CHAPTER 50

Smoking Cessation

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In 1982, the U.S. Surgeon General C. Everett Koop stated that 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 25 years later. Because the recommended treatment for tobacco dependence involves both behavioral counseling and pharmacotherapy,[2] health care providers are strategically positioned to make significant contributions toward reducing the prevalence of tobacco use. The U.S. Public Health Service's clinical practice guideline for treating tobacco use and dependence,[2] which summarizes more than 6000 published articles, indicates that clinicians can significantly increase patients' likelihood of quitting, even with brief interventions (less than 3 minutes). More intensive counseling, a greater number of counseling sessions, and teaming multiple types of clinicians (e.g., physicians, pharmacists, nurses, physician assistants, dental hygienists, and dentists) yields enhanced quit rates.[2]

While clinicians should address use of all forms of tobacco (smoked and smokeless), this chapter focuses on cigarette smoking, as it is the most commonly used form of tobacco in the United States and the only form for which nonprescription nicotine replacement therapy (NRT) products are indicated. This chapter provides an overview of currently available nonprescription medications for smoking cessation and outlines practical strategies clinicians that can use when assisting patients prior to and during a quit attempt.

Epidemiology of Tobacco Use and Dependence

In the United States, cigarette smoking is the leading known cause of preventable death,[3] resulting in an estimated 437,902 deaths each year.[4] In addition to lives lost, the economic impact of smoking is enormous—for each of approximately 22 billion packs of cigarettes sold in 1999, the associated medical and lost productivity costs were $3.45 and $3.73, respectively, totaling $7.18 per pack and $157 billion overall.[5]

Because smoking initiation occurs primarily during adolescence,[6] tobacco-use trends among youth are key indicators of the overall health of our nation.[7] An estimated 89% of adult smokers smoked their first cigarette by age 18, and 71% of adult daily smokers initiated regular smoking by age 18.[6] Since 1999, the prevalence of smoking among adolescents has decreased—in 2004, an estimated 25% of 12th graders had smoked one or more cigarettes in the past 30 days.[8]

Despite the well-established and well-publicized negative effects of smoking, an estimated 20.9% of adult Americans (23.4% of males and 18.5% of females) continue to smoke; 81.3% of these persons smoke daily.[9] The prevalence of smoking among adult Americans varies by sociodemographic factors, including sex, race/ethnicity, education level, age, and socioeconomic status.[9] In 2004, the prevalence of smoking in the United States was highest among American Indian/Alaska Natives (33.4%) and next highest among non-Hispanic whites (22.2%), followed by non-Hispanic blacks (20.2%), Hispanics (15.0%), and Asians (11.3%).[9] Smoking also tends to be more common among persons of lower educational levels and those living below the U.S. threshold poverty level.[9] The median prevalence of smoking varies by state, with Utah exhibiting the lowest prevalence at 10.5% and Kentucky exhibiting the highest, at 27.6%.[10]

Although the overall prevalence of smoking in the United States has exhibited a fairly stable decline over the past two decades, annual reports from the Centers for Disease Control and Prevention suggest this downward trend has leveled in recent years. An estimated 70% of smokers want to quit,[11] and, in 2004, approximately 14.6 million (40.5%) of 36.1 million every-day, current smokers stopped smoking at least 1 day during the past year because they were trying to quit.[9] Yet, smoking cessation rates remain low, and much effort is needed if our nation is to reach the Healthy People 2010 goals of (a) an adult smoking prevalence of no more than 12% and (b) an adult smoking cessation attempt rate of 75%.[7]

Etiology of Tobacco Use and Dependence

In 1988 the U.S. Surgeon General released a landmark report, concluding that tobacco products are effective nicotine delivery systems capable of inducing and sustaining chemical dependence. The primary criteria used to categorize nicotine as an addictive substance included its (1) psychoactive effects, (2) use in a highly controlled or compulsive manner, and (3) reinforcement of behavioral patterns of tobacco use. The underlying pharmacologic and behavioral processes associated with tobacco dependence are considered to be similar to those that determine addiction to drugs such as heroin and cocaine.[12]

As with other addictive substances (e.g., opiates, cocaine, amphetamines), nicotine stimulates the mesolimbic dopaminergic system in the midbrain inducing pleasant or rewarding effects that promote continued use of the drug.[13] Psychosocial and environmental factors also

play an important role in establishing and maintaining dependence.[14] For example, smokers commonly associate smoking with specific activities such as driving, talking on the telephone, drinking coffee or alcohol, being around other smokers, or eating. Over time, the habitual use of cigarettes under these circumstances can lead to the development of smoking routines that can be difficult to break. Indeed, specific environmental situations can become powerful stimuli capable of triggering "automatic" smoking patterns. It is well established that tobacco is a detrimental substance,[15] and its use dramatically increases one's odds of dependence, disease, disability, and death. Cigarettes are carefully engineered and heavily marketed products—in 2003, the tobacco industry spent $15.15 billion advertising cigarettes in the United States.[16] It is the only marketed consumable product that, when used as intended, will kill half or more of its users.[17]

Pathophysiology of Tobacco Use and Dependence

Cigarette smoke, which is classified by the Environmental Protection Agency as a Class A carcinogen (i.e., a carcinogen with no safe level of exposure for humans), is a complex mixture of an estimated 4800 compounds found in gaseous and particulate phases. Approximately 500 compounds are present in the vapor phase, including nitrogen, carbon monoxide, ammonia, hydrogen cyanide, and benzene. The remaining constituents of tobacco smoke, the most important of which is the alkaloid nicotine, are found in the particulate phase. The particulate fraction, excluding the nicotine and water components, is collectively referred to as tar. Numerous carcinogens, including polycyclic aromatic hydrocarbons and nitrosamines, have been identified in the tar fraction of tobacco smoke.[18]

Nicotine, the addictive component of tobacco, is distilled from burning tobacco and carried in tar droplets to the small airways of the lung, where it is absorbed rapidly into the arterial circulation and distributed throughout the body. Most U.S. cigarettes contain between 6 and 13 mg of nicotine, and the typical smoker absorbs between 1 and 3 mg of nicotine per cigarette, regardless of the nicotine-yields obtained during standardized machine testing conditions.[19] Nicotine readily penetrates the central nervous system and has been estimated to reach the brain within 11 seconds after inhalation.[20] Nicotine binds to receptors in the brain and other organs and stimulates the release of numerous neurotransmitters including norepinephrine, acetylcholine, dopamine, and others that induce a variety of predominantly stimulatory effects on the cardiovascular, endocrine, nervous, and metabolic systems.[20, 21] Pharmacodynamic effects associated with nicotine administration include increases in the heart rate, blood pressure, and force of myocardial contraction; vasoconstriction of coronary and peripheral blood vessels; pleasure, arousal, enhanced task performance; increases in the metabolic rate; and appetite suppression.[20]

Signs and Symptoms of Tobacco Use and Dependence

The majority of chronic tobacco users develop tolerance to the effects of nicotine, and abrupt cessation precipitates symptoms of nicotine withdrawal, which include depression, insomnia, irritability/frustration/anger, anxiety, difficulty concentrating, restlessness, increased appetite and weight gain, and decreased heart rate. Typically, the physiologic nicotine withdrawal symptoms peak within 48 hours after tobacco cessation and gradually dissipate over the following 2 to 4 weeks.[20] For most individuals, withdrawal symptoms completely resolve within 1 month of quitting; however, increased appetite and weight gain can persist for 6 or more months. Multiple factors influence tobacco use behavior, including the desire to experience the pleasurable effects of nicotine, exposure to various environmental cues, and relief of nicotine withdrawal symptoms.

Complications of Smoking

According to a report issued by the U.S. Surgeon General in 2004, smoking adversely affects nearly every organ system in the body and plays a causal role in the development of numerous diseases (Table 50-1).[15] Furthermore, the report concludes that smoking cigarettes with lower machine-measured yields of tar and nicotine (e.g., "light" cigarettes) provides no clear benefit to health.[15] In nonsmokers, passive exposure to secondhand smoke, which includes the smoke emanating from burning tobacco and that exhaled by the smoker, also increases the risk of lung cancer, cardiovascular disease, and chronic respiratory conditions.[15, 22]

Drug Interactions With Tobacco Smoke

Many clinically significant interactions between tobacco smoke and medications have been identified. Tobacco smoke interacts with medications through pharmacokinetic or pharmacodynamic mechanisms that may lead to reduced therapeutic efficacy or, less commonly, increased toxicity.[23] The majority of pharmacokinetic interactions are the result of induction of hepatic cytochrome P-450 enzymes (primarily the CYP1A2 isozyme) by polycyclic aromatic hydrocarbons present in tobacco smoke.[23] Induction of the CYP1A2 enzyme can increase the hepatic metabolism of fluvoxamine (Luvox), olanzapine (Zyprexa), tacrine (Cognex), and theophylline, potentially resulting in a reduced therapeutic response or need for higher dosages in smokers; conversely, the dosages of these agents might need to be reduced in patients who quit smoking.[23] Similarly, the clearance of caffeine is significantly increased (by 56%) in smokers. Upon cessation, smokers who drink caffeinated beverages should be advised to decrease their usual caffeine intake to avoid higher levels of caffeine, which may induce symptoms similar to nicotine withdrawal.

A significant pharmacodynamic drug interaction occurs with tobacco smoke and oral contraceptives. Data indicate that cigarette smoking substantially increases the risk of serious adverse cardiovascular events (mainly stroke and myocardial infarction) in women using oral contraceptives.[24-29]

TABLE 50-1 Health Consequences of Smoking[15]

Cancer

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
  Poor asthma control
  Reduced lung function

Reproductive Effects

Reduced fertility in women
Pregnancy and pregnancy outcomes
  Preterm, 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 infected with *Helicobacter pylori*)
Surgical outcomes
  Poor wound healing
  Respiratory complications

This risk is markedly increased in women who are 35 years of age or older and smoke 15 or more cigarettes per day.[28] Accordingly, most experts consider use of oral contraceptives to be a contraindication in this population, and an alternative form of contraception should be used.[25,29] Additional interactions, with corresponding underlying mechanisms for the interactions, are depicted in Table 50-2.

During the course of routine patient care, it is important to assess tobacco use status at each visit, assess for potential drug-smoking interactions, and make appropriate adjustments to the medication regimen. For patients who are preparing to quit smoking, dosage adjustments might be necessary for some medications.

Benefits of Smoking Cessation

The 1990 Surgeon General's Report on the health benefits of smoking cessation outlines the numerous and substantial health benefits incurred when patients quit smoking.[31] Some health benefits are incurred shortly (e.g., within 2 weeks to 3 months) after quitting, and others are incurred over time (Figure 50-1). Recent findings show a clear picture of the risks associated with smoking. On average, cigarette smokers die approximately 10 years earlier than nonsmokers, and, of those who continue smoking, at least half will eventually die from a tobacco-related disease. Quitting at ages 30, 40, 50, and 60 results in a gain of 10, 9, 6, and 3 years of life, respectively.[17] Thus, although it is important to educate tobacco users that it is never too late to incur many of the benefits of quitting, there are significant benefits to quitting earlier in life.

Smoking Cessation Treatment

Treatment Goals

For most smokers, tobacco dependence is a chronic disease characterized by multiple failed attempts to quit before long-term cessation is achieved.[2] Because tobacco use is a complex, addictive behavior, helping a patient to quit and prevent relapse is best achieved by combining appropriate pharmacotherapy with behavioral counseling. For any patient who uses tobacco, the primary goal is complete, long-term abstinence from all nicotine-containing products. To increase the chances of quitting, smokers should be encouraged to adhere closely to pharmacotherapy regimens and to participate in tobacco cessation counseling throughout their quit attempt. In prescribing or dispensing pharmaceutical aids for quitting, clinicians can have a significant impact on a patient's likelihood of quitting by supplementing medication counseling with behavioral counseling, as described here.

General Treatment Approach

Most quit attempts end in relapse. According to the Centers for Disease Control and Prevention, in 2000 only 4.7% of current smokers were able to quit and maintain abstinence for 3 to 12 months.[11] Although the majority of smokers quit without assistance,[32] typically after multiple attempts, decades of research demonstrate clearly that patients who receive assistance have increased odds of quitting. In 2000, the U.S. Public Health Service published a clinical practice guideline for treating tobacco use and dependence,[2] which presents evidence-based recommendations and effective strategies for clinician-facilitated tobacco cessation counseling. Although even brief advice from a clinician is associated with increased odds of quitting,[2,33] more intensive behavioral counseling (longer and

TABLE 50-2 Drug Interactions with Tobacco Smoke[23,30]

Drug/Class	Mechanism of Interaction and Effects
Benzodiazepines (diazepam, chlordiazepoxide)	Pharmacodynamic: ↓ sedation and drowsiness, possibly caused by nicotine stimulation of CNS
β-Blockers	Pharmacodynamic: ↓ control of hypertensive and heart rate, possibly caused by nicotine-mediated sympathetic activation
Caffeine	↑ Metabolism (induction of CYP 1A2); clearance ↑ 56%; possible ↑ caffeine levels after smoking cessation
Chlorpromazine	↓ AUC (36%) and serum concentrations (24%); ↓ sedation and hypotension possible in smokers; smokers may need ↑ dosages
Clozapine	↑ Metabolism (induction of CYP 1A2); ↓ plasma concentrations (28%)
Flecainide	↑ Clearance (61%); ↓ trough serum concentrations (25%); smokers may need ↑ dosages
Fluvoxamine	↑ Metabolism (induction of CYP 1A2); ↑ clearance (24%); ↓ AUC (31%); ↓ plasma concentrations (32%); dosage modifications not routinely recommended but smokers may need ↑ dosages
Haloperidol	↑ Clearance (44%); ↓ serum concentrations (70%)
Heparin	Mechanism unknown but ↑ clearance and ↓ half-life observed; smokers may need ↑ dosages
Insulin	Possible ↓ insulin absorption secondary to peripheral vasoconstriction; possible release of endogenous substances that antagonize insulin's effects; interactions likely not clinically significant; smokers may need ↑ dosages
Mexiletine	↑ Clearance (25%; via oxidation and glucuronidation); ↓ half-life (36%)
Olanzapine	↑ Metabolism (induction of CYP 1A2); ↑ clearance (98%); ↓ serum concentrations (12%); dosage modifications not routinely recommended but smokers may need ↑ dosages
Opioids (propoxyphene, pentazocine)	Pharmacodynamic: unknown mechanism, ↓ analgesic effect; smokers may need ↑ dosages for pain relief
Oral contraceptives	Pharmacodynamic: ↑ risk of cardiovascular adverse effects (e.g., stroke and myocardial infarction) in women who smoke and use oral contraceptives; substantially ↑ risk in women at least 35 years of age who smoke at least 15 cigarettes per day
Propranolol	↑ Clearance (77%; via side-chain oxidation and glucuronidation)
Tacrine	↑ Metabolism (induction of CYP 1A2); ↓ half-life (50%); serum concentrations 3-fold lower; smokers may need ↑ dosages
Theophylline	↑ Metabolism (induction of CYP 1A2); ↑ clearance (58%-100%); ↓ half-life (63%); levels should be monitored if smoking is initiated, discontinued, or changed; ↑ clearance with passive smoking (secondhand smoke); considerably ↑ maintenance doses in smokers

Key: AUC, area under the curve; CNS, central nervous system.

Source: Adapted with permission from reference 30.

more frequent counseling sessions, or greater overall contact time) and use of pharmacotherapy (excluding patients who should not self-treat, as listed in Figure 50-2) result in increased quit rates.[2] Three particularly effective types of counseling and behavioral therapies are practical counseling (problem solving and skills training), support from a health care provider, and support from others (family, friends, and coworkers).[2]

Clinicians can have an important impact on their patients' likelihood of achieving cessation. In a meta-analysis of 29 studies,[2] 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 (at 5 or more months postcessation), respectively, compared with patients who do not receive an intervention from a clinician. Self-help materials are only slightly better than no clinician intervention. Because the use of pharmacotherapy approximately doubles a patient's chances of quitting,[2,34,35] cessation interventions should combine pharmacotherapy with behavioral counseling, when feasible and not contraindicated.[2] Figure 50-2 outlines a self-treatment approach for smoking cessation.

Nonpharmacologic Therapy

Helping Patients Quit: Five Key Counseling Components (the "5 A's")

Five key components of comprehensive counseling for tobacco cessation are (1) asking patients whether they use tobacco; (2) advising tobacco users to quit; (3) assessing patients' readiness to quit; (4) assisting patients with quitting; and (5) arranging follow-up care. These steps are referred to as the "5 A's."[2]

20 minutes after quitting: Blood pressure drops to a level close to that before the last cigarette. Temperature of hands and feet increases to normal.

8 hours after quitting: Blood levels of carbon monoxide drop to normal.

24 hours after quitting: Chance of having a heart attack decreases.

2 weeks to 3 months after quitting: Circulation improves, and lung function improves by up to 30%.

1 to 9 months after quitting: Coughing, sinus congestion, fatigue, and shortness of breath decrease, and cilia regain normal function in the lungs, increasing the ability to handle mucus, clear the lungs, and reduce infection.

1 year after quitting: Excessive risk of coronary heart disease is half that of a smoker's.

5 years after quitting: Risk of stroke is reduced to that of a nonsmoker 5 to 15 years after quitting.

10 years after quitting: Lung cancer death rate is about half that of continuing smokers. Risk of cancer of the mouth, throat, esophagus, bladder, kidney, and pancreas also are lower than that of continuing smokers.

15 years after quitting: Risk of coronary heart disease is similar to that of a nonsmoker.

FIGURE 50-1 Health benefits of smoking cessation.[31]

Ask A key first step is asking about tobacco use. Because tobacco use is the primary known preventable cause of mortality in the United States, and because smoking interacts with multiple medications, screening for tobacco use is crucial and should be a routine component of care provided by all clinicians. The following question can be used to identify all types of tobacco use, even for infrequent users: "Do you ever smoke or use any type of tobacco?" Tobacco use status should be considered a vital sign, and collected routinely along with blood pressure, pulse, weight, temperature, and respiratory rate.[2] At a minimum, tobacco use status (current, former, never a user) and level of use (e.g., number of cigarettes smoked per day) should be documented in the medical record and reassessed periodically.

Advise All tobacco users should be advised to quit. The advice should be clear and compelling, yet delivered with sensitivity and a tone of voice that communicates concern for the patient and a willingness to assist the patient with quitting when he or she is ready. When possible, clinicians should personalize the messages by linking their advice to the patient's health status, current medication regimen, personal reasons for wanting to quit, and/or the impact of tobacco on others. For example, "Ms. Bettis, I see that you now are on two different inhalers for your emphysema. As your clinician, I need to tell you that quitting smoking is the single most important treatment for your emphysema. I strongly encourage you to quit, and I would like to help you."

Assess Because many patients will not be ready to quit in the near future, it is important for clinicians to gauge patients' readiness to quit before recommending a treatment regimen. Patients should be categorized as (1) not ready to quit in the next month; (2) ready to quit in the next month; (3) a recent quitter, having quit in the past 6 months; or (4) a former user, having quit more than 6 months ago.[2] This classification defines the clinician's next course of action, which is to provide counseling that is tailored to the patient's readiness to quit. As an example for a current smoker: "Mr. Ward, have you given any thought to quitting? Is this something that you might consider doing in the next month?" Counseling a patient who is ready to quit in the next month should be very different from counseling a patient who is not considering quitting in the near future.

Assist Important elements of the "assist" component of treatment include helping patients to make the decision and commitment to quit and setting an actual quit date. Clinicians should be sympathetic to the fact that quitting is a difficult process. As such, the goal is to help maximize patients' chances of success by designing an individualized treatment plan.

Except in the presence of special circumstances, all patients attempting to quit should be encouraged to use pharmacotherapy (described below) combined with some form of nonpharmacologic intervention (described below), as this combination will yield higher quit rates than either approach alone.[2,34] Nonpharmacologic methods, which focus on promoting behavior change, include tapering the number of cigarettes (e.g., setting a quit date and applying a scheduled, gradual reduction strategy), reading self-help materials, and entering a formal cessation program (face-to-face counseling, telephone counseling, or group program). Acupuncture and hypnosis also are common nonpharmacologic aids; however, limited data are available to support their effectiveness in promoting quitting.[2]

Arrange Because a patient's ability to quit increases substantially when multiple counseling interactions are provided, arranging follow-up counseling is an important, yet typically neglected, element of treatment for tobacco dependence. Follow-up contact should occur soon after the quit date, preferably during the first week. This does not have to be done in person and could be performed by telephone or e-mail. A second follow-up contact is recommended within the first month after quitting.[2] Periodically, additional follow-up contacts should occur, to monitor patient progress (including adherence with pharmacotherapy) and to provide ongoing support. Quit rates at 5 or more months postcessation are associated with the total number of contacts: 12.4% for 0 to 1 contact, 16.3% for 2 to 3 contacts, 20.9% for 4 to 8 contacts, and 24.7% for more than 8 contacts.[2]

Counseling Interventions for Quitting

When counseling a patient, the goal is to facilitate forward progress in the process of change, assisting patients to develop "readiness" for permanent cessation. It is important that clinicians view quitting as a process that might take months or even years to achieve, rather than a "now or never" event.

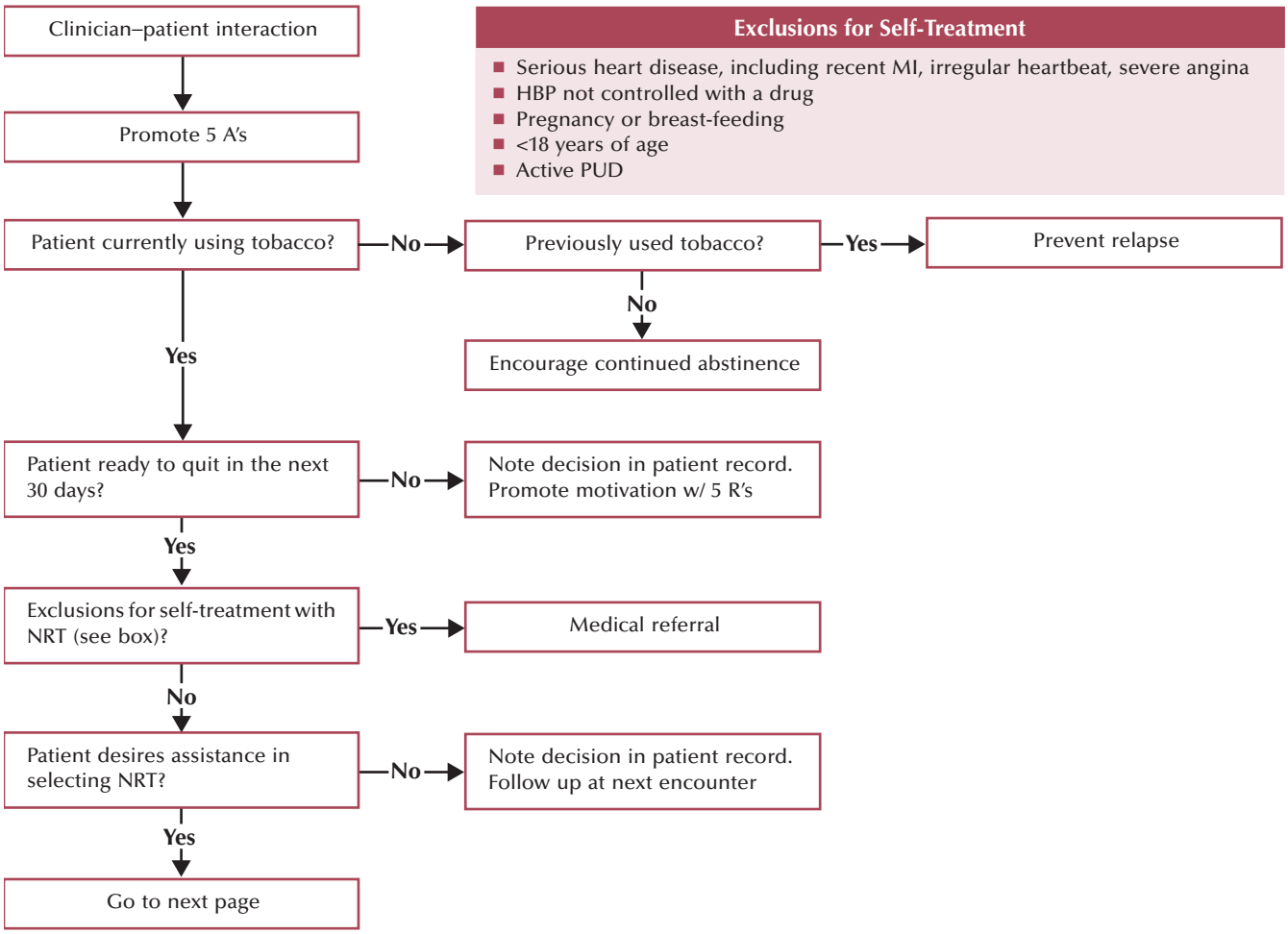

FIGURE 50-2 Self-care of tobacco use and dependence. Key: 5 A's, ask, advise, assess, assist, arrange; 5 R's, relevance, risks, rewards, roadblocks, repetition; HBP, high blood pressure; MI, myocardial infarction; NRT, nicotine replacement therapy; OTC, over-the-counter; PUD, peptic ulcer disease; Rx, prescription; TMJ, temporomandibular joint.

Counseling Patients Who Are Not Ready to Quit When counseling patients who are not ready to quit, an important first step is to motivate the patient to start thinking about quitting and to consider making the difficult decision to quit sometime in the foreseeable future. Sometimes patients who are not ready truly do not understand the need to quit. In general, most smokers will recognize the need to quit but are not yet ready to make the commitment to quit. Many patients will have tried to quit multiple times and relapsed, and thus might feel too discouraged to try again.

Strategies for working with patients who are not ready to quit include increasing patient awareness of the available treatment options, having patients identify their reasons for smoking and for wanting to quit, and identifying barriers to quitting. Clinicians can motivate patients to begin thinking about quitting by raising awareness of specific drug interactions between medications and smoking (Table 50-2), and how tobacco use can induce or exacerbate medical conditions (e.g., COPD and coronary heart disease). While it may be useful to provide patients with information about the medications available for quitting, it is not appropriate to recommend a treatment regimen until a patient is ready to quit in the near future (e.g., within the next month). A treatment goal at this stage should be to promote motivation to quit, and this can be accomplished by providing tailored, motivational messages, applying what is referred to as the "5 R's."[2]

Relevance Encourage patients to think about why quitting is important to them. Because information has a greater impact if it takes on a personal meaning, counseling should be framed to relate to the patient's risk for disease or exacerbation of disease, other health concerns, family or social situation (e.g., having children with asthma), age, and other patient factors such as prior experience with quitting.

Risks Ask patients to identify negative health consequences of smoking, such as acute risks (e.g., shortness of breath, asthma exacerbations, pregnancy complications, infertility), long-term risks (e.g., cancer, cardiac and pulmonary disease), and environmental risks (e.g., effects of secondhand smoke on others, including children and pets, role modeling unhealthy behaviors around children and adolescents).

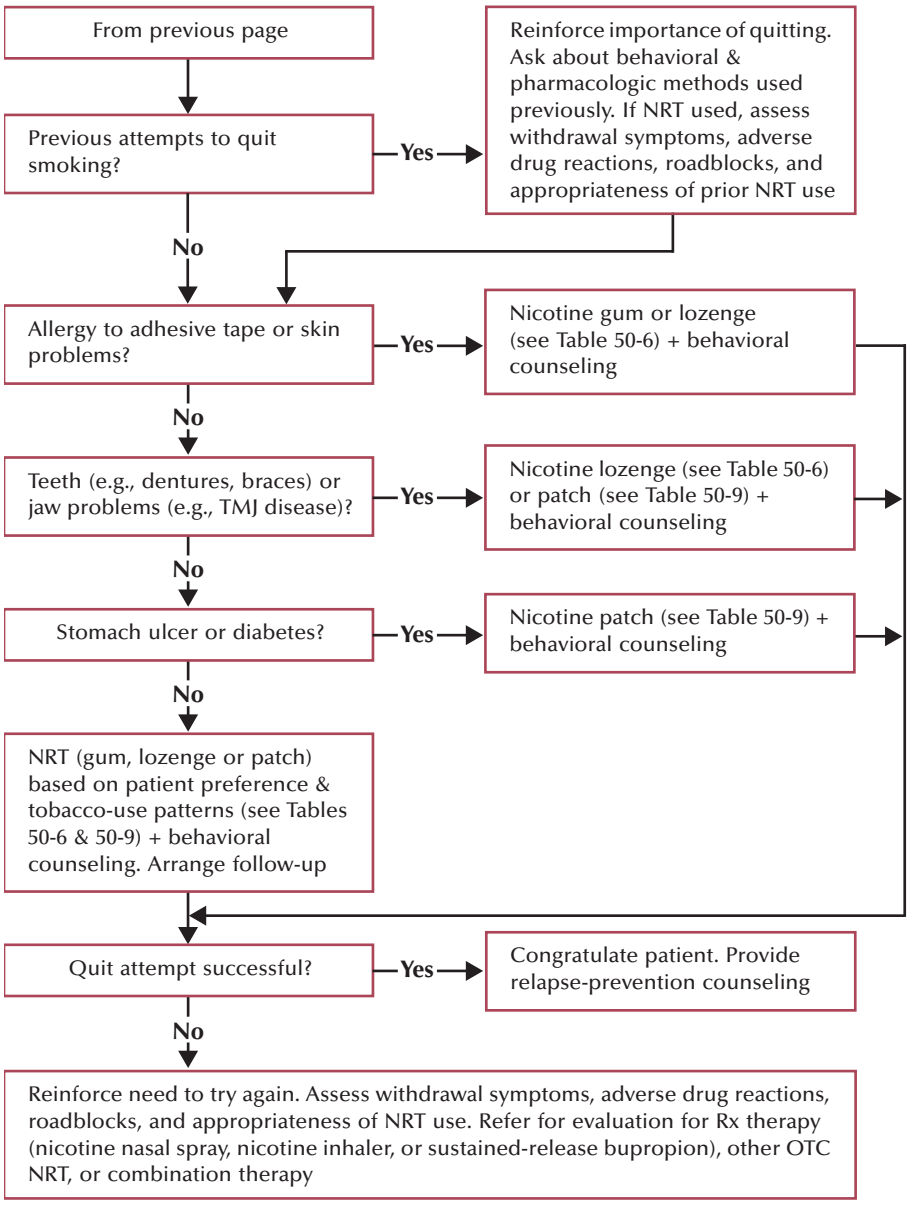

FIGURE 50-2 (continued)

Rewards Ask patients to identify specific benefits of quitting, such as improved health, enhanced physical performance, acuity of taste and smell, reduced expenditures for tobacco, less time wasted or work missed, reduced health risks to others (fetus, children, housemates), and reduced aging of the skin.

Roadblocks Help patients identify significant barriers to quitting, and assist in developing coping skills to address or circumvent each barrier. Common barriers include nicotine withdrawal symptoms, fear of failure, a need for social support while quitting, depression, concern about weight gain, and a sense of deprivation or loss.

Repetition Continue to work with patients who are either not motivated to quit or have been unsuccessful in quitting. Discussing circumstances in which smoking occurred will help identify triggers for relapse and should be viewed as part of the learning process. Repeat interventions whenever possible.

Counseling Patients Who Are Ready to Quit For patients who are ready to quit in the next month, clinicians can either provide comprehensive counseling or refer patients to local cessation programs or a toll-free telephone quitline.

The goal for patients who are ready to quit is to achieve cessation by providing an individualized treatment plan, addressing the key issues listed in Table 50-3. The first step is to discuss the patient's tobacco use history, inquiring about levels of smoking, number of years smoked, methods used previously for quitting, and reasons for previous failed quit attempts. Clinicians should understand fully the patient's preferences for the different pharmacotherapies

TABLE 50-3 Key Topics for Individualized Smoking Cessation Plans

Topic	Description
Assess tobacco use history	■ Current use: – Type(s) of tobacco used – Brand and amount currently used ■ Past use: – Duration of smoking – Recent changes in levels of use ■ Past quit attempts: – Number of attempts, date of most recent attempt, duration of abstinence – Previous methods: What did or didn't work? Why or why not? – Prior experience with cessation pharmacotherapy: agent used, adequacy of dose, adherence, duration of treatment – Reasons for relapse
Discuss key issues for the upcoming or current quit attempt	■ Reasons/motivation for wanting to quit (or stay quit) ■ Confidence in ability to quit (or stay quit) ■ Triggers for smoking ■ Routines and situations associated with smoking ■ Stress-related smoking ■ Social support for quitting ■ Concerns about weight gain ■ Concerns about withdrawal symptoms
Facilitate the quitting process	■ Discuss methods for quitting: pros and cons of the different methods ■ Set a quit date: more than 2 days but less than 2 weeks away ■ Discuss coping strategies ■ Discuss withdrawal symptoms ■ Discuss concept of slip (occasional smoking) versus full relapse ■ Provide medication counseling: adherence and proper use ■ Offer to assist throughout the quit attempt
Arrange and provide follow-up counseling	■ Monitor the patient's progress throughout the quit attempt ■ Evaluate the current quit attempt – Status of attempt – Slips (occasional smoking) and relapses – Medication use: • Adherence with regimen • Plans for discontinuation – Address temptations and triggers; discuss relapse prevention strategies – Provide encouragement throughout the quit attempt ■ Follow-up contacts: First follow-up contact should occur during first week after quitting, a second follow-up contact within the first month, and additional contacts scheduled as needed. Can occur face-to-face, by telephone, or by e-mail

Source: Adapted with permission from reference 30.

for quitting, and work with patients in selecting the quitting methods (e.g., medications, behavioral counseling programs). While it is important to recognize that pharmaceutical aids might not be desirable or affordable for all patients, clinicians should educate patients that medications, when taken correctly, can substantially increase the likelihood of quitting.

In general, patients should be encouraged to select a quit date that is more than 2 days but less than 2 weeks away. This time frame provides patients with ample time to prepare themselves and their environment prior to the actual quit date. This includes removing all tobacco products and ashtrays from the home, car, and workplace. Patients should be advised to discuss their desire to quit with their family, friends, and coworkers and request their support and assistance. It is helpful to have patients think about when and why they smoke; this information is useful for anticipating situations that might trigger a desire to smoke and contribute to relapse. Additional counseling strategies to address with patients during a quit attempt are listed in Table 50-4. Patients should be counseled on proper medication use (including administration), side effects, and adherence, and it is crucial to emphasize the importance of receiving behavioral counseling throughout the quit attempt.

When the clinician's or patient's time is limited, patients who are ready to quit can be referred to local tobacco cessation programs or a toll-free quitline. With the recent introduction of a national toll-free quitline number (1-800-QUIT-NOW), all Americans can receive tobacco cessation counseling at no cost. Counseling provided by telephone

TABLE 50-4 Cognitive and Behavioral Strategies for Smoking Cessation[30]

Cognitive strategies focus on *retraining the way a patient thinks*. Often, patients mentally deliberate on the fact that they are thinking about a cigarette, and this leads to relapse. Patients must recognize that thinking about a cigarette does not mean they need to have one.	
Review commitment to quit, focus on the downside of tobacco	Remind oneself that cravings and temptations are temporary and will pass. Announce, either silently or aloud, "I want to be a nonsmoker, and the temptation will pass."
Distractive thinking	Practice deliberate, immediate refocusing of thinking when cued by thoughts about tobacco use.
Positive self-talks, "pep-talks"	Say "I can do this" and remember previous difficult situations in which tobacco use was avoided with success.
Relaxation through imagery	Mentally focus on a scene, place, or situation that is peaceful, relaxing, and positive.
Mental rehearsal, visualization	Prepare for situations that might arise by envisioning how best to handle them. For example, envision what would happen if offered a cigarette by a friend, mentally craft and rehearse a response, and perhaps even practice it by saying it aloud.
Behavioral strategies involve *specific actions to reduce risk for relapse*. For maximal effectiveness, these should be considered prior to quitting, after determining patient-specific triggers for smoking. Below are some behavioral strategies for responding to several common cues or triggers for relapse.	
Stress	Anticipate upcoming challenges at work, at school, or in personal life. Develop a substitute plan for smoking during times of stress (e.g., deep breathing, take a break/leave the situation, call supportive friend or family member, self-massage, use nicotine replacement therapy).
Alcohol	Drinking alcohol can lead to relapse. Consider limiting/abstaining from alcohol during the early stages of quitting.
Other smokers	Quitting is more difficult when other smokers are around. This is especially difficult if there is another smoker in the household. Limit prolonged contact with individuals who are smoking during the early stages of quitting. Ask coworkers, friends and housemates not to smoke in your presence.
Oral gratification needs	Have nontobacco oral substitutes (e.g., gum, sugarless candy, straws, toothpicks, lip balm, toothbrush, nicotine replacement therapy, bottled water) readily available.
Automatic smoking routines	Anticipate routines that are associated with tobacco use and develop an alternative plan. Examples: ■ *Smoking with morning coffee:* change morning routine, drink tea instead of coffee, take shower before drinking coffee, take a brisk walk shortly after awakening. ■ *Smoking while driving:* remove all tobacco from car, have car interior detailed, listen to a book on tape or talk radio, use oral substitute. ■ *Smoking while on the phone:* stand while talking, limit call duration, change phone location, keep hands occupied by doodling or sketching. ■ *Smoking after meals:* get up and immediately do dishes or take a brisk walk after eating, call supportive friend.
Postcessation weight gain	The majority of tobacco users gain weight after quitting. Most quitters will gain less than 10 lb, but there is a broad range of weight gain reported, with up to 10% of quitters gaining as much as 30 lb.[2] In general, attempting to modify multiple behaviors at one time is not recommended. If weight gain is a barrier to quitting, engage in regular physical activity and adhere to a healthy diet (as opposed to strict dieting). Carefully plan and prepare meals; increase fruit, vegetable, and water intake to create a feeling of fullness; and chew sugarless gum or eat sugarless candy. Consider use of pharmacotherapy that has been shown to delay weight gain (e.g., nicotine gum, bupropion).
Cravings for tobacco	Cravings for tobacco are temporary and usually pass within 5-10 minutes. Handle cravings through distractive thinking, taking a break, changing activities/tasks, taking deep breaths, or performing self-massage.

Source: Adapted with permission from reference 30.

quitlines has been shown to be effective in promoting quitting among users,[36,37] and even the busiest of clinicians can serve an important role by simply identifying tobacco users and referring them to the quitlines for more comprehensive counseling. All patients, whether counseled face-to-face by a clinician or referred to external sources of counseling, should be commended for making the important and difficult decision to quit.

TABLE 50-5 Tobacco Cessation Withdrawal Symptoms Management

Symptoms	Cause	Duration	Relief
Chest tightness	Tightness is likely caused by tension created by the body's need for nicotine or may be caused by sore muscles from coughing.	A few days	Use relaxation techniques Try deep breathing Use of NRT might help
Constipation, stomach pain, gas	Intestinal movement decreases.	Up to 2 weeks	Drink plenty of fluids Add fruits, vegetables, and whole grain cereals to diet
Cough, dry throat, nasal drip	The body is getting rid of mucus, which has blocked airways and restricted breathing.	A few days	Drink plenty of fluids
Craving for a cigarette	Nicotine is a strongly addictive drug, and abstinence causes cravings.	Frequent for up to 3 days; can happen for months or years	Avoid additional stress during first few weeks Wait out the urge (which lasts only a few minutes) Distract yourself Exercise (take walks)
Difficulty concentrating	The body needs time to adjust to not having constant stimulation from nicotine.	A few weeks	Plan workload accordingly Avoid additional stress during first few weeks
Dizziness	The body is getting extra oxygen.	1-2 days	Use extra caution Change positions slowly
Fatigue	Nicotine is a stimulant.	2-4 weeks	Take naps Do not push yourself Use of NRT might help
Hunger	Cravings for a cigarette can be confused with hunger. Sensation may result from oral cravings, or the desire for something in the mouth.	Up to several weeks	Drink water or low-calorie liquids Be prepared with low-calorie snacks
Insomnia	Nicotine affects brain wave function and influences sleep patterns. Coughing and dreams about smoking are common.	1 week	Avoid caffeine after 12 PM Use relaxation techniques
Irritability	The body's craving for nicotine can produce irritability.	2-4 weeks	Take walks Try hot baths Use relaxation techniques

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Counseling Patients Who Recently Quit Patients who recently quit will face frequent, difficult challenges in countering withdrawal symptoms (Table 50-5) and cravings or temptations to use tobacco. It is important to help them identify situations that might trigger relapse and suggest appropriate coping strategies. Because smoking is a habitual behavior, patients should be advised to alter their daily routines. This helps to disassociate the behaviors from the tobacco.

Often, patients expect that they can change their behavior over a short period of time (weeks to months), yet experts believe patients must remain vigilant for at least 6 months before a new behavior is adopted or an old behavior is extinguished.[38] If a patient indicates he or she has quit smoking, it is important to ask *for how long* he or she has been abstinent. Many persons who quit using tobacco will experience cravings years and even decades after quitting. Thus, *relapse prevention* counseling should be part of every follow-up contact with patients who have recently quit smoking. Patients who slip and smoke a cigarette (or use any form of tobacco) or experience a full relapse back to habitual smoking should be encouraged to think through the scenario in which smoking first recurred and identify the trigger for relapse. Identifying triggers will provide valuable information for future quit attempts.

Counseling Patients Who Are Former Smokers Although patients who have been smoke-free for 6 or more months can be considered former smokers, many remain vulnerable to relapse. The strategies to be applied for former tobacco users are similar, but typically less intensive, than

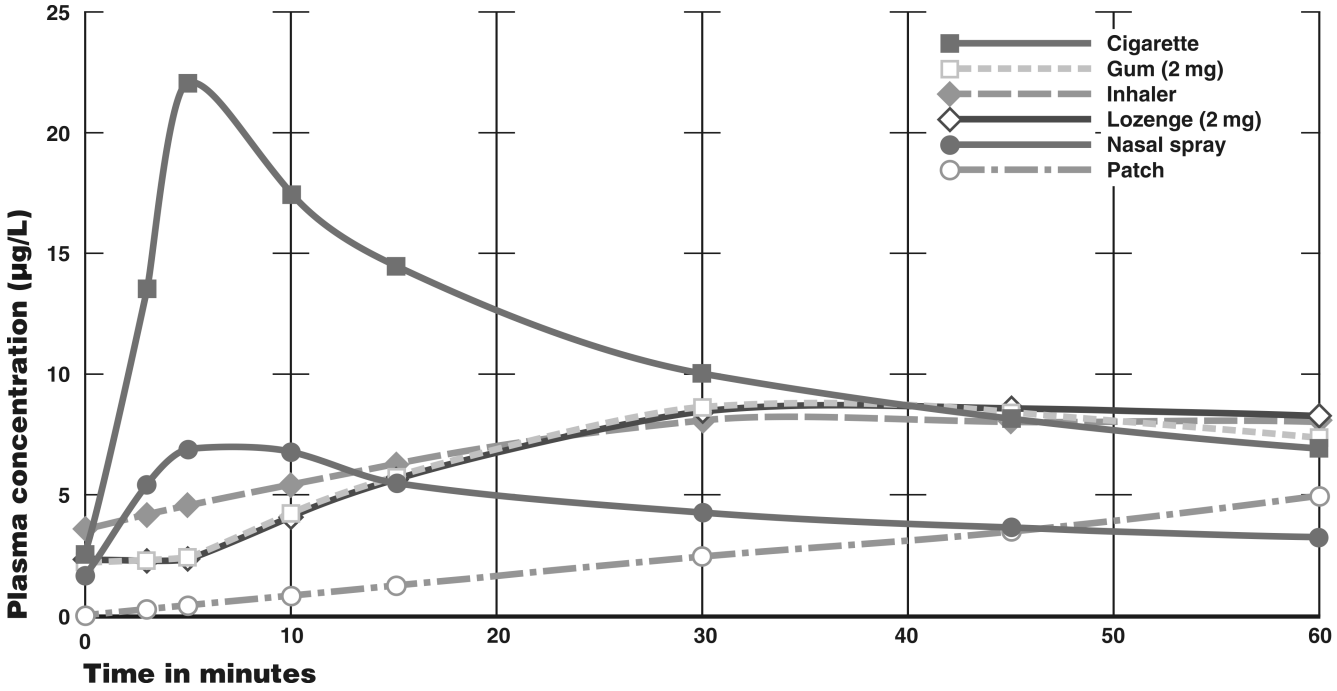

FIGURE 50-3 Plasma nicotine concentrations for various nicotine delivery systems. (Adapted with permission from reference 30. Copyright © 1999-2006 The Regents of the University of California, University of Southern California, and Western University of Health Sciences. All rights reserved.)

those to be applied for recent quitters. The goal for these patients is to remain tobacco-free for life. Clinicians should evaluate their patient's quit attempt and coping strategies—has the patient had any strong temptations to use tobacco, or any occasional use of tobacco products (even a puff)? Also, it is important to ensure that patients are appropriately terminating or tapering off of pharmacotherapy products. Patients who have been smoke-free should be congratulated for their enormous success.

Pharmacologic Therapy

Although there are select situations in which pharmacotherapy should be used with caution or only while under the supervision of a primary care provider (see Safety Considerations), the vast majority of quitters should be advised to incorporate pharmacotherapy as a component of their treatment plan. Currently, there are six Food and Drug Administration (FDA)-approved, first-line[2] agents for smoking cessation, including five formulations of NRT and sustained-release bupropion. Three of the NRT formulations (gum, lozenge, and transdermal patch) are available without a prescription, whereas the nicotine inhaler, nicotine nasal spray, and bupropion require a prescription. Although nortriptyline and clonidine are considered as second-line agents and significantly increase long-term cessation rates compared with placebo, these medications require a prescription and currently do not have an FDA-approved indication for smoking cessation.

Nicotine Replacement Therapy

When nicotine gum and transdermal patches were originally approved, both were available only with a prescription. In 1996, these agents were switched to nonprescription status, enabling consumers to self-treat their tobacco dependence. The most recent NRT formulation to receive an FDA approval for smoking cessation is the nicotine lozenge, which was released directly to the nonprescription market in late 2002.

Mechanism of Action/Pharmacokinetics The main mechanism of action of NRT is thought to be stimulation of the nicotine receptors in the brain's ventral tegmental area, which results in release of dopamine into the nucleus accumbens. One rationale for using NRT during a quit attempt is that it provides smokers with a nontobacco source of nicotine, which lessens the severity of the symptoms of nicotine withdrawal. This assists quitters by allowing them to focus their efforts on breaking the behavioral habit of smoking. Because the onset of action for nicotine replacement therapy is not as rapid as that of nicotine obtained through smoking, patients who use NRT become less habituated to the nearly immediate, reinforcing effects of inhaled nicotine.[2]

Nicotine is well absorbed (Figure 50-3) from many sites, including the lung, skin, and nasal and buccal (oral) mucosa. Nicotine absorption is pH dependent, and lower systemic concentrations are achieved under acidic conditions. Nicotine also is well absorbed from the gastrointestinal tract (small intestine) but undergoes extensive first-pass hepatic metabolism resulting in negligible systemic levels of nicotine.[20]

The major difference between the various NRT formulations is the site and rate of nicotine absorption (Figure 50-3). All of the NRT formulations deliver nicotine less rapidly and achieve lower serum nicotine levels than do

TABLE 50-6 Dosages for Nonprescription Nicotine Polacrilex Gum and Lozenge

	Gum	Lozenge
Product strength	Nicorette: 2 mg, 4 mg; regular, mint, fresh mint, orange Generic: 2 mg, 4 mg; regular, mint, orange	Commit: 2 mg, 4 mg; mint
Dose	≥25 cigarettes/day: 4 mg <25 cigarettes/day: 2 mg Weeks 1-6: 1 piece q1-2h Weeks 7-9: 1 piece q2-4h Weeks 10-12: 1 piece q4-8h	1st cigarette ≤30 minutes after waking: 4 mg 1st cigarette >30 minutes after waking: 2 mg Weeks 1-6: 1 lozenge q1-2h Weeks 7-9: 1 lozenge q2-4h Weeks 10-12: 1 lozenge q4-8h

cigarettes. Peak serum concentrations[19,39] are achieved most rapidly with the nasal spray (10 to 15 minutes) followed by the gum, lozenge, and inhaler (15 to 30 minutes), and then the transdermal patch (4 to 9 hours). In contrast, significantly higher peak nicotine levels are attained within 10 minutes of smoking a cigarette.

General Safety Considerations

Concomitant Use of Tobacco Patients should be instructed not to smoke cigarettes or use other forms of tobacco (e.g., snuff, chewing tobacco, cigars, pipes) while using NRT. Use of tobacco in combination with NRT may result in serum nicotine concentrations that are higher than those achieved from tobacco products alone, increasing the likelihood of nicotine-related adverse effects, including nausea, vomiting, hypersalivation, perspiration, abdominal pain, dizziness, weakness, and palpitations.

Patients With Severe Cardiovascular Disease NRT should be used with caution in patients with serious underlying cardiovascular disease, including those who have had a recent myocardial infarction (i.e., in the preceding 2 weeks), those with serious arrhythmias, and those with serious or worsening angina pectoris.[2] Nicotine may increase the myocardial workload by increasing the heart rate and blood pressure and may constrict coronary arteries, leading to cardiac ischemia.[40,41] While most experts believe the risks of NRT in patients with cardiovascular disease are small relative to the risks of continued smoking,[41,42] patients with serious underlying cardiovascular disease (as previously delineated) are advised to use NRT only while under the supervision of a primary care provider.

Use in Pregnant/Nursing Women and Adolescents Nicotine is classified by the FDA as Pregnancy Category D, meaning there is evidence of risk to the human fetus.[43] Although nicotine is excreted in breast milk, the nicotine levels produced by NRT are quite low and likely not hazardous to infants.[44] Despite potential risks, the use of NRT during pregnancy is probably safer than smoking,[44,45] and NRT might be warranted in selected patients who are unable to quit using nonpharmacologic methods alone, or in situations in which the increased likelihood of quitting outweighs the risks associated with NRT use.[2] Furthermore, the safety and efficacy of NRT have not been established in adolescent smokers, and none of the NRT products are currently indicated for use in this population.[2] Accordingly, behavioral counseling would be the preferred treatment method for smokers under 18 years of age and women who are pregnant or nursing, unless under the supervision of a primary care provider.

Patients Taking Prescription Medicine for Depression or Asthma The manufacturers of nicotine gum, lozenge, and patch recommend that patients taking a prescription medicine for depression or asthma speak with their doctor or pharmacist before using NRT. As indicated in Table 50-2, fluvoxamine and theophylline, both now used infrequently, are the only two agents for depression or asthma that have a known clinically significant interaction with smoking.

Nicotine Polacrilex Gum Nicotine polacrilex gum is a resin complex of nicotine and polacrilin in a sugar-free (0.8 cal/piece) chewing gum base. The product is available as 2 and 4 mg strengths, in regular (tobaccolike), mint, and orange flavors (Table 50-6). Recently, a second "fresh mint" formulation of the nicotine gum became available. This product differs from the previous formulations in that it is softer to chew and has a longer-lasting mint taste. All gum formulations contain buffering agents (sodium carbonate and sodium bicarbonate) to increase salivary pH, thereby enhancing absorption of nicotine across the buccal mucosa. When the 2 mg strength gum is used properly, approximately 1 mg of nicotine is absorbed from each dose.[19] Peak serum concentrations of nicotine are achieved approximately 30 minutes after chewing a single piece of gum and then slowly decline over 2 to 3 hours.[39]

Dosage Individuals who smoke fewer than 25 cigarettes per day should initiate therapy with the 2 mg strength, and heavier smokers should initiate with the 4 mg strength. Table 50-6 provides the manufacturer's recommended dosing schedule. During the initial 6 weeks of therapy, patients should use one piece of gum every 1 to 2 hours while awake. In general, this amounts to at least nine pieces of gum daily. Table 50-7 provides specific instructions for proper use of the nicotine gum. The "chew and park" method described in this table allows for the slow, consistent release of nicotine from the polacrilin

TABLE 50-7 Usage Guidelines for Nicotine Polacrilex Gum

- Do not smoke cigarettes or use other forms of tobacco (e.g., snuff, chewing tobacco, cigars, pipes) while on nicotine gum therapy.
- Note that nicotine gum is a nicotine delivery system, not a chewing gum.
- Proper administration technique is necessary when using this product. Nicotine from the gum is released using the "chew and park" method:
  - Chew each piece of gum *very slowly* several times.
  - Stop chewing at first sign of peppery, minty, or citrus taste or after experiencing a slight tingling sensation in the mouth. This usually occurs after about 15 chews, but varies.
  - "Park" the gum between the cheek and gum to allow absorption of nicotine across the lining of the mouth.
  - When the taste or tingling dissipates (generally after 1-2 minutes), slowly resume chewing.
  - When the taste or tingle returns, stop chewing and park the gum in a different place in the mouth. Parking the gum in different areas of the mouth will decrease the incidence of mouth irritation.
  - The chew/park steps should be repeated until most of the nicotine is gone, which is when the taste or tingle does not return after continued chewing. On average, each piece of gum lasts 30 minutes.
- To minimize withdrawal symptoms, use the nicotine gum on a scheduled basis rather than as needed.
- Follow the dosage regimen carefully; reduce the dosage at the recommended intervals and stop using the product after 12 weeks of treatment.
- Do not chew more than 24 pieces per day.
- Do not eat or drink 15 minutes before or while using the nicotine gum.
- If acidic drinks (e.g., fruit juices, cola drinks, coffee, wine) or foods (e.g., citrus fruits, tomatoes, vinegar-containing condiments) have been consumed, rinse the mouth with water before placing the gum in the mouth.
- Note that chewing the gum too quickly will result in an unpleasant taste caused by too much nicotine in the saliva and, if the nicotine is swallowed, may cause effects similar to those produced by excess smoking (e.g., nausea, throat irritation, lightheadedness, hiccups).
- Carry or have at least one full sleeve of nicotine polacrilex gum (12 pieces per sleeve) readily available at all times. Keep the nicotine gum in the same place you previously kept your cigarettes (e.g., shirt pocket, purse, or desk).
- Keep this product, including used pieces, out of the reach of children or pets.

resin. Patients can use additional pieces of gum (up to the daily maximum of 24 pieces per day) if cravings occur between the scheduled doses. In general, heavier smokers will need more pieces to alleviate their cravings.

It is important to emphasize that patients often do not use enough of the gum to derive its full benefit. Commonly, patients chew too few pieces per day or shorten the duration of treatment. For this reason, it is preferable to recommend a fixed schedule of administration, tapering over 1 to 3 months rather than using the gum "as needed" to control cravings.[2]

Safety Considerations The most common side effects associated with use of the nicotine gum include unpleasant taste, mouth irritation, jaw muscle soreness/fatigue, hypersalivation, hiccups, and dyspepsia. Many of these side effects can be minimized or prevented by using proper chewing technique. The nicotine polacrilin resin is more viscous than ordinary chewing gum and more likely to adhere to fillings, bridges, dentures, crowns, and braces. If excessive sticking or damage to dental work occurs, the patient should stop using the nicotine gum and consult a dentist. Patients should be warned that chewing the gum too rapidly may result in excessive release of nicotine, leading to lightheadedness, nausea, vomiting, irritation of the throat and mouth, hiccups, and indigestion.

The effectiveness of nicotine gum may be reduced by acidic beverages such as coffee, juices, wine, or soft drinks. These beverages transiently reduce the salivary pH, resulting in decreased absorption of nicotine across the buccal mucosa. Patients should be advised not to eat or drink for 15 minutes before or while using the nicotine gum.

Patients with severe cardiac disease, women who are pregnant or nursing, and adolescents under the age of 18 should use the nicotine gum only while under the supervision of a medical provider. Patients with active temporomandibular joint disease should not use the nicotine gum because the highly viscous consistency of the formulation and the need for frequent chewing may exacerbate this condition. Additionally, the manufacturer recommends that patients with stomach ulcers or diabetes contact their medical provider before use as these conditions are more serious and might require further monitoring.

Nicotine Polacrilex Lozenge The nicotine polacrilex lozenge is a resin complex of nicotine and polacrilin in a sugar-free (4 cal/lozenge), lightly mint-flavored lozenge (Table 50-6). The lozenges are available as 2 and 4 mg dime-sized tablets intended for use similar to other medicinal lozenges or troches (i.e., sucked and rotated within the mouth until it dissolves). The pharmacokinetics of the nicotine lozenge and gum formulations are comparable, but a nicotine lozenge delivers approximately 25% more nicotine than does an equivalent dose of nicotine gum because of complete dissolution of the dosage form.[46] Like nicotine gum, the lozenge also contains buffering agents (sodium carbonate and potassium bicarbonate) to increase salivary pH, enhancing the buccal absorption of nicotine.

Dosage Unlike other forms of NRT, which are dosed based on the number of cigarettes smoked per day, the recommended dosage of the nicotine lozenge is based on the "time to first cigarette" of the day. Some studies suggest that the best indicator of nicotine dependence is having a strong desire or need to smoke soon after waking.[46] Thus, patients who smoke their first cigarette of the day within 30 minutes of waking are likely to be more highly dependent on nicotine and require higher dosages than those who delay smoking for more than 30 minutes after waking (Table 50-6).

During the initial 6 weeks of therapy, patients should use 1 lozenge every 1 to 2 hours while awake. In general,

TABLE 50-8 Usage Guidelines for Nicotine Polacrilex Lozenge

- Do not smoke cigarettes or use other forms of tobacco (e.g., snuff, chewing tobacco, cigars, pipes) while using the nicotine lozenge.
- Proper administration technique is necessary when using the nicotine lozenge:
  - Place the lozenge in the mouth and allow it to dissolve slowly (20-30 minutes). As the nicotine is released from the lozenge, you may experience a warm, tingling sensation.
  - To reduce the risk of side effects (nausea, hiccups, heartburn), the lozenge should *not* be chewed or swallowed.
  - Occasionally rotate the lozenge to different areas of the mouth to decrease mouth irritation.
- To minimize withdrawal symptoms, use the nicotine lozenge on a scheduled, rather than an as-needed basis.
- Follow the dosage regimen carefully; reduce the dosage at the recommended intervals and stop using the product after 12 weeks of treatment.
- Do not use more than 5 lozenges in 6 hours, or more than 20 lozenges per day.
- Do not eat or drink 15 minutes before or while using the nicotine lozenge.
- If acidic drinks (e.g., fruit juices, cola drinks, coffee, wine) or foods (e.g., citrus fruits, tomatoes, vinegar-containing condiments) have been consumed, rinse the mouth with water before using the lozenge.
- Patients who use more than 1 lozenge at a time, continuously use 1 lozenge after another, or chew or swallow the lozenge are more likely to experience heartburn or indigestion.
- Carry or have at least one full sleeve of nicotine polacrilex lozenges (12 pieces per sleeve) readily available at all times. Keep the nicotine lozenge in the same place you previously kept your cigarettes (e.g., shirt pocket, purse, or desk).
- Keep this product out of the reach of children or pets.

this amounts to at least 9 lozenges daily. Table 50-8 provides further instructions for proper use of the nicotine lozenge. Patients can use additional lozenges (up to 5 lozenges in 6 hours or a maximum of 20 lozenges per day) if cravings occur between the scheduled doses.

Safety Considerations Side effects associated with the nicotine lozenge include mouth irritation, nausea, hiccups, cough, heartburn, headache, flatulence, and insomnia. Patients who use more than one lozenge at a time, continuously use one lozenge after another, or chew or swallow the lozenge are more likely to experience heartburn or indigestion.

The effectiveness of the nicotine lozenge may be reduced by acidic beverages such as coffee, juices, wine, or soft drinks. These beverages may transiently reduce the salivary pH, resulting in decreased absorption of nicotine across the buccal mucosa. Patients should be advised not to eat or drink for 15 minutes before or while using the nicotine lozenge.

Patients with severe cardiac disease, women who are pregnant or nursing, and adolescents under the age of 18 should use the nicotine lozenge only under the supervision of a medical provider. Additionally, the manufacturer recommends that patients with stomach ulcers or diabetes contact their medical provider before use as these conditions, which are more serious, may require further monitoring.

Nicotine Transdermal Systems (Nicotine Patch) Nicotine transdermal systems deliver continuous, low levels of nicotine across the skin over 16 or 24 hours. The patch consists of a waterproof surface layer, a nicotine reservoir, an adhesive layer, and a disposable protective liner. Currently, there are three marketed products (Table 50-9). Two of the products (Nicoderm CQ and the generic formulation) deliver the labeled dose of nicotine continuously over 24 hours. The Nicotrol formulation provides continuous nicotine delivery over 16 hours. This system, which more closely approximates typical smoking patterns, is applied in the morning and removed at bedtime.

Dosage The dosing schedules for the nicotine patches vary (Table 50-9). Before recommending a specific product and a dosing schedule, it is important to know how many cigarettes the patient smokes per day. In general, heavier smokers (e.g., more than 10 cigarettes per day) will require higher-strength formulations for a longer duration of therapy. Patients with strong morning cravings for cigarettes might consider a 24-hour patch, because some data suggest this formulation is more effective in reducing cravings in the morning and throughout the day, during the initial 2 weeks after quitting (21 mg, 24-hour patch compared to 15 mg, 16-hour patch).[47] Patients experiencing side effects such as dizziness, perspiration, nausea, vomiting, diarrhea, or headache should consider a lower dose. Eight weeks of nicotine patch therapy has been shown to be as effective as longer durations of therapy, and there is no evidence that dose tapering of the patch results in better quit rates than those seen with abrupt discontinuation.[34] Additional instructions for proper use of the nicotine patch are listed in Table 50-10.

Safety Considerations The most common side effects associated with the nicotine patch are local skin reactions (erythema, burning, and pruritus) at the application site. These reactions, which occur more commonly with the 24-hour products, are caused by skin occlusion or sensitivity to the patch adhesives. Skin reactions can be minimized or prevented by rotating the patch application site on a daily basis. Other less common side effects include vivid or abnormal dreams, insomnia, and headache. Sleep disturbances are more commonly reported in patients using the 24-hour formulations and may be the result of nocturnal nicotine absorption. If this side effect becomes troublesome, patients using the 24-hour products should consider the using the 16-hour Nicotrol patch or removing the 24-hour patch at bedtime.

Patients with severe cardiac disease, women who are pregnant or nursing, and adolescents under the age of 18 should use the nicotine patch only while under the supervision of a medical provider. Patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis) or those with an allergy to adhesive tape are more likely to experience skin irritation and should not use the nicotine patch.

TABLE 50-9 Dosages for Nonprescription Transdermal Systems (Nicotine Patch)

	Nicotrol Patch	Nicoderm CQ Patch (regular and clear)	Generic Patch (formerly Habitrol)
Product strength	5, 10, 15 mg (16 hour)	7, 14, 21 mg (24 hour)	7, 14, 21 mg (24 hour)
Dose	>10 cigarettes/day: 15 mg/day × 6 weeks; 10 mg/day × 2 weeks; 5 mg/day × 2 weeks ≤10 cigarettes/day: *not* recommended	>10 cigarettes/day: 21 mg/day × 6 weeks; 14 mg/day × 2 weeks; 7 mg/day × 2 weeks ≤10 cigarettes/day: 14 mg/day × 6 weeks; 7 mg/day × 2 weeks	>10 cigarettes/day: 21 mg/day × 4 weeks; 14 mg/day × 2 weeks; 7 mg/day × 2 weeks ≤10 cigarettes/day: 14 mg/day × 6 weeks; 7 mg/day × 2 weeks

Prescription Medications for Smoking Cessation

Nicotine Inhaler The nicotine inhaler consists of a plastic mouthpiece and a nicotine-containing cartridge that delivers 4 mg of nicotine as an inhaled vapor, which is absorbed across the oropharyngeal mucosa. The inhaler reduces nicotine withdrawal symptoms and may give some degree of comfort by providing a hand-to-mouth ritual that emulates smoking. Side effects of the inhaler include mild mouth and throat irritation, cough, and rhinitis.

Nicotine Nasal Spray The nicotine nasal spray is an aqueous solution of nicotine for administration to the nasal mucosa. Each actuation delivers a 0.5 mg bolus of nicotine that is absorbed rapidly (within 10 to 15 minutes) across the nasal mucosa. Because of its rapid onset of action, the spray is a potential option for patients who prefer a medication to rapidly manage withdrawal symptoms. Initially, most patients will experience nose and throat irritation (peppery sensation), watery eyes, sneezing, or coughing when using this product. This product is to be administered without sniffing (i.e., not administered like standard allergy nasal sprays). With regular use, tolerance generally develops and after the first week, most patients have minimal difficulty tolerating the spray.

Sustained-release Bupropion Sustained-release bupropion is the only non-nicotine pharmaceutical aid approved for smoking cessation. This agent is thought to affect dopamine and norepinephrine levels, decreasing the cravings for cigarettes and symptoms of nicotine withdrawal.[2]

Therapy is initiated with a dose of 150 mg orally every morning for 3 days, followed by 150 mg twice daily for 7 to 12 weeks. Because steady-state levels are reached after approximately 7 days of therapy, patients set their quit date for 1 to 2 weeks after commencing therapy. Insomnia and dry mouth are the most common side effects reported with bupropion. Because seizures have been reported in approximately 0.1% of patients, bupropion is contraindicated in patients who (1) have a seizure disorder, (2) have a current or prior diagnosis of anorexia or bulimia nervosa, (3) are undergoing abrupt discontinuation of alcohol or sedatives (including benzodiazepines), (4) are currently using or have used a monoamine oxidase inhibitor within the past 14 days, or (5) are currently being treated with any other medications that contain bupropion. Other factors that might increase the odds of seizure and are classified as warnings for this medication include a history of head trauma or prior seizure, central nervous system tumor, the presence of severe hepatic cirrhosis, and concomitant use of medications that lower the seizure threshold. Bupropion can be used safely in combination with NRT and may be beneficial for use in patients with underlying depression.

Pharmacotherapeutic Comparison

Currently, there are insufficient data to evaluate the relative effectiveness of the different agents for smoking cessation.[2] In general, all of the approved agents (Table 50-11) approximately double the long-term quit rates compared with placebo.[2,34,35] For the NRT products, the pooled abstinence rate is 17% at the longest available follow-up assessment point for all nicotine replacement therapy products, compared with 10% for placebo.[34] In a randomized controlled trial comparing four NRT formulations, all products exhibited similar efficacy, but compliance with therapy was higher with the patch, followed by the gum, which was higher than the inhaler and nasal spray.[48]

Product Selection Guidelines

Little information is available to guide the selection of one form of pharmacotherapy over another for a given patient. The choice of therapy is therefore based largely on patient preference and tolerability of the available dosage forms.

Patient Factors When recommending a nonprescription agent for smoking cessation, it is essential to determine the patient's smoking patterns, lifestyle habits, and coexisting medical conditions. In general, higher levels of smoking will require higher dosages of NRT and longer treatment durations. Patients who smoke continuously throughout the day might have better success with the nicotine patches, because these provide a sustained, steady release of nicotine over 16 or 24 hours. Conversely, patients

TABLE 50-10 Usage Guidelines for Nicotine Transdermal Systems (Nicotine Patch)

- Do not smoke cigarettes or use other forms of tobacco (e.g., snuff, chewing tobacco, cigars, pipes) while using the nicotine patch.
- Apply the patch to a clean, dry, hairless area of the skin on the upper body or the upper outer part of the arm at approximately the same time each day.
- The patch should be applied to a different area of skin each day. To minimize the potential for local skin reactions, the same area should not be used again for at least 1 week.
- During application, apply firm pressure to the patch with the palm of the hand for 10 seconds. Be sure that the patch adheres well to the skin, especially around the edges; this is necessary for a good seal.
- Wash your hands after applying or removing the patch.
- The patch should not be left on the skin for more than 16 hours (Nicotrol) or 24 hours (Nicoderm CQ, generic patch) as this may lead to skin irritation.
- Any adhesive remaining on the skin after the patch removal may be removed with rubbing alcohol.
- Water will not reduce the effectiveness of the nicotine patch if it is applied correctly. You may bathe, swim, shower, or exercise while wearing the patch.
- Do not cut patches in half or into smaller pieces to adjust or reduce the nicotine dosage. Nicotine in the patch may evaporate from the cut edges and the patch may be less effective.
- Local skin reactions (itching, burning, and redness) are common with the nicotine patch. These reactions are generally caused by adhesives; they can be minimized by rotating patch application sites and, if they occur, treated with nonprescription hydrocortisone cream.
- Remove the nicotine patch prior to having a magnetic resonance imaging (MRI) procedure. Burns from nicotine patches worn during MRIs have been reported, and are likely caused by the metallic component in the backing of some patches.
- Individuals experiencing vivid dreams or other sleep disruptions should either use the 16-hour patch or remove the 24-hour patch after 16 hours (e.g., before bedtime).
- Discard the removed nicotine patch by folding it onto itself, completely covering the adhesive area.
- Keep new and used patches out of the reach of children and pets.

who smoke intermittently throughout the day or who smoke intensely for short periods of time followed by long periods of abstinence might prefer a relatively short-acting formulation such as nicotine gum or lozenges to more closely mimic their tobacco use patterns. For some quitters, frequent gum chewing may not be feasible or socially acceptable. The nicotine patch, which can be concealed under clothing, might be a reasonable choice for these individuals. Others may find nicotine lozenges, which can be used more discreetly, to be an acceptable alternative. Smokers with underlying dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis) are more likely to experience skin irritation and should not use the nicotine patch. The nicotine lozenge or patch is better suited for patients with temporomandibular joint disease or dentures. Finally, patients with serious cardiovascular disease, women who are pregnant or nursing, and adolescents should be referred for further evaluation before initiating self-treatment with NRT.

Patient Preferences Too often, clinicians are quick to "dispense" instructions or information without first eliciting the patient's preference and/or point of view. When assisting patients with quitting, it is particularly important to understand the patient's perceptions and expectations regarding pharmacotherapy, including the ability to comply with the regimen, previous experience with cessation medications, concern about weight gain, and other issues. Because NRT formulations require frequent dosing or nontraditional routes of administration, patient education regarding proper use of these products is essential. Patients who have difficulty taking multiple doses of medications throughout the day or those who want a simplified regimen might achieve greater success with the nicotine patch. In contrast, the gum or lozenge may be preferable for patients desiring the ability to titrate nicotine levels to manage withdrawal symptoms. This may include smokers who need a more flexible nicotine dosage form to avoid injury, such as transportation workers or persons who work with heavy machinery. Some quitters may find they need an oral substitute for tobacco; the oral gratification afforded by the nicotine gum, lozenge, or inhaler might be beneficial in these patients.

All smokers making a repeat quit attempt should be queried about their prior use of pharmacotherapy and their perceptions of the treatment options. For patients reporting a favorable past experience with a given product, retreatment with the same agent may be appropriate, with consideration given to increasing the dose, frequency, or duration of therapy. For patients reporting a negative experience with pharmacotherapy (e.g., poor adherence, side effects, palatability issues, and cost) a different regimen should be considered. For example, if a patient had short-term success with the 24-hour patch but discontinued therapy because of intolerable nightmares, he or she may quit again using the patch, but it should be worn only during the waking hours. A patient who is unable to tolerate nicotine gum because of jaw muscle ache may switch to the nicotine lozenge or patch. For patients expressing concern about postcessation weight gain, nicotine gum may be particularly helpful as this product has been shown to delay weight gain after quitting.[2] Because most health insurance plans do not cover the cost of pharmacotherapy, the out-of-pocket expense of NRT might be a barrier to treatment. For these patients, use of the generic formulations of the nicotine patch and gum may be preferable.

In recalcitrant quitters who have experienced numerous failed attempts using monotherapy, combination therapy might be appropriate. Combination therapy generally involves the use of a long-acting medication (nicotine patch or sustained-release bupropion) in combination with a short-acting formulation (nicotine gum, lozenge, inhaler, or nasal spray). The long-acting formulation, which delivers relatively constant levels of drug, is used to prevent the onset of severe withdrawal symptoms, whereas the short-acting formulation, which delivers nicotine more

TABLE 50-11 Methods for Smoking Cessation: Estimates of Treatment Efficacy for First-line Agents

Pharmacotherapy Agent	Number of Studies	Estimated OR for Tobacco Abstinence, Compared with Control at ≥6 months (95% CI)*
Nicotine gum[34]	52	1.66 (1.52-1.81)
Nicotine lozenge[34]	4	2.05 (1.62-2.59)†
Nicotine transdermal patch[34]	37	1.81 (1.63-2.02)
Nicotine oral inhaler[34]	4	2.14 (1.44-3.18)
Nicotine nasal spray[34]	4	2.35 (1.63-3.38)
Bupropion SR[35]	19	2.06 (1.77-2.40)

Key: CI, confidence interval; OR, odds ratio.

* Odds ratios also depend on the duration of therapy, intensity of additional support provided, and setting in which the NRT was offered.[34]

† Values include two studies conducted using the sublingual tablet, which currently is not available in the United States.

rapidly, is used "as needed" to control withdrawal symptoms that may occur during potential relapse situations (e.g., after meals, or when stressed or around other smokers). While research suggests that combination therapy may be somewhat (but not convincingly) more efficacious than monotherapy,[2,34] this approach should be reserved for patients who have failed with monotherapy, because of the increased risk of nicotine toxicity and lack of long-term safety data. Furthermore, patients considering combination NRT should be referred for further evaluation to ensure they are appropriate candidates for this more aggressive form of treatment.

Complementary Therapies

Although a variety of herbal and homeopathic products are available to aid cessation, data are lacking to support their safety and efficacy. Many herbal preparations for cessation contain lobeline (*Lobelia inflata*), an herbal alkaloid with partial nicotinic agonist properties. A recent meta-analysis found no evidence to support the role of lobeline as an aid for smoking cessation.[49] Controlled trials to test the effects of other complementary therapies, including hypnosis and acupuncture, similarly have not been found to be effective treatments for smoking cessation.[2,50] Patients should be cautioned that "herbal" cigarettes are not safe alternatives; similar to cigarettes, these products also result in the inhalation of tar, carbon monoxide, and other harmful byproducts of combustion.

Assessment of Smoking Cessation: A Case-based Approach

To help the smoker succeed at smoking cessation, the clinician must help patients evaluate how they smoke, what they have or have not tried in the past, and how willing they are to try different cessation therapies. Analysis of the patient's smoking patterns and the reasons for smoking helps the clinician work with the patient to develop an appropriate treatment plan. Cases 50-1 and 50-2 illustrate the assessment of patients who want to quit.

CASE 50-1

Relevant Evaluation Criteria	Scenario/Model Outcome
Information Gathering	
1. Gather essential information about the patient's symptoms, including:	
a. description of symptom(s) (i.e., nature, onset, duration, severity, associated symptoms)	Patient is interested in quitting smoking within the next month. He smokes approximately 1 pack per day and has been smoking for 25 years.
b. description of any factors that seem to precipitate, exacerbate, and/or relieve the patient's symptom(s)	He smokes during breaks at work; very few of his coworkers smoke. He likes to have 1 to 2 cigarettes before getting out of bed in the morning and then another 1 to 2 cigarettes shortly thereafter with his morning coffee. He smokes in the evenings after dinner and while watching TV.

CASE 50-1 (continued)

Relevant Evaluation Criteria	Scenario/Model Outcome
c. description of the patient's efforts to relieve the symptoms	The patient has tried to quit several times. Last attempt was years ago when nonprescription nicotine gum first became available. He was successful for 1 week, but disliked the taste of the gum and felt it didn't work well (he experienced frequent withdrawal symptoms). He likes the idea of the nicotine patch, because he can put it on and not have to think about it for the rest of the day.
2. Gather essential patient history information:	
a. patient's identity	Pat Maddox
b. patient's age, sex, height, and weight	53 y/o M, 5'10", 220 lb
c. patient's occupation	High school chemistry teacher
d. patient's dietary habits	Recently (1 week ago) started the diet recommended by the American Diabetes Association
e. patient's sleep habits	Generally retires before 10 PM (sleeps ~8 hours night)
f. concurrent medical conditions, prescription and nonprescription medications, and dietary supplements	Hypertension well controlled on medication; dyslipidemia, recently diagnosed with type 2 diabetes; metformin 500 mg twice daily; ramipril 5 mg once daily; atorvastatin 10 mg once daily; aspirin 81 mg once daily
g. allergies	NKDA
h. history of other adverse reactions to medications	None
i. other (describe)_____	Married with 2 teenage sons living at home. His wife also smokes (~1 pack daily).
Assessment and Triage	
3. Differentiate the patient's signs/symptoms and correctly identify the patient's primary problem(s).	Current smoker. Pat would like to quit smoking as soon as possible. He has five cardiovascular risk factors (smoking, diabetes, hypertension, dyslipidemia, and age).
4. Identify exclusions for self-treatment (see Figure 50-2).	None
5. Formulate a comprehensive list of therapeutic alternatives for the primary problem to determine if triage to a medical practitioner is required, and share this information with the patient.	Work with Pat to set a quit date within the next 1-2 weeks. Options include: (1) Recommend nicotine gum; new flavors have become available since Pat last used it. (2) Recommend nicotine transdermal patch. (3) Recommend nicotine lozenge. (4) Refer to medical provider for prescription pharmacotherapy (nicotine inhaler, nicotine nasal spray, or sustained-release bupropion). (5) Take no action.
Plan	
6. Select an optimal therapeutic alternative to address the patient's problem, taking into account patient preferences.	Pat has expressed interest in using a nicotine patch. Select a patch type and dose (see Table 50-9) based on the number of cigarettes smoked daily (20 per day).
7. Describe the recommended therapeutic approach to the patient.	Behavioral counseling: See Tables 50-3, 50-4, and 50-5. Pharmacologic therapy: Use of nicotine replacement therapy will help reduce nicotine withdrawal symptoms. The nicotine patch should be applied at approximately the same time each day. Duration of treatment is 6-10 weeks, depending on the specific patch selected.
8. Explain to the patient the rationale for selecting the recommended therapeutic approach from the considered therapeutic alternatives.	You do not have any medical conditions in which nicotine replacement therapy should be used with caution (e.g., recent heart attack, serious arrhythmias, or angina). Your blood pressure is controlled with medication but should continue to be monitored while on NRT. Because you said you are interested in using the nicotine patch, this would be an appropriate agent for you.

CASE 50-1 (continued)

Relevant Evaluation Criteria	Scenario/Model Outcome
Patient Education	
9. When recommending self-care with nonprescription medications and/or nondrug therapy, convey accurate information to the patient, including:	
a. appropriate dose and frequency of administration	We have a choice of initiating step-down therapy with Nicoderm CQ 21 mg/day for 6 weeks; Nicotrol 15 mg/day for 6 weeks; or generic 21 mg/day for 4 weeks. See Table 50-9 for patch dosages for tapering schedule for Nicoderm CQ, Nicotrol, and the generic patch.
b. maximum number of days the therapy should be employed	Depending on the product we select, you should plan to use the patch for 8-10 weeks. Shorter treatment courses might increase the severity of nicotine withdrawal symptoms.
c. product administration procedures	See Table 50-10.
d. expected time to onset of relief	The level of nicotine in your body will gradually rise and level off within 4-9 hours, then remain steady with continued use of the patch. The blood nicotine levels are lower than those from smoking but should be sufficient to help control your nicotine withdrawal.
e. degree of relief that can be reasonably expected	Most patients find that nicotine withdrawal symptoms peak 24-48 hours after the last cigarette; withdrawal symptoms then gradually diminish over the next 2-4 weeks. Use of nicotine replacement therapy will help minimize these symptoms.
f. most common side effects	The most common side effects include skin reactions (redness, burning, itching) at the application site, sleep disturbances (vivid dreams, insomnia), and headaches.
g. side effects that warrant medical intervention should they occur	You should seek medical attention if you experience severe skin irritation (rash or redness of the skin that does not go away after 4 days, or if the skin swells); irregular heartbeats or palpitations; symptoms of nicotine overdose (nausea, vomiting, dizziness, weakness, or rapid heartbeat).
h. patient options in the event that condition worsens or persists	If you experience withdrawal symptoms or severe cigarette cravings you should contact your medical provider because you might need a higher dosage of nicotine. If you have side effects related to nicotine excess (see above), you should use the next lower patch dose.
i. product storage requirements	Store at room temperature. Keep unused patch in closed, protective pouch. After removing the patch from your skin, fold the adhesive ends together and discard. Keep both new and used patches out of the reach of children and pets.
j. specific nondrug measures	Think about ways to make your environment conducive to your quit attempt. Some coping strategies are shown in Table 50-4. It would be helpful if you and your wife quit together. Is she willing to quit smoking at this time, too? You should be very proud of your decision to quit. Let's talk again in 1 week to discuss how you are doing.
10. Solicit patient's follow-up questions.	(1) Can I cut the patch in half when I decrease the dose? (2) Can I swim with the patch on? (3) Will the patch interact with any of my medications?
11. Answer patient's questions.	(1) The patch should not be cut in half, because nicotine can evaporate rapidly from the cut edges, resulting in erratic or reduced delivery of nicotine from the patch. (2) Exposure to water (e.g., swimming, showering, or bathing) for short periods of time should not affect the patch if it is applied correctly (see Table 50-10). The nicotine contained in the patch will not interact with any of the medications you are taking. (3) Some medications may require dosage adjustment when a person quits smoking. However, none of the medications you are taking (aspirin, atorvastatin, metformin, ramipril) require dosage adjustment after quitting smoking.

Key: NKDA, no known drug allergies; NRT, nicotine replacement therapy.

CASE 50-2

Relevant Evaluation Criteria	Scenario/Model Outcome
Information Gathering	
1. Gather essential information about the patient's symptoms, including:	
a. description of symptom(s) (i.e., nature, onset, duration, severity, associated symptoms)	Patient would like information about the various nonprescription medications for smoking cessation. She would like to start a family in the next 6-12 months and wants to quit smoking soon. She has been smoking 1-1.5 packs per day for 10 years. She smokes her first cigarette of the day immediately after waking. She has not received any counseling from a clinician.
b. description of any factors that seem to precipitate, exacerbate, and/or relieve the patient's symptom(s)	Patient smokes during breaks at work, after meals, and when she is stressed.
c. description of the patient's efforts to relieve the symptoms	The patient tried to quit "cold turkey" last year but resumed smoking after 2 days. She would like to try a nonprescription medication during her next quit attempt.
2. Gather essential patient history information:	
a. patient's identity	Cynthia Phelps
b. patient's age, sex, height, and weight	28 y/o F, 5'8", 125 lb
c. patient's occupation	Postdoctoral research scientist in a biochemistry laboratory
d. patient's dietary habits	Reasonably healthy, low-fat diet
e. patient's sleep habits	Works long hours, so sleeps about 6 hours during work week
f. concurrent medical conditions, prescription and nonprescription medications, and dietary supplements	Eczema treated with Elocon (mometasone) cream 0.1% as needed for "flares"
g. allergies	NKDA
h. history of other adverse reactions to medications	None
i. other (describe)_____	None
Assessment and Triage	
3. Differentiate the patient's signs/symptoms and correctly identify the patient's primary problem(s).	Patient is a young smoker in reasonably good health who would like to quit smoking before trying to become pregnant.
4. Identify exclusions for self-treatment (see Figure 50-2).	None
5. Formulate a comprehensive list of therapeutic alternatives for the primary problem to determine if triage to a medical practitioner is required, and share this information with the patient.	Options include: (1) Recommend nicotine gum. (2) Recommend nicotine lozenge. (3) Recommend nicotine transdermal patch. (4) Refer Cynthia to her primary medical provider for prescription pharmacotherapy (nicotine inhaler, nicotine nasal spray, or sustained-release bupropion). (5) Take no action.
Plan	
6. Select an optimal therapeutic alternative to address the patient's problem, taking into account patient preferences.	Cynthia would like to use a nonprescription medication and therefore her options include the nicotine gum, the nicotine lozenge, and the transdermal nicotine patch. The transdermal patch is not recommended for use in patients with eczema because of an increased risk for developing skin reactions. Alternatives include the nicotine gum and lozenge. Cynthia indicates a preference for the nicotine lozenge.

CASE 50-2 (continued)

Relevant Evaluation Criteria	Scenario/Model Outcome
7. Describe the recommended therapeutic approach to the patient.	Behavioral counseling: Some coping strategies are listed in Tables 50-3, 50-4, and 50-5. Pharmacologic therapy: Use of the nicotine lozenge will help reduce the symptoms of nicotine withdrawal. The combination of pharmacotherapy and behavioral counseling will increase Cynthia's chances for quitting smoking.
8. Explain to the patient the rationale for selecting the recommended therapeutic approach from the considered therapeutic alternatives.	Given you have eczema, I would not recommend the nicotine patch because patients with skin conditions are more likely to experience skin irritation with the patch. Other medications for smoking cessation that do not require a prescription include the nicotine gum or nicotine lozenge. You have expressed interest in the lozenge formulation (Cynthia further agrees, indicating that she is not a "gum chewer") and this is a reasonable choice. Because you smoke your first cigarette of the day immediately after waking, I would recommend the 4 mg strength lozenge.
Patient Education	
9. When recommending self-care with nonprescription medications and/or nondrug therapy, convey accurate information to the patient, including:	
a. appropriate dose and frequency of administration	Nicotine lozenge 4 mg. See Table 50-6 for nicotine lozenge dosing.
b. maximum number of days the therapy should be employed	You should use this treatment for 12 weeks. A shorter treatment duration will increase your chances of experiencing withdrawal symptoms.
c. product administration procedures	See Table 50-8 for use of the nicotine lozenge.
d. expected time to onset of relief	The level of nicotine in your body will rise within 30 minutes after you take a lozenge.
e. degree of relief that can be reasonably expected	Most patients find that nicotine withdrawal symptoms peak 24-48 hours after the last cigarette; withdrawal symptoms then gradually diminish over the next 2-4 weeks. Use of nicotine replacement therapy, such as the nicotine lozenge, will help minimize these symptoms.
f. most common side effects	The most common side effects are mouth irritation, nausea, hiccups, cough, heartburn, headache, flatulence, and insomnia.
g. side effects that warrant medical intervention should they occur	You should seek medical attention if you experience severe mouth problems; persistent indigestion or severe sore throat; irregular heartbeats or palpitations; or symptoms of nicotine overdose (nausea, vomiting, dizziness, weakness, or rapid heartbeat).
h. patient options in the event that condition worsens or persists	During the initial stages of quitting you should use at least 9 lozenges daily. If you experience withdrawal symptoms or cigarette cravings, you may need additional lozenges (up to 5 lozenges in 6 hours or a maximum of 20 lozenges per day). If you have side effects related to nicotine excess (see above), you should use fewer lozenges per day.
i. product storage requirements	Store at room temperature. Protect from light.
j. specific nondrug measures	Some coping strategies are shown in Table 50-4. You should be very proud of your decision to quit. Women who smoke are more likely to have fertility problems and among those who become pregnant, smoking can cause serious health effects including pregnancy complications, premature birth, low birth weight infants, and sudden infant death. By quitting smoking now you will improve your health and increase your chances for having a healthy baby.
10. Solicit patient's follow-up questions.	I don't want to gain weight after I quit. How many calories are in each lozenge?
11. Answer patient's questions.	The nicotine lozenge is sugar-free and does not contain a significant number of calories (~4 calories per lozenge). See Table 50-4 for additional counseling points regarding postcessation weight gain.

Key: NKDA, no known drug allergies.

PATIENT EDUCATION FOR SMOKING CESSATION

Tobacco use and dependence is a chronic medical condition optimally treated with a combination of behavioral counseling and medications. The primary objective of smoking cessation treatment is to attain complete, long-term abstinence from all nicotine-containing products. For most patients, carefully following product instructions and the self-care measures listed here will help ensure optimal therapeutic outcomes.

Nondrug Measures

- Receiving counseling from a clinician will increase success of smoking cessation.
- A clinician can help develop a tailored smoking cessation treatment plan.
- Telephone quitlines (1-800-QUIT-NOW) are also available to provide comprehensive counseling services at no cost.

Nonprescription Medications

Nicotine Replacement Therapy

- NRT helps relieve and prevent symptoms of nicotine withdrawal by partially replacing the high levels of nicotine your body is used to obtaining from cigarettes. Use of NRT helps you focus on changing your smoking routines and practice new coping skills while decreasing your withdrawal symptoms.
- NRT does not contain any of the harmful tars and other toxins present in tobacco smoke.
- Symptoms and management of nicotine withdrawal are listed in Table 50-5.
- Recommended daily dosages for NRT are shown in Tables 50-6 and 50-9.
- See Table 50-7 for guidelines for the use of nicotine gum, Table 50-8 for the nicotine lozenge, and Table 50-10 for the nicotine patch.
- Follow the dosage regimen of the selected product carefully. Failure to do so will increase the chance of having withdrawal symptoms.
- Use the selected product as recommended. Discontinue use of any form of NRT if you relapse back to smoking.
- Symptoms of nicotine excess include nausea, vomiting, dizziness, diarrhea, weakness, and rapid heartbeat.
- Do not eat or drink 15 minutes before or while using the nicotine gum or lozenge.
- Store NRT products at room temperature and protect from light.
- Keep new and used products out of the reach of children or pets.
- For all forms of NRT, consult your primary care provider before use if you have had a recent (in the past 2 weeks) heart attack, experience frequent pain caused by severe angina, have irregular heartbeats, are pregnant or breast-feeding, or are less than 18 years of age.
- Do not use more than one form of nicotine replacement medication (gum, lozenge, patch, inhaler, or nasal spray) at the same time unless directed by a primary care provider to use combination therapy.

⚠ For all forms of NRT, stop use and seek medical attention if irregular heartbeat or palpitations occur or if you have symptoms of nicotine overdose, such as nausea, vomiting, dizziness, diarrhea, and weakness.

⚠ *Nicotine gum*: stop use if mouth, teeth, or jaw problems develop.

⚠ *Nicotine lozenge*: stop use if mouth problems, persistent indigestion, or severe sore throat develop.

⚠ *Nicotine patch*: stop use if the skin swells, a rash develops, or skin redness caused by the patch does not go away after 4 days.

Patient Counseling for Smoking Cessation

Smoking is the leading known cause of preventable morbidity and mortality in the United States. Substantial benefits of quitting can be realized at any age. While approximately 70% of adult smokers would like to quit,[11] few are able to do so on their own. Research has shown that tobacco cessation rates can be substantially improved with treatment that includes behavioral counseling and pharmacotherapy.[2] (See Nonpharmacologic Therapy for a detailed discussion of behavioral counseling.) Health care providers are in an ideal position to identify tobacco users and provide assistance throughout the quit attempt.

Evaluation of Patient Outcomes for Smoking Cessation

Follow-up contact is an essential component of treatment for tobacco use and dependence.[2] At each follow-up contact, the clinician should assess the patient's tobacco use status and, if appropriate, assess and monitor pharmacotherapy use. If the patient has remained abstinent, congratulate success and provide encouragement to remain tobacco-free. If the patient has used tobacco, review the specific circumstances and reassess the commitment to abstinence. Encourage the patient to learn from his or her mistakes and identify strategies to prevent future lapses. Determine if the patient is experiencing nicotine withdrawal symptoms or adverse effects from the pharmacotherapy. Finally, offer ongoing support; if a practitioner is unable to provide the level of ongoing support a patient needs or desires, refer the patient to a specialist for more intensive treatment.

Key Points for Smoking Cessation

- Clinicians should use the "5 A's" to provide smoking cessation counseling: ask, advise, assess, assist, and arrange.
- For a patient not ready to quit, provide brief counseling addressing the "5 R's": relevance, risks, rewards, roadblocks, and repetition.
- For a patient who is ready to quit, offer behavioral counseling and pharmacotherapy. If time is limited, refer patient to a toll-free quit line (1-800-QUIT-NOW).

- Effective medications are available to help patients quit smoking. Unless medically contraindicated, all patients who are trying to quit should be encouraged to use pharmacotherapy. Drug therapy should be combined with behavioral counseling to further increase the patient's chances for success.
- If a patient has exclusions to self-treatment with NRT, refer to primary care provider for further assessment.
- It is never too late to quit. Quitting smoking at any age has immediate as well as long-term benefits by reducing the risk for smoking-related diseases and improving health in general.

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