General's report "The Health Effects of Involuntary Exposure to Tobacco Smoke" included the following:

1. Many millions of Americans, both children and adults, are still exposed to secondhand smoke in their homes and workplaces despite substantial progress in tobacco control,
2. Secondhand smoke exposure causes disease and premature death in children and adults who do not smoke,
3. Children exposed to secondhand smoke are at an increased risk for sudden infant death syndrome (SIDS), acute respiratory infections, ear problems, and more severe asthma; smoking by parents causes respiratory symptoms and slows lung growth in their children,
4. Exposure of adults to secondhand smoke has immediate adverse effects on the cardiovascular system and causes coronary heart disease and lung cancer,
5. The scientific evidence indicates that there is no risk-free level of exposure to secondhand smoke, and
6. Eliminating smoking in indoor spaces fully protects nonsmokers from exposure to secondhand smoke; separating smokers from nonsmokers, cleaning the air, and ventilating buildings cannot eliminate exposures of nonsmokers to secondhand smoke.

Supplementing the evidence presented in the Surgeon General's report,[3] the California Environmental Protection Agency in January 2006 designated secondhand smoke as a "toxic air contaminant" and, in addition to noting the tobacco-related diseases described in the Surgeon General's report, specified that exposure to smoke is associated with breast cancer in younger, primarily premenopausal women.[32]

Drug interactions with tobacco smoke. Various substances in tobacco interact with several commonly prescribed drugs.[33,34] It is widely recognized that polycyclic aromatic hydrocarbons (PAHs), the products of the incomplete combustion of tobacco, are largely responsible for the majority of drug interactions with smoking. PAHs are found in appreciably large quantities in tobacco smoke and are potent inducers of hepatic microsomal (cytochrome P-450) enzymes CYP1A1, CYP1A2, and possibly CYP2E1. Although other substances in tobacco smoke such as acetone, pyridines, benzene, nicotine, carbon monoxide, and heavy metals (e.g., cadmium) might also interact with hepatic enzymes, their effects appear to be less significant.[34] To enable more effective screening for tobacco use and drug interactions with smoking, all patient records, including those stored and accessed via medical records and pharmacy information technology systems, should include a designated field for collection of tobacco-use data. This field should be integrated into the system so that relevant drug interactions with tobacco smoke can be identified.

Health benefits of smoking cessation

Quitting smoking produces immediate as well as long-term benefits, reducing the risk of developing diseases caused by smoking and improving health in general.[35] Some benefits are incurred almost immediately—within the first 24 hours—after quitting. Within two weeks to three months after quitting, circulation improves, walking becomes easier, and lung function increases up to 30%. Within 1 year, the excess risk of coronary heart disease is decreased to half that of a smoker, and after 5–15 years, stroke risk is reduced to a rate similar to that of people who have never smoked. Ten years after quitting, an individual's chance of dying of lung cancer is approximately half that of continuing smokers. In addition, the risk for mouth, throat, esophagus, bladder, kidney, or pancreatic cancer is decreased. Fifteen years after quitting, an individual's risk of coronary heart disease is reduced to a rate similar to that of people who have never smoked. Quitting at ages 30, 40, 50, and 60 has been shown to be associated with 10, 9, 6, and 3 years of life gained, respectively.[4] Thus, the benefits of quitting the use of tobacco are significant. It is never too late to quit to incur health benefits, but there are clear advantages to quitting earlier.

Strategies for promoting tobacco cessation

Because of the immense societal burden that smoking imposes, tobacco use and dependence should be addressed during each clinical encounter. Routine screening for tobacco-use status enables clinicians to prevent the initiation of tobacco use among nonusers, facilitate cessation among current users, and promote continued abstinence among former users.

For most smokers, the quitting process is characterized by a series of quit attempts and subsequent relapses. On average, former smokers report 10.8 quit attempts over a period of 18.6 years before achieving long-term cessation.[36] Most quit attempts are undertaken without as-

sistance, and approximately 95% of attempts end in relapse.[37]

Given the decades of strong, consistent findings in support of the efficacy and cost-effectiveness of both behavioral and pharmacologic interventions to facilitate tobacco cessation, ASHP recommends the use of evidenced-based behavioral and pharmacologic strategies for all patients attempting to quit smoking (except when medically contraindicated or in specific populations for which there is insufficient evidence of effectiveness [e.g., pregnant women, smokeless tobacco users, light smokers, adolescents]). Treatment for tobacco dependence is highly cost-effective relative to other medical interventions (e.g., periodic mammography screening, treatment for hypertension and hyperlipidemia) and should be made available to all tobacco users.[37] In accordance with recommendations set forth in the 2008 clinical practice guideline, Treating Tobacco Use and Dependence,[37] ASHP recommends that (1) all insurance plans include counseling and evidence-based pharmacotherapy treatments as a reimbursable benefit and (2) clinicians be reimbursed for providing treatment for tobacco dependence, just as they are reimbursed for treatment of other chronic conditions.

Data consistently reveal that behavioral interventions (e.g., counseling from a health care provider) and pharmacotherapy, used either alone or in combination, increase patients' odds for quitting their use of tobacco.[37] In a meta-analysis of 29 studies, it was determined that patients who receive a tobacco-cessation intervention from a nonphysician clinician or a physician clinician are 1.7 and 2.2 times as likely to quit (for at least five months), respectively, compared with patients who do not receive an intervention from a clinician.[37] Estimates of the efficacy of various behavioral and pharmacotherapy treatment strategies are shown in Table 2.

As delineated in the clinical practice guideline, clinicians should routinely screen for tobacco use and apply appropriate interventions (Figure 1), addressing five key components for comprehensive tobacco-cessation counseling (the 5 A's): (1) asking patients about tobacco use, (2) advising tobacco users to quit, (3) assessing their willingness to make a quit attempt, (4) assisting patients with quitting, and (5) arranging follow-up care (Appendix A). To increase the odds for success, patients who are not ready to quit should receive tailored motivational interventions that address the 5 R's[37] (Appendix B). Patients who are ready to quit should be provided with a treatment plan that includes behavioral counseling plus pharmacotherapy (as appropriate) and follow-up counseling.

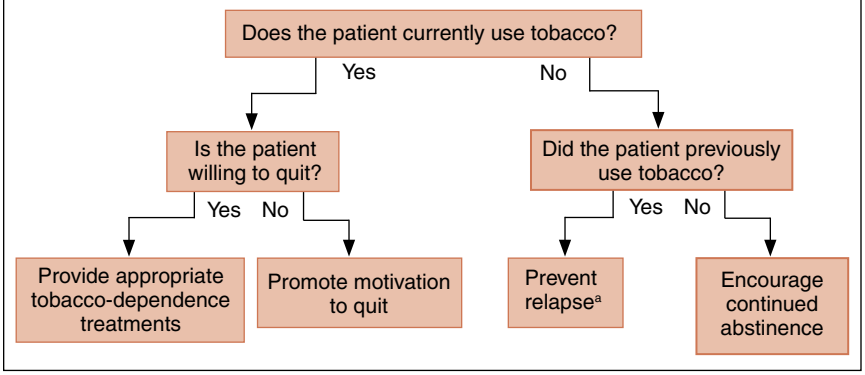
Clinicians should become familiar with local community-based

Table 2.
Efficacy of Treatment Methods for Tobacco Use and Dependence[a,b]

Treatment Method	Estimated Odds Ratio[c] (95% CI)	Estimated Abstinence[d] Rate (95% CI)
Behavioral interventions		
Advice to quit		
No advice to quit	1.0	7.9
Physician advice to quit	1.3 (1.1–1.6)	10.2 (8.5–12.0)
Clinician intervention		
No counseling by a clinician	1.0	10.2
Counseling by a nonphysician	1.7 (1.3–2.1)	15.8 (12.8–18.8)
Counseling by a physician	2.2 (1.5–3.2)	19.9 (13.7–26.2)
Format of smoking cessation counseling		
No format	1.0	10.8
Self-help	1.2 (1.0–1.3)	12.3 (10.9–13.6)
Proactive telephone counseling[e]	1.2 (1.1–1.4)	13.1 (11.4–14.8)
Group counseling	1.3 (1.1–1.6)	13.9 (11.6–16.1)
Individual counseling	1.7 (1.4–2.0)	16.8 (14.7–19.1)
Pharmacotherapy		
Placebo	1.0	13.8
First-line agents		
Bupropion SR	2.0 (1.8–2.2)	24.2 (22.2–26.4)
Nicotine gum (6–14 wk)	1.5 (1.2–1.7)	19.0 (16.5–21.9)
Nicotine inhaler	2.1 (1.5–2.9)	24.8 (19.1–31.6)
Nicotine lozenge (2 mg)	2.0 (1.4–2.8)	24.2[f]
Nicotine patch (6–14 wk)	1.9 (1.7–2.2)	23.4 (21.3–25.8)
Nicotine nasal spray	2.3 (1.7–3.0)	26.7 (21.5–32.7)
Varenicline (2 mg/day)	3.1 (2.5–3.8)	33.2 (28.9–37.8)
Second-line agents		
Clonidine	2.1 (1.2–3.7)	25.0 (15.7–37.3)
Nortriptyline	1.8 (1.3–2.6)	22.5 (16.8–29.4)
Combination therapy		
Patch (>14 weeks) + *ad lib* nicotine	3.6 (2.5–5.2)	36.5 (28.6–45.3)
Nicotine patch + bupropion SR	2.5 (1.9–3.4)	28.9 (23.5–35.1)
Nicotine patch + nortriptyline	2.3 (1.3–4.2)	27.3 (17.2–40.4)
Nicotine patch + nicotine inhaler	2.2 (1.2–3.6)	25.8 (17.4–36.5)

[a]Reprinted from reference 43, with permission.
[b]Data from reference 37.
[c]Estimated relative to referent group. CI = confidence interval.
[d]Abstinence percentages for specified treatment method.
[e]A quitline that responds to incoming calls and makes outbound follow-up calls. After an initial request by the smoker or via a fax-to-quit program, the clinician initiates telephone contact to counsel the patient.
[f]One qualifying randomized trial; 95% CI not reported.

Figure 1. Assessing readiness to quit.[38] Algorithm for treating tobacco use.



[a]Relapse-prevention interventions are not necessary for adults who have not used tobacco for many years.

resources for tobacco cessation, including group programs and telephone counseling.[37] When expertise, practice site logistics, or time constraints do not afford an opportunity to provide comprehensive tobacco-cessation counseling, clinicians should apply a truncated 5 A's model whereby they *ask* about tobacco use, *advise* tobacco users to quit, and then *refer* patients to appropriate cessation providers or programs. With the October 2004 introduction of a national toll-free quit line number (1-800-QUIT NOW), all residents of the United States can receive tobacco-cessation counseling at no cost. In clinical trials, telephone counseling services for smoking cessation have been shown to be effective among the patients who use them.[37-39] These positive results have been shown to translate into real-world effectiveness,[40] as evidenced in several meta-analytic reviews.[37,38,41,42]

Even the busiest of clinicians can serve an important role by spending approximately one minute per patient to identify tobacco users and to provide referrals to the quit line for more comprehensive counseling. When patients indicate a willingness to set a quit date in the next month, clinicians should consider a proactive approach whereby they obtain the patient's permission to contact the quit line directly on the patient's behalf as opposed to their providing a passive referral (by simply offering the patient contact information for the quit line).[38]

Pharmacotherapy for cessation. All patients attempting to quit using tobacco should be encouraged to use effective pharmacotherapies (Table 3) for smoking cessation,[43] except when medically contraindicated or in specific populations in which there is insufficient evidence of effectiveness (e.g., pregnant women, smokeless tobacco users, light smokers, adolescents).[37] Currently, the agents with approved FDA labeling for smoking cessation include five nicotine-replacement therapy (NRT) dosage forms, sustained-release bupropion, and varenicline. Pharmacologic agents that have not received FDA approval for use in smoking cessation but have demonstrated efficacy are clonidine and nortriptyline.[37]

NRT. Formulations of NRT products currently available in the United States include nicotine gum, lozenge, transdermal patch, nasal spray, and oral inhaler (Table 3). These agents improve quit rates by reducing the symptoms of nicotine withdrawal, enabling the patient to focus on behavior modification and coping with the psychological aspects of quitting. In addition, because the onset of action with NRT is not as rapid as that of nicotine obtained through tobacco (Figure 2), patients become less accustomed to the nearly immediate, reinforcing effects of tobacco. Patients using NRT are approximately two times as likely to quit smoking than are those receiving placebo.[37]

For selected patients with cardiovascular disease,[37] NRT should be used with caution, because nicotine can increase the heart rate and blood pressure and also act as a coronary vasoconstrictor.[44] Despite these effects, randomized, controlled trials have found no significant increase in the incidence of cardiovascular events or mortality among patients with cardiovascular disease receiving NRT when compared with that of patients receiving placebo.[45-47] However, because these studies specifically excluded patients with severe, underlying cardiac diseases, the clinical practice guideline[37] recommends that because of a lack of safety data in these higher-risk populations, NRT should be used with caution among patients who have experienced a myocardial infarction within the past two weeks and among those with serious arrhythmias or unstable angina.[37] A large observational study of more than 33,000 patients found that NRT use was not associated with an increased risk of myocardial infarction, stroke, or death.[48] Because the serum concentrations of nicotine achieved with the recommended dosages of NRT are generally much lower than those attained with smoking, most experts have concluded that the risks associated with NRT use in patients with cardiovascular disease are minimal relative to the risks of continued tobacco use.[44,49-52]

Other conditions for which NRT should be used with caution include active temporomandibular joint disease, pregnancy, and lactation. Patients with active temporomandibular joint disease should not use nicotine gum because doing so might exacerbate their condition. FDA classifies prescription formulations of

nicotine as pregnancy category D, indicating that there is evidence of risk to the human fetus. Accordingly, none of the NRT formulations have received FDA approval for use during pregnancy. Although NRT may pose a risk to the developing fetus, it is arguably less than the risks associated with continued smoking.[53] However, because NRT has the potential to cause fetal harm and because of insufficient evidence supporting its efficacy in pregnant women, the 2008 clinical practice guideline does not recommend use during pregnancy.[37] Nicotine is secreted in breast milk[53] and, while the risk is slight, clinicians should be aware that the nursing infant is at risk for nicotine toxicity, especially if the mother concomitantly smokes and uses NRT.

Sustained-release bupropion. The first nonnicotine medication FDA approved for smoking cessation was sustained-release bupropion (Zyban, GlaxoSmithKline, Philadelphia). This agent, which was originally marketed as an antidepressant, is hypothesized to promote smoking cessation by inhibiting the reuptake of dopamine and norepinephrine in the central nervous system[54] and may function as a nicotinic acetylcholine-receptor antagonist.[55] The neurochemical effects are believed to modulate the dopamine reward pathway and reduce the cravings for nicotine and symptoms of withdrawal.[37] Bupropion is effective in smokers with or without a history of major depression,[56] suggesting that the mechanism of action is independent of the agent's antidepressant effects. Clinical trials involving almost 10,000 participants have confirmed the effectiveness of sustained-release bupropion as an aid to tobacco cessation; a recent meta-analysis of 31 trials concluded that the odds of tobacco abstinence at six or more months was 1.9 (sustained-release bupropion relative to placebo, 95% CI, 1.7–2.2).[57] Patients receiving sustained-release bupropion are approximately two times more likely to quit smoking than are patients receiving placebo.[44]

Bupropion is contraindicated in patients (1) with a seizure disorder, (2) with a history of anorexia or bulimia nervosa, (3) who are using another formulation of bupropion (Wellbutrin, Wellbutrin SR, Wellbutrin XL), (4) who have used a monoamine oxidase inhibitor within the past 14 days, and (5) who are undergoing abrupt discontinuation of alcohol or sedatives (including benzodiazepines).[58] In clinical trials for smoking cessation, the frequency of seizures with bupropion was <0.1% (seven seizures among 8000 bupropion-treated patients).[57] This frequency is comparable to the report rate of seizures (0.1%) when sustained-release bupropion was used in the treatment of depression.[59] For this reason, bupropion should be used with extreme caution in patients with a history of seizures, those who have experienced cranial trauma, and those receiving medications known to lower the seizure threshold or those with underlying severe hepatic cirrhosis. In addition, caution should be exercised in patients with certain depressive or psychiatric disorders. FDA has recently reclassified bupropion as a pregnancy category C drug, meaning that either (1) animal studies have demonstrated that the drug exerts animal-teratogenic or embryocidal effects, but there are no controlled studies in women, or (2) no studies are available in either animals or women. The pregnancy category reclassification resulted after the reanalysis of preclinical animal data demonstrated an increased incidence of fetal malformations and skeletal variations in rabbits receiving dosages approximately twofold higher than the maximum recommended human dose (on a milligram per square meter basis) of bupropion. The manufacturer continues to recommend that bupropion be used during pregnancy only if clearly needed.[58]

Varenicline. A partial agonist selective for the $\alpha_4\beta_2$ nicotinic acetylcholine receptor, varenicline (Chantix, Pfizer, Inc., New York, NY) was approved in May 2006 for use as an aid to smoking cessation. The drug's efficacy in smoking cessation is believed to be the result of low-level agonist activity at the receptor site combined with the competitive inhibition of nicotine binding. The partial agonist activity induces modest receptor stimulation that attenuates the symptoms of nicotine withdrawal. In addition, by blocking the ability of nicotine to activate $\alpha_4\beta_2$ nicotinic acetylcholine receptors, varenicline inhibits the surges of dopamine release that are believed to be responsible for the reinforcement and reward associated with smoking.[60]

Data from meta-analyses suggest that the use of varenicline significantly increases long-term smoking-abstinence rates relative to placebo and sustained-release bupropion.[37,61] FDA has classified varenicline as a pregnancy category C drug. The manufacturer recommends varenicline use during pregnancy only if the potential benefit justifies the potential risk to the fetus.[62]

In February 2008, FDA issued a public health advisory to alert health care providers about reports of serious neuropsychiatric symptoms in patients attempting to quit smoking while using varenicline, including changes in behavior, depressed mood, agitation, and suicidal ideation and behavior. The warnings and precautions sections of the drug's prescribing information have been updated, and FDA recommends that (1) patients tell their health care providers about any history of psychiatric illness before starting varenicline and (2) clinicians and patients monitor for changes in mood and behavior during treatment with varenicline.[63]

Second-line agents. Second-line agents that have not received an FDA indication for smoking cessation

Table 3.
Medications with FDA-Approved Indications for Smoking Cessation [43,a]

Product Name and Availability	Precautions	Dosing	Administration and Pt Information
Nicorette gum, generic, nonprescription, 2 or 4 mg	Pregnancy[c] (Category D), breastfeeding, recent (≤2 wk) MI, serious underlying arrhythmia, serious or worsening angina pectoris, TMJ disease	≥25 cigarettes/day: 4 mg, <25 cigarettes/day: 2 mg Wk 1–6: 1 piece every 1–2 hr, wk 7–9: 1 piece every 2–4 hr, wk 10–12: 1 piece every 4–8 hr Maximum, 24 pieces/day Duration, up to 12 wk	Chew each piece slowly, park between cheek and gum when peppery or tingling sensation appears (~15–30 chews), resume chewing when taste or tingle fades, repeat chew/park steps until most of the nicotine is gone (taste or tingle does not return; generally 30 min), park in different areas of mouth, no food or beverages 15 min before or during use
Commit lozenges, generic nonprescription, 2 or 4 mg	Pregnancy[c] (Category D), breastfeeding, recent (≤2 wk) MI, serious underlying arrhythmia, serious or worsening angina pectoris	First cigarette ≤30 min after waking: 4 mg, first cigarette >30 min after waking: 2 mg Wk 1–6: 1 lozenge every 1–2 hr, wk 7–9: 1 lozenge every 2–4 hr, wk 10–12: 1 lozenge every 4–8 hr Maximum, 20 lozenges/day Duration, up to 12 wk	Allow to dissolve slowly (20-30 min), nicotine release may cause a warm, tingling sensation, do not chew or swallow, occasionally rotate to different areas of the mouth, no food or beverages 15 min before or during use
Nicoderm CQ transdermal patch, nonprescription, 24-hr release; 7,14, or 21 mg	Pregnancy[c] (Category D), breastfeeding, recent (≤2 wk) MI, serious underlying arrhythmia, serious or worsening angina pectoris	>10 cigarettes/day: 21 mg/day × 6 wk, 14 mg/day × 2 wk, 7 mg/day × 2 wk ≤10 cigarettes/day: 14 mg/day × 6 wk, 7 mg/day × 2 wk Duration: 8–10 wk	May wear patch for 16 hr if pt has sleep disturbances (remove at bedtime
Generic patch (formerly Habitrol) (prescription or nonprescription) 24-hour release; 7,14, or 21 mg	Pregnancy[c] (Category D), breastfeeding, recent (≤2 wk) MI, serious underlying arrhythmia, serious or worsening angina pectoris	>10 cigarettes/day: 21 mg/day × 4 wk, 14 mg/day × 2 wk, 7 mg/day × 2 wk ≤10 cigarettes/day: 14 mg/day x 6 wk, 7 mg/day × 2 wk Duration: 8–10 wk	May wear patch for 16 hr if pt has sleep disturbances (remove at bedtime)

include the prescription medications clonidine and nortriptyline.[37] Controlled trials suggest that these agents are effective in treating tobacco dependence (Table 2), but they have a greater incidence of adverse effects and should be reserved for patients unable to quit with medications approved for smoking cessation.[37]

Combination therapy. Certain combinations of medications have been shown to be effective smoking-cessation treatments. In the previous guideline, combination therapy was recommended only for patients unable to quit after monotherapy with first-line agent. Based on data from eight clinical trials, the 2008 clinical practice guideline recommends that clinicians consider using combinations of first-line agents for patients who are willing to quit.[37] Combination NRT involves the use of a long-acting formulation (e.g., nicotine patch) along with a short-acting formulation (i.e., gum, lozenge, inhaler, or nasal spray). The long-acting

Adverse Effects	Advantages	Disadvantages	Cost/Day[b]
Mouth/jaw soreness, hiccups, dyspepsia, hypersalivation, effects associated with incorrect chewing technique (lightheadedness, nausea/vomiting, throat and mouth irritation)	Might satisfy oral cravings, may delay weight gain, pts can adjust therapy to manage withdrawal symptoms; available in a variety of flavors	Gum chewing may not be socially acceptable, might be problematic for patients with significant dental work, pts must use proper chewing technique to minimize adverse effects	2 mg: $3.28–$6.58 (9 pieces), 4 mg: $4.31–$6.58 (9 pieces)
Nausea, hiccups, cough, heartburn, headache, flatulence, insomnia	Might satisfy oral cravings, might delay weight gain, easy to use and conceal pts can adjust therapy to manage withdrawal symptoms; available in a variety of flavors	Adverse gastrointestinal effects (nausea, hiccups, heartburn) might be bothersome; need for frequent dosing can compromise adherence	2 mg or 4 mg: $3.66–$5.26 (9 pieces)
Local skin reactions (erythema, pruritus, burning), headache, sleep disturbances (insomnia), abnormal or vivid dreams (associated with nocturnal nicotine absorption)	Provides consistent nicotine levels over 24 hr, easy to use and conceal, once-daily administration associated with fewer adherence problems	Pts cannot adjust dosage, allergic reactions to adhesive might occur, pts with dermatological conditions should not use patch	$1.90–$3.89 (1 patch)
Local skin reactions (erythema, pruritus, burning), headache, sleep disturbances (insomnia), abnormal or vivid dreams (associated with nocturnal nicotine absorption)	Provides consistent nicotine levels over 24 hr, easy to use and conceal, once-daily administration associated with fewer adherence problems	Pts cannot adjust dosage, allergic reactions to adhesive might occur, pts with dermatological conditions should not use patch	$1.90–$3.89 (1 patch)

Continued on next page

formulation, which delivers nicotine at relatively constant levels, is used to prevent the onset of severe withdrawal symptoms; the short-acting formulation, which delivers nicotine at a more rapid rate, is used as needed to control the withdrawal symptoms that may occur during potential relapse situations (e.g., after meals, during times of stress, when around other smokers).

Controlled trials suggest that the nicotine patch in combination with short-acting NRT formulations (i.e., gum, nasal spray, or inhaler) significantly increases quit rates relative to placebo.[37] Similar results have been observed in trials using combination therapy with sustained-release bupropion and the nicotine patch. Results from an open-label trial suggest that a more-aggressive approach consisting of triple agent NRT (e.g., inhaler, patch, and nasal spray) with or without sustained-release bupropion is safe and effective among highly dependent smokers.[64] Clini-

Table 3 *(continued)*

Product Name and Availability	Precautions	Dosing	Administration and Pt Information
Nicotrol NS, metered spray, prescription 0.5 mg nicotine in 50 µL aqueous nicotine solution	Pregnancy[c] (Category D), breastfeeding, recent (≤2 wk) MI, serious underlying arrhythmia, serious or worsening angina pectoris, underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis), severe reactive airway disease	1–2 doses/hr (8–40 doses/day) 1 dose = 2 sprays (1 in each nostril); each spray delivers 0.5 mg of nicotine Maximum of 5 doses/hr or 40 doses/day Duration, 3–6 mo	For best results, initially use at least 8 doses/day; pts should not sniff, swallow, or inhale through nose as spray is administered
Nicotrol inhaler, prescription, 10-mg cartridge delivers 4 mg inhaled nicotine vapor	Pregnancy[c] (Category D), breastfeeding, recent (≤2 wk) MI, serious underlying arrhythmia, serious or worsening angina pectoris, bronchospastic disease	6–16 cartridges/day for up to 6 mo, individualized dosing, Duration, 3–6 mo	Initially, use at least 6 cartridges/day; best effects with continuous puffing for 20 min; nicotine in cartridge depleted after 20 min of active puffing; pt should inhale into back of throat or puff in short breaths; do not inhale into lungs (like a cigarette) but "puff" as if lighting a pipe; open cartridge retains potency for 24 hr
Zyban (bupropion SR), generic and prescription 150-mg sustained-release tablets	Pregnancy[c] (Category C), breastfeeding, concomitant therapy with medications or medical conditions known to lower the seizure threshold, severe hepatic cirrhosis *Contraindications:* Seizure disorder, concomitant bupropion (e.g., Wellbutrin) therapy, current or prior diagnosis of bulimia or anorexia nervosa, simultaneous abrupt discontinuation of alcohol or sedatives (including benzodiazepines), MAOI therapy in previous 14 days	150 mg p.o. every morning x 3 days, then increase to 150 mg p.o. twice daily; not to exceed 300 mg/day Duration: 7–12 wk, with maintenance up to 6 mo in selected patients	Treatment should be initiated while pt is still smoking, set quit date 1–2 wk after initiation of therapy, allow at least 8 hr between doses, avoid bedtime administration to minimize insomnia, dose tapering not necessary, can be used safely with NRT
Chantix (varenicline), prescription, 0.5- and 1-mg tablets	Pregnancy[c] (Category C), breastfeeding, severe renal impairment (dosage adjustment is necessary), safety and efficacy have not been established in patients with serious psychiatric illness.	Days 1–3: 0.5 mg p.o. every morning, days 4–7: 0.5 mg p.o. twice daily, wk 2–12:1 mg p.o. twice daily Duration: 12 wks; an additional 12-wk course may be used in selected patients	Pts should begin therapy 1 wk before quit date, take dose after eating with full glass of water, dose tapering is not necessary, nausea and insomnia are side effects that are usually temporary

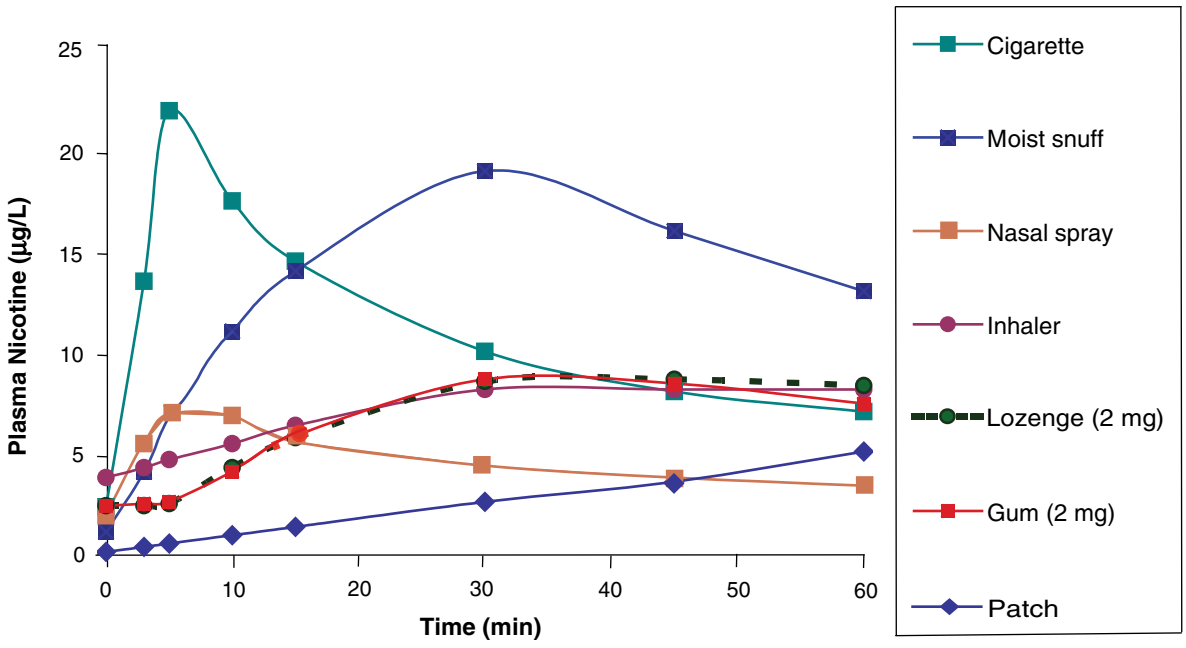
[a]Reprinted from reference 43, with permission. For complete prescribing information, please refer to the manufacturers' package inserts. FDA = Food and Drug Administration, MI = myocardial infarction, TMJ = temporomandibular joint, NRT = nicotine-replacement therapy, MAOI = monoamine oxidase inhibitor.

Adverse Effects	Advantages	Disadvantages	Cost/Day[b]
Nasal or throat irritation (hot, peppery, or burning sensation), rhinitis, tearing, sneezing, cough, headache	Pts can adjust therapy to manage withdrawal symptoms	Nasal or throat irritation may be bothersome, dependence can result, Pts must wait 5 min before driving or operating heavy machinery, pts with chronic nasal disorders or severe reactive airway disease should not use spray; need for frequent dosing can compromise adherence	$3.72 (8 doses)
Mouth or throat irritation, unpleasant taste, cough, headache, rhinitis, dyspepsia, hiccups	Pts can adjust therapy to manage withdrawal symptoms, mimics hand-to-mouth ritual of smoking	Initial throat or mouth irritation can be bothersome, cartridges should not be stored in very warm conditions or used in very cold conditions, pts with underlying bronchospastic disease must use inhaler with caution; need for frequent dosing can compromise adherence	$5.29 (6 cartridges)
Insomnia, dry mouth, nervousness/difficulty concentrating, rash, constipation, seizures (risk is 1/1,000 [0.1%])	Easy to use; oral formulation might be associated with fewer compliance problems, can be used with NRT, might be beneficial in patients with depression	Seizure risk is increased, several contraindications and precautions can preclude use	$3.62–$7.40 (2 tablets)
Nausea, sleep disturbances (insomnia, abnormal dreams), constipation, flatulence, vomiting, neuropsychiatric symptoms (behavior changes, agitation, depressed mood, suicidal ideation or behavior)	Easy to use, oral formulation might be associated with fewer compliance problems, offers new mechanism of action for pts who have not succeeded with other agents	May induce nausea in up to one third of pts, Postmarketing surveillance data indicate potential for neuropsychiatric symptoms	$4.49–$4.75 (2 tablets)

[b]Average wholesale price from Medi-Span Electronic Drug File. Indianapolis, IN; Wolters Kluwer Health, September 2008.

[c]The U.S. clinical practice guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence and hypothetical concerns with safety. Pregnant smokers should be offered cessation counseling interventions that exceed minimal advice to quit.[37]

Figure 2. Plasma nicotine concentrations for nicotine-containing products. Reprinted with permission from reference 43.



cians should be aware that while the combination of the nicotine patch and sustained-release bupropion has been approved by FDA, the concurrent use of two NRT products is not FDA-approved for tobacco cessation. Furthermore, the optimal combinations, dosages, and duration of dual NRTs are currently unknown. The safety and effectiveness of varenicline used with sustained-release bupropion or NRT have not been established. Pilot data suggest that patients receiving both varenicline and the nicotine patch are more likely to experience adverse effects (nausea, headache, vomiting, dizziness, dyspepsia, and fatigue) than are those receiving the patch alone.[62]

Smoke-free environments

Smoking initiation and cessation result from the interplay of numerous factors, including but not limited to environmental influences.[21] Smokers in one's environment can both promote initiation and inhibit cessation.

Data on state-specific trends in smoke-free working environments indicate that 73.4% of employees who work indoors were covered by a smoke-free workplace policy, according to a survey of 14 states conducted in 2005.[65] Smoke-free workplaces have been shown to not only protect individuals from secondhand smoke but also to reduce the prevalence of smoking.[66] In a simulation study, smoke-free workplace policies were estimated to be approximately nine times more cost-effective per patient than are programs that provide NRT at no cost.[67]

Over the past few years, numerous cities and states have adopted clean indoor air laws in workplaces.[68] Nationally, the effects of transitioning all workplaces to smoke-free environments would yield an estimated 4.5% decrease in the overall prevalence of smoking.[66] In its first year of implementation, a nationwide smoke-free workplace policy would produce an estimated 1.3 million new quitters, 1500 fewer myocardial infarctions, 350 fewer strokes, and a direct saving of nearly $60 million in medical costs.[69] Given this substantial impact on public health, ASHP supports the implementation of smoke-free policies for the employees and patrons of all workplaces and public venues, including but not limited to offices, restaurants, bars, bowling alleys, and casinos, and for establishments where health care services are rendered. ASHP also strongly supports smoke-free campuses for all health care institutions and facilities. In practice, clinicians should educate patients about the dangers of secondhand smoke and encourage patients who continue to smoke to do so outdoors.

The clinician's role

To ensure that all future clinicians have received adequate training for treating tobacco use and dependence, schools offering health-profession courses or degrees are advised to incorporate comprehensive tobacco-

Table 4.
Tobacco-Cessation Resources

Resource	Contact Information
Governmental agencies	
Centers for Disease Control and Prevention	www.cdc.gov
Environmental Protection Agency	www.epa.gov
Federal Trade Commission	www.ftc.gov
Office of the Surgeon General	www.surgeongeneral.gov
National Institutes of Health	www.nih.gov
National Cancer Institute	www.cancer.gov
National Heart, Lung, and Blood Institute	www.nhlbi.nih.gov
National Institute on Drug Abuse	www.nida.nih.gov
Organizations	
American Cancer Society	www.cancer.org
American Heart Association	www.americanheart.org
American Legacy Foundation	www.americanlegacy.org
American Lung Association	www.lungusa.org
American Society of Health-System Pharmacists	www.ashp.org/s_ashp/tobacco
Campaign for Tobacco-Free Kids	www.tobaccofreekids.org
Global Network of Pharmacists Against Tobacco	www.fip.org/pharmacistsagainsttobacco
North American Quitline Consortium	www.naquitline.org
Society for Research on Nicotine & Tobacco	www.srnt.org
University of California Smoking Cessation Leadership Center	smokingcessationleadership.ucsf.edu
University of California Tobacco-Related Disease Research Program	www.trdrp.org
World Health Organization	www.who.int
Documents	
Clinical Practice Guideline for Treating Tobacco Use and Dependence	www.surgeongeneral.gov/tobacco
Legacy Tobacco Industry Documents Archive	www.legacy.library.ucsf.edu
Pharmacologic aids for cessation—online support	
Committed Quitters Program	
Nicorette gum	www.nicorette.com
Nicoderm patch	www.nicodermcq.com
Commit lozenge	www.commitlozenge.com
GETQUIT Support Plan	
Chantix	www.chantix.com
Helping Hand Program	
Nicotrol nasal spray and inhaler	www.nicotrol.com
Smoke-Free Program	
Generic patch (formerly Habitrol)	www.habitrol.com
Nonpharmaceutical cessation support and programs	
QuitKey (handheld computer for scheduled gradual reduction of smoking)	www.quitkey.com
QuitNet (comprehensive online tobacco-cessation support program)	www.quitnet.com
Rx for Change: Clinician-Assisted Tobacco Cessation (evidence-based tobacco-cessation training materials for educating health professional students and licensed clinicians)	rxforchange.ucsf.edu
Tobacco-Free Nurses (national program focused on helping nurses and student nurses to stop smoking)	www.tobaccofreenurses.org
Toll-free quit lines (telephone counseling for cessation, available at no cost to all callers)	1-800-QUIT NOW

cessation training as part of the required curriculum for all students.[37] Licensed clinicians who have not received the formal training necessary to provide comprehensive tobacco-cessation counseling are encouraged to complete continuing-education programs. Furthermore, clinicians should systematically integrate the identification of tobacco users and the delivery of evidence-based tobacco-use cessation interventions into routine patient care. In the absence of time or expertise to provide comprehensive cessation counseling,

clinicians should—at a minimum—ask patients about tobacco use, advise patients to quit, and refer these patients to external resources such as the toll-free quit line (1-800-QUIT NOW) or a group program.[37] Because higher quit rates result when patients receive assistance from multiple health care providers,[37] clinicians are encouraged to work in tandem with other providers as part of a team approach to helping patients quit smoking. Table 4 provides useful online links to assist clinicians in tobacco-control initiatives.

Given that the sale of tobacco contradicts both the clinician's role in promoting health and the pharmacist's code of ethics,[70] ASHP strongly opposes the sale or distribution of tobacco products in all establishments where health care services are rendered (e.g., hospitals, clinics, retail chain and community pharmacies).[71] For more than three decades, the pharmacy profession has repeatedly voiced opposition to the sale of tobacco products in pharmacies,[72] including formal resolutions from state and national organizations. Notably, few licensed pharmacists (estimated at <2%)[73] and pharmacy students (3.5%)[74] are in favor of tobacco sales in pharmacies. Given this overwhelming lack of support, members of the profession are advised to insist that tobacco sales no longer occur in the environments where pharmaceutical care is rendered. Furthermore, in accordance with a 2003 resolution set forth by the American Association of Colleges of Pharmacy, ASHP encourages colleges and schools of pharmacy to give preference as clerkship sites to those pharmacies that choose not to sell tobacco products.[74]

Conclusion

Given the extensive body of data implicating tobacco as the primary known preventable cause of death in the United States, ASHP strongly supports evidence-based tobacco-control initiatives that aim to reduce the prevalence of tobacco use. These efforts should address a continuum of services, activities, and policies ranging from the integration of tobacco-cessation counseling as a routine component of patient care to the adoption of clean indoor air laws. ASHP believes that the active involvement of health care providers is crucial to effective tobacco control at the population level and that the pharmacy profession—as a primary and accessible point of contact between the health care system and the public (including the medically underserved)—has a unique opportunity to serve as a cornerstone for the nation's tobacco-control efforts.

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Appendix A—The 5 A's of tobacco cessation counseling[37]

Step	Action	Strategies for Implementation
Ask—Systematically identify all tobacco users at every visit	Implement a system that ensures that, for every patient at every clinic visit, tobacco use status is queried and documented.[a]	Expand the vital signs to include tobacco use, or use an alternative universal identification system.[b] VITAL SIGNS Blood Pressure: _____ Pulse: ___ Weight: _____ Temperature: _____ Respiratory Rate: _____ Tobacco Use (circle one): Current Former Never
Advise—Strongly urge all tobacco users to quit	In a clear, strong, and personalized manner, urge every tobacco user to quit.	Advice should be: • Clear—"It is important that you quit smoking (or using chewing tobacco) now, and I can help you." "Cutting down while you are ill is not enough." "Occasional or light smoking is still dangerous." • Strong—"As your clinician, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you." • Personalized—Tie tobacco use to current symptoms and health concerns, and/or its social and economic costs, and/or the impact of tobacco use on children and others in the household. "Continuing to smoke makes your asthma worse, and quitting may dramatically improve your health." "Quitting smoking may reduce the number of ear infections your child has."
Assess—Determine willingness to make a quit attempt	Assess every tobacco user's willingness to make a quit attempt at the time.	Assess patient's willingness to quit: "Are you willing to give quitting a try?" • If the patient is willing to make a quit attempt at the time, provide assistance. – If the patient will participate in an intensive treatment, deliver such a treatment or link/refer to an intensive intervention. – If the patient is a member of a special population (e.g., adolescent, pregnant smoker, racial/ethnic minority), consider providing additional information. • If the patient clearly states that he or she is unwilling to make a quit attempt at the time, provide an intervention shown to increase future quit attempts.
Assist—Aid the patient in quitting (provide counseling and medication)	Help the patient with a quit plan.	STAR: A patient's preparations for quitting: • **S**et a quit date. Ideally, the quit date should be within 2 weeks. • **T**ell family, friends, and coworkers about quitting, and request understanding and support. • **A**nticipate challenges to the upcoming quit attempt, particularly during the critical first few weeks. These include nicotine withdrawal symptoms. • **R**emove tobacco products from your environment. Prior to quitting, avoid smoking in places where you spend a lot of time (e.g., work, home, car). Make your home smoke-free.
	Recommend the use of approved medication, except when contraindicated or with specific populations for which there is insufficient evidence of effectiveness.	Recommend the use of medications found to be effective. Explain how these medications increase quitting success and reduce withdrawal symptoms. The first-line medications include: bupropion SR, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, nicotine patch, and varenicline; second-line medications include: clonidine and nortriptyline. There is insufficient evidence to recommend medications for certain populations (e.g., pregnant women, smokeless tobacco users, light smokers, adolescents).
	Provide practical counseling (problem solving/skills training).	• Abstinence: Striving for total abstinence is essential. Not even a single puff after the quit date. • Past quit experience: Identify what helped and what hurt in previous quit attempts. Build on past success. • Anticipate triggers or challenges in the upcoming attempt. Discuss challenges/triggers and how the patient will successfully overcome them (e.g., avoid triggers, alter routines). • Alcohol: Because alcohol is associated with relapse, the patient should consider limiting/abstaining from alcohol while quitting. (Note that reducing alcohol intake could precipitate withdrawal in alcohol-dependent persons.) • Other smokers in the household: Quitting is more difficult when there is another smoker in the household. Patients should encourage housemates to quit with them or to not smoke in their presence.

Continued on next page

Appendix A (*continued*)

Step	Action	Strategies for Implementation
	Provide intratreatment social support.	Provide a supportive clinical environment while encouraging the patient in his or her quit attempt. "My office staff and I are available to assist you." "I'm recommending treatment that can provide ongoing support."
	Provide supplementary materials, including information on quitlines.	• Sources: Federal agencies, nonprofit agencies, national quitline network (1-800-QUIT-NOW), or local/state/tribal health departments/quitlines. • Type: Culturally/racially/educationally/age-appropriate for the patient. • Location: Readily available at every clinician's workstation.
Arrange—Ensure follow-up contact	Arrange for follow-up contacts, either in person or via telephone.	• Timing: Follow-up contact should begin soon after the quit date, preferably during the first week. A second follow-up contact is recommended within the first month. Schedule further follow-up contacts as indicated. • Actions during followup contact: For all patients, identify problems already encountered and anticipate challenges in the immediate future. Assess medication use and problems. Remind patients of quitline support (1-800-QUIT-NOW). Address tobacco use at next clinical visit (treat tobacco use as a chronic disease). • For patients who are abstinent, congratulate them on their success. If tobacco use has occurred, review circumstances and elicit recommitment to total abstinence. Consider use of or link to more intensive treatment.

[a]Repeated assessment is not necessary in the case of the adult who has never used tobacco or has not used tobacco for many years and for whom this information is clearly documented in the medical record.

[b]Alternatives to expanding the vital signs include using tobacco use status stickers on all patient charts or indicating tobacco use status via electronic medical records or computerized reminder systems.

Appendix B—Enhancing Motivation to Quit: The 5 R's of tobacco-cessation counseling[37]

Relevance

Encourage the patient to indicate why quitting is personally relevant, being as specific as possible. Motivational information has the greatest impact if it is relevant to a patient's disease status or risk, family or social situation (e.g., having children in the home), health concerns, age, gender, and other important patient characteristics (e.g., prior quitting experience, personal barriers to cessation).

Risks

The clinician should ask the patient to identify potential negative consequences of tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient. The clinician should emphasize that smoking low-tar/low-nicotine cigarettes or use of other forms of tobacco (e.g., smokeless tobacco, cigars, and pipes) will not eliminate these risks. Examples of risks are:

- Acute risks: Shortness of breath, exacerbation of asthma, increased risk of respiratory infections, harm to pregnancy, impotence, infertility.
- Long-term risks: Heart attacks and strokes, lung and other cancers (e.g., larynx, oral cavity, pharynx, esophagus, pancreas, stomach, kidney, bladder, cervix, and acute myelocytic leukemia), chronic obstructive pulmonary diseases (chronic bronchitis and emphysema), osteoporosis, long-term disability, and need for extended care.
- Environmental risks: Increased risk of lung cancer and heart disease in spouses; increased risk for low birth-weight, sudden infant death syndrome (SIDS), asthma, middle ear disease, and respiratory infections in children of smokers.

Rewards

The clinician should ask the patient to identify potential benefits of stopping tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient. Examples of rewards include:

- Improved health
- Food will taste better
- Improved sense of smell
- Saving money
- Feeling better about oneself
- Home, car, clothing, breath will smell better
- Setting a good example for children and decreasing the likelihood that they will smoke
- Having healthier babies and children
- Feeling better physically
- Performing better in physical activities
- Improved appearance, including reduced wrinkling/aging of skin and whiter teeth

Roadblocks

The clinician should ask the patient to identify barriers or impediments to quitting and provide treatment (problem solving counseling, medication) that could address barriers. Typical barriers might include:

- Withdrawal symptoms
- Fear of failure
- Weight gain
- Lack of support
- Depression
- Enjoyment of tobacco
- Being around other tobacco users
- Limited knowledge of effective treatment options

Repetition

The motivational intervention should be repeated every time an unmotivated patient visits the clinic setting. Tobacco users who have failed in previous quit attempts should be told that most people make repeated quit attempts before they are successful.