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Tobacco use and dependence: an updated review of treatments

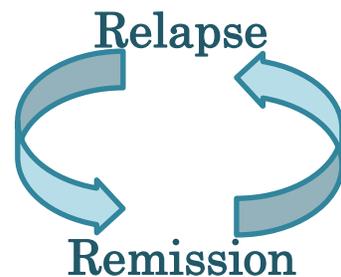
WHY SHOULD I TREAT TOBACCO DEPENDENCE?

Tobacco use stands out as the chief avoidable cause of illness and death in our society. Tobacco use is a known cause of multiple cancers, heart disease, stroke, complications of pregnancy, chronic obstructive pulmonary disease (COPD), and oral health issues. It exacerbates many other conditions such as asthma and diabetes, and compromises wound or surgical healing. In addition, recent research has documented the substantial health dangers of involuntary exposure to secondhand tobacco smoke. Globally, 1.3 billion people are current smokers and about 650 million persons will die prematurely of tobacco-related disease. In the United States about 21% of adult Americans (45 million) continue to smoke, and more than 435,000 Americans die prematurely from tobacco use. Each day in the U.S. approximately 4,000 youth ages 12 to 17 smoke their first cigarette and 1,200 children and adolescents become daily smokers. The toll of tobacco use and the enormous health and economic burden it imposes on individuals and society will continue to rise worldwide and up to half of all persistent tobacco users will die prematurely.

70% of smokers report wanting to quit

With 70 percent of U.S. smokers seeing a physician each year and many having contact with a dentist, nurse, physician assistant, pharmacist or other healthcare professional, clinicians are uniquely poised to intervene with patients who use tobacco. Moreover, 70% of smokers report wanting to quit and 44% make at least one quit attempt each year. Finally, smokers who are advised to quit by a physician and those who received cessation counseling from a nurse are 50% more likely to make a quit attempt than those who do not receive such counseling. These data suggest that most smokers are interested in quitting, clinicians are frequently in contact with smokers, and clinicians have high credibility with smokers.

Tobacco Use as a True Drug Dependence



All drug addictions warrant clinical intervention, including tobacco dependence. Tobacco dependence exhibits classic characteristics of drug dependence. For example, nicotine is psychoactive, tolerance producing, and causes physical and psychological dependence characterized by withdrawal symptoms and cravings. Many smokers typically cycle through multiple periods of relapse and remission and persist in tobacco use for many years.

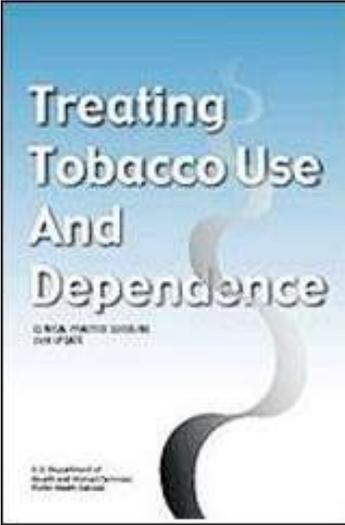
Pharmacokinetics of cigarette smoke

Within seconds of inhaling cigarette smoke, a bolus of nicotine travels from the alveoli to the brain where the molecules bind to nicotine receptors. Nicotine stimulates the norepinephrine and serotonin systems, enhancing concentration and memory and decreasing anxiety. This results in dopamine secretion that causes pleasurable sensations and relief of symptoms of nicotine deprivation. Nicotine also interacts with acetylcholine receptors, creating a variety of physiologic reactions. Some reactions are beneficial, such as suppressing appetite and pain, while others are not, such as elevated BP and nicotine addiction. Nicotine replacement therapy mimics but does not match these intense effects caused by the nicotine in cigarette smoke.

Tobacco dependence shows many features of a chronic disease

Only a minority of tobacco users achieve permanent abstinence in an initial quit attempt. The majority of users persist in tobacco use for many years and typically cycle through multiple periods of relapse and remission. By recognizing that tobacco dependence is a chronic condition, clinicians will better understand the relapsing nature of the ailment and the requirement for ongoing, rather than just acute care. This framework helps clinicians view relapse as a component of this chronic disease, rather than a lack of motivation or commitment on the patients' part or lack of ability on the clinicians' part. A failure to appreciate the chronic nature of tobacco dependence may impede the clinicians' consistent assessment and treatment of the tobacco user over time.

How Can the Public Health Service Guideline *Treating Tobacco Use and Dependence Assist Me in Intervening with Tobacco Users?*



In May 2008 the Public Health Service released the Clinical Practice Guideline *Treating Tobacco Use and Dependence 2008 Update*. This Guideline is directed toward clinicians, allied health professionals, health care insurers, purchasers and administrators and set a new standard of care for smoking cessation treatment. This Guideline was created by a multidisciplinary panel comprised of 24 experts in the field of tobacco treatment. The recommendations and strategies contained within the Guideline are based upon a review of more than 8,700 articles and more than 50 meta-analyses. It was supported by a consortium of eight public and non-profit funding organizations and endorsed by 58 professional healthcare organizations.

This educational activity is based upon the 2008 Guideline Update and many of the tables describing intervention strategies and clinical recommendations for the use of cessation medications can be found in the Guideline, which is available in several formats suitable for health care practitioners, the scientific community, educators and consumers. The full text of the Guideline, with and without the references, is available by visiting the Surgeon General's Web site

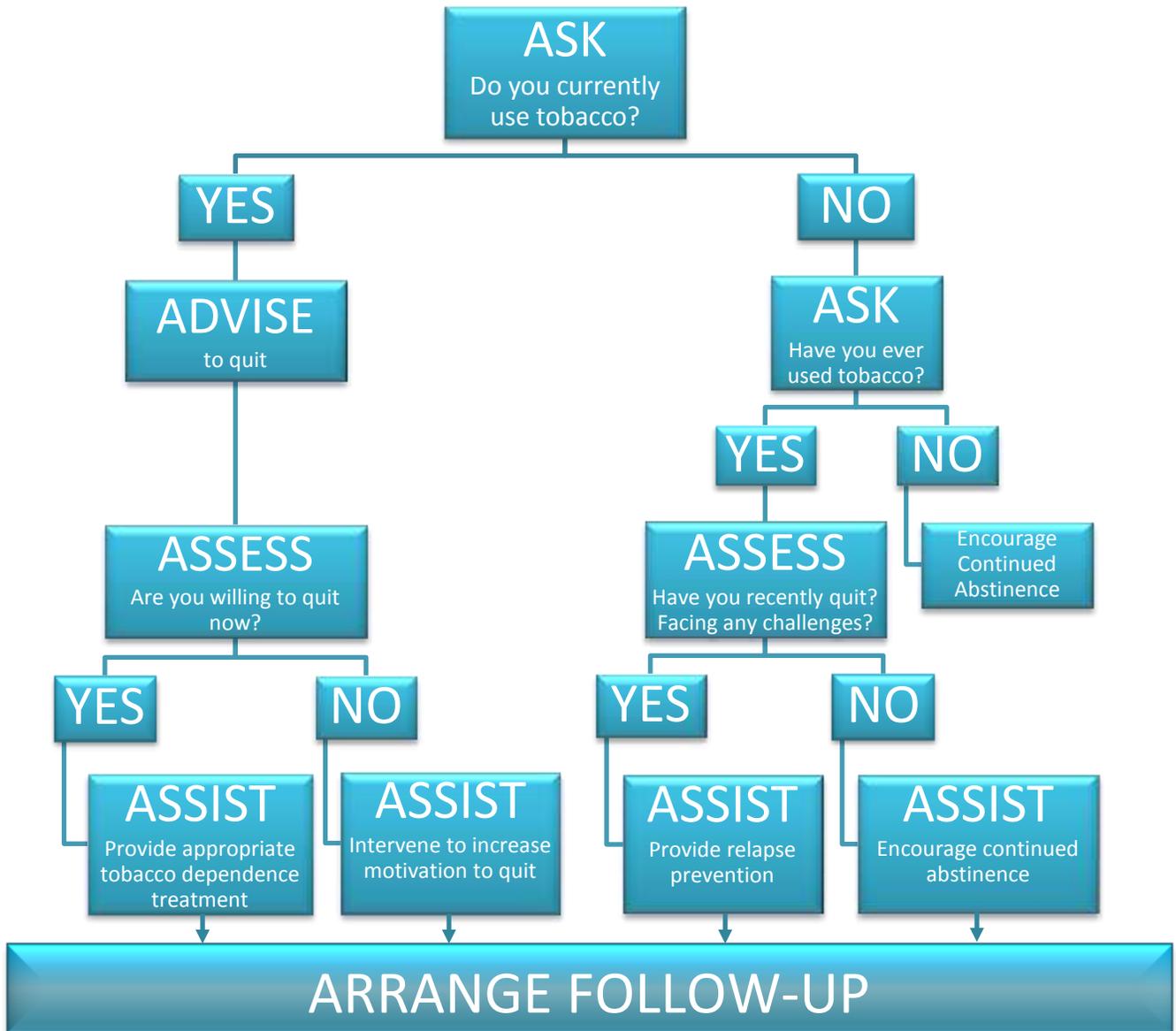
at: <http://www.surgeongeneral.gov/tobacco> or by calling the Agency for Healthcare Research and Quality at 1-800-358-9295.

How Do I Treat Tobacco Users?

Thousands of tobacco users visit a primary care clinician or other healthcare professional each year and the Guideline emphasizes the importance of treating all patients who use tobacco at every healthcare clinic. Many different treatments can promote long-term abstinence. The five major steps (the 5 A's) to intervention with a tobacco user are to **ASK** the patient if he or she uses tobacco, to **ADVISE** him or her to quit, to **ASSESS** willingness to make a quit attempt, to **ASSIST** him or her in making a quit attempt or motivating him or her to consider quitting in the future, and to **ARRANGE** for follow-up contacts to prevent relapse.

A single clinician need not provide all 5 A's. In fact, it is often cost-effective to have the 5 A's delivered by a team made up of clinicians and ancillary staff. For example, reception staff can **ask** about tobacco use while collecting the vital signs or through a routine questionnaire. This can be followed with **advice** to quit and **assessment** of willingness to quit by patient service staff (nurses, hygienists, etc.). **Assistance** can then be provided by the clinician working collaboratively with other staff who also **arrange** for follow-up. When a team delivers the 5 A's, it is especially important for a single clinician to retain overall responsibility for the entire intervention. Quit-line counseling, website interventions, and tailored self-help materials can be incorporated into the 5 A's; but these measures do not replace the vital role of the clinician.

The following flowchart demonstrates the process involved in using the 5 A's Model. Each of the 5 A activities is then described with examples and suggestions for the clinician or healthcare professional.



ASK

It is imperative that clinicians ask EVERY patient about tobacco use status at EVERY visit. This occurs most consistently when there are systems in place, such as a vital signs stamp or electronic prompt on electronic medical records that systematically result in universal tobacco use status documentation.

Strategy A1. Ask -- Systematically Identify All Tobacco Users at Every Visit

Action	Strategies for implementation												
Implement an office-wide system that ensures that, for EVERY patient at EVERY clinic visit, tobacco-use status is queried and documented.	<p>Expand the vital signs to include tobacco use or use an alternative universal identification system.</p> <table border="1"> <thead> <tr> <th colspan="2">VITAL SIGNS</th> </tr> </thead> <tbody> <tr> <td>Blood Pressure:</td> <td>_____</td> </tr> <tr> <td>Pulse: _____</td> <td>Weight: _____</td> </tr> <tr> <td>Temperature:</td> <td>_____</td> </tr> <tr> <td>Respiratory Rate:</td> <td>_____</td> </tr> <tr> <td>Tobacco Use:</td> <td>Current Former Never (circle one)</td> </tr> </tbody> </table>	VITAL SIGNS		Blood Pressure:	_____	Pulse: _____	Weight: _____	Temperature:	_____	Respiratory Rate:	_____	Tobacco Use:	Current Former Never (circle one)
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Repeated assessment is *not* necessary in the case of the adult who has never used tobacco or has not used tobacco for many years, and for whom this information is clearly documented in the medical record.

ADVISE

Even brief advice to quit by a clinician results in greater quit rates. Smokers cite a clinician's advice to quit as an important motivator for attempting to stop smoking. Therefore, clinicians should urge all tobacco users to quit. This advice should be clear and strong. For example, "As your health care provider, I must tell you that the most important thing you can do to improve your health is to stop smoking" or "As your dentist, I must tell you that tobacco use is directly linked to an increased risk of tooth decay, periodontal (gum) disease, tooth loss, and oral cancer."

Asking whether or not a patient uses tobacco increases the rates of clinician intervention

The advice should be personalized to the individual's own situation (e.g. medical condition, family status, costs of tobacco).

Strategy A2. Advise -- Strongly Urge All Tobacco Users to Quit

Action	Strategies for implementation
In a <i>clear, strong, and personalized</i> manner, urge every tobacco user to quit.	<p>Advice should be:</p> <ul style="list-style-type: none"> ▪ <i>Clear</i> -- "It is important that you quit smoking (or using chewing tobacco) now and I can help you." "Cutting down while you are ill is not enough." "Occasional or light smoking is still dangerous." ▪ <i>Strong</i> -- "As your clinician, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you." ▪ <i>Personalized</i> -- Tie tobacco use to current symptoms and health concerns, and/or its social and economic costs, and/or the impact of tobacco use on children and others in the household. "Continuing to smoke makes your asthma worse and quitting may dramatically improve your health." "Quitting smoking may reduce the number of ear infections your child has."

ASSESS

After providing a clear, strong, and personalized message to quit smoking, the clinician must determine whether or not the patient is willing to quit at this time. One direct way to assess readiness to quit is to follow the ADVISE message with the simple question, "Are you willing to try to quit at this time?"

Strategy A3. Assess -- Determine Willingness to Make a Quit Attempt

Action	Strategies for implementation
Assess every tobacco user's willingness to make a quit attempt at this time.	<p>Assess patient's willingness to quit: "Are you willing to give quitting a try?"</p> <ul style="list-style-type: none">▪ If the patient is willing to make a quit attempt at this time, provide assistance.<ul style="list-style-type: none">▪ If the patient will participate in an intensive treatment, deliver such a treatment or link or refer to an intensive intervention.▪ If the patient is a member of a special population (e.g., adolescent, pregnant smoker, racial/ethnic minority), consider providing additional information.▪ If the patient clearly states he or she is unwilling to make a quit attempt at this time, provide an intervention shown to increase future quit attempts.

ASSIST

Assisting the patient in his or her quit attempt can be done using either a **brief** or an **intensive** intervention. Level of intensity of the intervention has a strong dose-response effect.

- **Brief intervention** -- Even a minimal intervention, lasting less than 3 minutes, can significantly increase overall tobacco abstinence rates.
- **Intensive intervention** -- The longer the session length, and the more overall person-to-person contact, and the greater the number of visits, the more successful the treatment outcome.

In a 3- to 10-minute intervention, a clinician can provide a counseling session which can significantly impact a smoker's quit success.

Assistance should be offered to all tobacco users -- those willing to quit, those not yet willing to make a quit attempt, and those who have recently quit. Strategies relevant to tobacco users in each of these groups are listed here. Assistance can be provided by multiple providers, in multiple formats, including counseling and proactive telephone support.

Assisting the patient willing to quit

Strategy A4. Assist -- Aid the Patient in Quitting (Provide Counseling and Medication)

Action	Strategies for implementation
<p>Help the patient with a quit plan.</p>	<p><i>A patient's preparations for quitting (STARS):</i></p> <ul style="list-style-type: none"> ▪ <i>Set a quit date.</i> Ideally, the quit date should be within 2 weeks. ▪ <i>Tell</i> family, friends, and coworkers about quitting and request understanding and support ▪ <i>Anticipate</i> challenges to the upcoming quit attempt, particularly during the critical first few weeks. These include nicotine withdrawal symptoms. ▪ <i>Remove</i> tobacco products from your environment. Prior to quitting, avoid smoking in places where you spend a lot of time (e.g., work, home, car). Make your home smoke-free. ▪ <i>Strive</i> for total abstinence from smoking. Not even a single puff after your quit date.
<p>Recommend the use of approved medication, except where contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers and adolescents).</p>	<p>Recommend the use of medications found to be effective in the PHS Guideline. Explain how these medications increase quitting success and reduce withdrawal symptoms. The first-line medications include: bupropion SR, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, nicotine patch and varenicline and second-line medications include: clonidine and nortriptyline. There is insufficient evidence to recommend medications for certain populations (e.g., pregnant women, adolescents, smokeless tobacco users, light smokers).</p>
<p>Provide practical counseling (problem-solving/skills training).</p>	<p><i>Abstinence.</i> Striving for total abstinence is essential. Not even a single puff after the quit date.</p> <p><i>Past quit experience.</i> Identify what helped and what hurt in previous quit attempts. Build on past success.</p> <p><i>Anticipate triggers or challenges in upcoming attempt.</i> Discuss challenges/triggers and how patient will successfully overcome them (e.g., avoid triggers, alter routines).</p> <p><i>Alcohol.</i> Since alcohol is associated with relapse, the patient should consider limiting or abstaining from alcohol while quitting. (Note that reducing alcohol intake could precipitate withdrawal in alcohol dependent persons.)</p> <p><i>Other smokers in the household .</i> Quitting is more difficult when there is another smoker in the household. Patients should encourage housemates to quit with them or not smoke in their presence.</p> <p><i>Address myths</i> about the addictiveness of cessation medications.</p>
<p>Provide intra-treatment social support.</p>	<p>Provide a supportive clinical environment while encouraging the patient in his or her quit attempt. "<i>My office staff and I are available to assist you.</i>" "<i>I'm recommending treatment that can provide ongoing support.</i>"</p>
<p>Provide supplementary materials, including information on quitlines.</p>	<p><i>Sources :</i> Federal agencies, nonprofit agencies, national quitline network (1-800-QUIT-NOW), or local/state/tribal health departments/quitlines.</p> <p><i>Type:</i> Culturally/racially/educationally/age appropriate for the patient.</p> <p><i>Location:</i> Readily available at every clinician's workstation.</p>

Assisting the patient unwilling to quit

Patients unwilling to make a quit attempt during a visit may lack information about the harmful effects of tobacco use and the benefits of quitting, may lack the required financial resources, may have fears or concerns about quitting, or may be demoralized because of previous failed quit attempts. Such patients may respond to brief motivational interventions based on principles of Motivational Interviewing (MI).



Strategy B1. Motivational Interviewing Strategies

Action	Strategies for implementation
Express Empathy	<ul style="list-style-type: none"> ▪ Use open ended questions to explore patient perceptions about quitting <ul style="list-style-type: none"> ▪ <i>How important do you think it is for you to quit smoking?</i> ▪ <i>What might happen if you quit?</i> ▪ Use reflective listening to seek shared understanding <ul style="list-style-type: none"> ▪ <i>So you think smoking helps you to maintain your weight.</i> ▪ <i>What I have heard so far is that you enjoy smoking. On the other hand, your boyfriend hates your smoking and you're worried you might develop a serious disease.</i> ▪ Normalize feelings and concerns <ul style="list-style-type: none"> ▪ <i>Many people worry about managing without cigarettes.</i> ▪ Support the patient's autonomy and right to choose or reject change <ul style="list-style-type: none"> ▪ <i>I hear you saying you're not ready to quit right now. I'm here to help when you are ready.</i>
Develop Discrepancy	<ul style="list-style-type: none"> ▪ Highlight discrepancies between the patient's present behavior and expressed priorities, values and goals <ul style="list-style-type: none"> ▪ <i>It sounds like you are very devoted to your family. How do you think your smoking is affecting your children?</i> ▪ Reinforce and support "change talk" and "commitment" language <ul style="list-style-type: none"> ▪ <i>So, you realize how smoking is affecting your breathing and making it hard to keep up with your kids.</i> ▪ <i>It's great that you are going to quit when you get through this busy time at work.</i> ▪ Strengthen the patient's values that conflict with smoking <ul style="list-style-type: none"> ▪ <i>I am impressed with your strong desire not to feel like an addict.</i> ▪ <i>There are effective treatments that will ease the pain of quitting, including counseling and many medication options.</i>
Roll with Resistance	<ul style="list-style-type: none"> ▪ Back off and use reflection when the patient expresses resistance <ul style="list-style-type: none"> ▪ <i>Sounds like you are feeling pressured about your smoking.</i> ▪ Express empathy <ul style="list-style-type: none"> ▪ <i>You are worried about how you would manage withdrawal symptoms.</i> ▪ Ask permission to provide information <ul style="list-style-type: none"> ▪ <i>Would you like to hear about some strategies that can help when you quit?</i>
Support Self-Efficacy	<ul style="list-style-type: none"> ▪ Help the patient to identify and build on past successes <ul style="list-style-type: none"> ▪ <i>So you were fairly successful the last time you tried to quit - that means you really have the skills to fight urges and resist temptation.</i> ▪ Offer options for achievable small steps toward change <ul style="list-style-type: none"> ▪ <i>Call the quitline (1-800-QUIT-NOW) for advice and information.</i> ▪ <i>I'd like you to read about quitting benefits and strategies.</i> ▪ <i>Work on changing your smoking patterns (e.g., no smoking in the home).</i> ▪ <i>Which of these treatments sounds good to you?</i> ▪ <i>What ideas do you have for trying to quit?</i>

Encourage Reduction of Smoking Before Quitting	<ul style="list-style-type: none"> ▪ Inform patient <ul style="list-style-type: none"> ▪ <i>There is a treatment that may help you reduce smoking.</i> ▪ Deliver a smoking reduction + nicotine replacement therapy (NRT) treatment for those willing to try it. <ul style="list-style-type: none"> ▪ Consider NRT use for up to 6 months pre-quit (patch, gum or inhaler). ▪ Help formulate a smoking reduction plan: Reduce daily smoking as much as possible. Cut out smoking in key contexts and activities (e.g., in car, watching TV).(See recommendation for clinical use of NRT below)
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The content areas to be addressed in a motivational counseling intervention can be captured by the 5 R's: Relevance, Risk, Rewards, Roadblocks, Repetition. Research suggests that the 5 R's enhance future quit attempts.

Strategy B2. Enhancing Motivation to Quit Tobacco -- The "5 R's"

Content Area	Strategies for implementation
Relevance	Encourage the patient to express why quitting is personally relevant. Motivational information has the greatest impact if it is relevant to a patient's disease status or risk, family or social situation (e.g., having children in the home), health concerns, age, gender, and other important patient characteristics (e.g., prior quitting experience, personal barriers to cessation).
Risks	<p>Ask the patient to identify negative consequences of tobacco use. Suggest and highlight those that seem most relevant to the patient. Emphasize that smoking low-tar or low-nicotine cigarettes or use of other forms of tobacco (e.g., smokeless tobacco, cigars, and pipes) will not eliminate these risks. Examples of risks are:</p> <ul style="list-style-type: none"> ▪ <i>Acute risks:</i> Shortness of breath, exacerbation of asthma, increased risk of respiratory infections, harm to pregnancy, impotence, infertility. ▪ <i>Long-term risks:</i> Heart attacks and strokes, lung and other cancers (e.g., larynx, oral cavity, pharynx, esophagus, pancreas, stomach, kidney, bladder, cervix and acute myelocytic leukemia), chronic obstructive pulmonary diseases (chronic bronchitis and emphysema), osteoporosis, tooth decay or loss, long-term disability and need for extended care. ▪ <i>Environmental risks:</i> Increased risk of lung cancer and heart disease in spouses; increased risk for low birth weight, sudden infant death syndrome (SIDS), asthma, middle ear disease, and respiratory infections in children of smokers.
Rewards	<p>Ask the patient to identify potential benefits of stopping tobacco use. Suggest and highlight those that seem most relevant to the patient. Examples of rewards are:</p> <ul style="list-style-type: none"> ▪ Improved health ▪ Food will taste better ▪ Improved sense of smell ▪ Saving money ▪ Whiter teeth ▪ Feeling better about yourself ▪ Home, car, clothing, breath will smell better ▪ Setting a good example for children and decreasing the likelihood that they will smoke ▪ Having healthier babies and children ▪ Feeling better physically ▪ Performing better in physical activities ▪ Improved appearance including reduced wrinkling/aging of skin

Roadblocks	<p>Ask the patient to identify barriers or impediments to quitting and provide treatment (problem-solving counseling, medication) that could address barriers. Typical barriers might include:</p> <ul style="list-style-type: none"> ▪ Withdrawal symptoms ▪ Fear of failure ▪ Weight gain ▪ Lack of support ▪ Depression ▪ Enjoyment of tobacco ▪ Being around other tobacco users ▪ Limited knowledge of effective treatment options
Repetition	<p>Repeat the motivational intervention every time an unmotivated patient visits the clinic setting. Tobacco users who have failed in previous quit attempts should be told that most people make repeated quit attempts before they are successful.</p>

Assisting the patient who has recently quit

The former tobacco user should receive congratulations on any success and strong encouragement to remain abstinent. Relapse is most likely to occur soon after quitting but the risk for relapse can continue for months or even years. All very recent quitters should be given assistance and it is important to ask those who have quit for some time if they are facing any challenges such as temptations to smoke, close calls, or serious thoughts about starting again. Former tobacco users who report such challenges should be given assistance regardless of the length of time since they have used tobacco.

Strategy C1. Intervening With the Patient Who Has Recently Quit

Use open-ended questions relevant to the topics below to discover if a patient wants to discuss his or her recent quitting:

- The benefits, including health benefits, the patient may derive from cessation.
- Any success the patient has had in quitting (duration of abstinence, reduction in withdrawal, etc.).
- The problems encountered or anticipated threats to maintaining abstinence (e.g., depression, weight gain, alcohol, other tobacco users in the household, significant stressors).
- A medication check-in, including effectiveness and side effects if the patient is still taking medication.

A patient who previously smoked might identify a problem that negatively affects health or quality of life. Specific problems likely to be reported by former smokers and potential responses follow:

Strategy C2. Addressing Problems Encountered by Former Smokers

Problems	Responses
Lack of support for cessation	<ul style="list-style-type: none"> ▪ Schedule follow-up visits or telephone calls with the patient. ▪ Urge the patient to call the national quitline network (1-800-QUIT-NOW) or other local quitline. ▪ Help the patient identify sources of support within his or her environment. ▪ Refer the patient to an appropriate organization that offers counseling or support.
Negative mood or depression	<ul style="list-style-type: none"> ▪ If significant, provide counseling, prescribe appropriate medication, or refer the patient to a specialist.
Strong or prolonged withdrawal symptoms	<ul style="list-style-type: none"> ▪ If the patient reports prolonged craving or other withdrawal symptoms, consider extending the use of an approved medication or adding or combining medications to reduce strong withdrawal symptoms.
Weight gain	<ul style="list-style-type: none"> ▪ Recommend starting or increasing physical activity. ▪ Reassure the patient that some weight gain after quitting is common and is usually self-limiting. ▪ Emphasize the health benefits of quitting relative to the health risks of modest weight gain. ▪ Emphasize the importance of a healthy diet and active lifestyle. ▪ Suggest low-calorie substitutes such as sugarless chewing gum, vegetables, or mints. ▪ Maintain the patient on medication known to delay weight gain (e.g., bupropion SR, NRTs, particularly 4 mg nicotine gum and lozenge). ▪ Refer the patient to a nutritional counselor or program.
Smoking lapses	<ul style="list-style-type: none"> ▪ Suggest continued use of tobacco use medications, which can reduce the likelihood that a lapse will lead to a full relapse. ▪ Encourage another quit attempt or a recommitment to total abstinence. ▪ Reassure that quitting may take multiple attempts and use the lapse as a learning experience. ▪ Provide or refer for intensive counseling.

One way to systematically integrate tobacco cessation is by the use of the cessation tear sheet. This tear sheet can allow clinicians to personalize an intervention and can be given to patients as a take away.

See [Tear Sheet for Use With Patients](#).

ARRANGE

Arranging follow-up contact is the final step in treating tobacco use and dependence.

Strategy A5. Arrange -- Ensure Followup Contact

Action	Strategies for implementation
Arrange for follow-up contacts, either in person or by telephone	<p><i>Timing</i> Follow-up contact should begin soon after the quit date, preferably during the first week. A second follow-up contact is recommended within the first month. Schedule further follow-up contacts as indicated.</p> <p><i>Actions during follow-up contact</i> For all patients, identify problems already encountered and anticipate challenges in the immediate future. Assess medication use and problems. Remind patients of quitline support (1-800-QUIT-NOW). Address tobacco use at next clinical visit (treat tobacco use as a chronic disease).</p> <p>For patients who are abstinent, congratulate them on their success.</p> <p>If tobacco use has occurred, review circumstances and help patient recommit to total abstinence. Consider use of or link to more intensive treatment.</p>
For smokers unwilling to quit at this time	Repeat a motivational intervention every time a patient not yet ready to quit visits the clinic setting.

What Are the Most Effective Treatments for Smokers and Other Tobacco Users?

Psychosocial Treatments

Individual counseling, proactive telephone counseling, and group counseling formats are effective and should be used in smoking cessation interventions. These interventions can be delivered in many formats and by any number of health care professionals who interact with the patient. Tailored materials, both print and Web-based are effective in helping people quit.

How do I counsel patients to quit?

Encourage

Support

Offer Resources

Common Elements of Practical Counseling (Problem-Solving/Skills-Training)

Treatment component	Examples
<i>Recognize danger situations -- Identify events, internal states, or activities that increase the risk of smoking or relapse.</i>	<ul style="list-style-type: none"> ▪ Negative affect and stress. ▪ Being around other tobacco users. ▪ Drinking alcohol. ▪ Experiencing urges. ▪ Smoking cues and availability of cigarettes.
<i>Develop coping skills -- Identify and practice coping or problem-solving skills. Typically, these skills are intended to cope with danger situations.</i>	<ul style="list-style-type: none"> ▪ Learn to anticipate and avoid temptation and trigger situations. ▪ Learn cognitive strategies that will reduce negative moods. ▪ Accomplish lifestyle changes that reduce stress, improve quality of life, and reduce exposure to smoking cues. ▪ Learn cognitive and behavioral activities to cope with smoking urges (e.g., distracting attention; changing routines).
<i>Provide basic information -- Provide basic information about smoking and successful quitting.</i>	<ul style="list-style-type: none"> ▪ The fact that any smoking (even a single puff) increases the likelihood of a full relapse. ▪ Withdrawal symptoms typically peak within 1-2 weeks after quitting but may persist for months. These symptoms include negative mood, urges to smoke, and difficulty concentrating. ▪ The addictive nature of smoking.

Common Elements of Intra-treatment Supportive Interventions

Supportive treatment component	Examples
Encourage the patient in the quit attempt.	<ul style="list-style-type: none"> ▪ Note that effective tobacco dependence treatments are now available. ▪ Note that one-half of all people who have ever smoked have now quit. ▪ Communicate belief in patient's ability to quit.
Communicate caring and concern.	<ul style="list-style-type: none"> ▪ Ask how patient feels about quitting. ▪ Directly express concern and willingness to help as often as needed. ▪ Ask about the patient's fears and ambivalence regarding quitting.
Encourage the patient to talk about the quitting process.	<ul style="list-style-type: none"> ▪ Ask about: <ul style="list-style-type: none"> ▪ Reasons the patient wants to quit. ▪ Concerns or worries about quitting. ▪ Success the patient has achieved. ▪ Difficulties encountered while quitting.

Medications

The PHS Guideline has identified 7 first-line FDA-approved medications for smoking cessation and recommends that clinicians encourage all patients attempting to quit to use effective medications for tobacco dependence treatment, except where contraindicated or for specific populations for which there is insufficient evidence of effectiveness (i.e. pregnant women, smokeless tobacco users, light smokers, and adolescents). These seven first-line therapies include two non-nicotine medications, bupropion SR and varenicline, and five nicotine medications, nicotine gum, nicotine inhaler, nicotine nasal spray, nicotine patch, and nicotine lozenge (known collectively as *nicotine replacement therapy* or NRT). The clinical guidelines for prescribing cessation medications in general appear below followed by a clinical guideline table for each separate medication. See FDA website and package inserts for more complete prescribing and safety information.

Clinical guidelines for prescribing medication for treating tobacco use and dependence

Who should receive medication for tobacco use? Are there groups of smokers for whom medication has not been shown to be effective?	All smokers trying to quit should be offered medication, except where contraindicated or for specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers and adolescents).
What are the first-line medications recommended in the PHS Clinical Practice Guideline, <i>Treating Tobacco Use and Dependence</i> -- 2008 Update?	All seven of the FDA-approved medications for treating tobacco use are recommended: bupropion SR, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, the nicotine patch and varenicline. The clinician should consider the first-line medications shown to be more effective than the nicotine patch alone: 2 mg/day varenicline or the combination of long-term nicotine patch use + ad libitum NRT. Unfortunately, there are no well accepted algorithms to guide optimal selection among the first-line medications.
Are there contraindications, warnings, precautions, other concerns, and side effects regarding the first-line medications recommended in the Guideline Update?	All seven FDA-approved medications have specific contraindications, warnings, precautions, other concerns, and side effects. Please refer to FDA package inserts for this complete information and FDA updates and to the individual drug tables in this document. (See information below regarding second-line medications.)
What other factors may influence medication selection?	Pragmatic factors may also influence selection such as insurance coverage or out-of-pocket patient costs, likelihood of adherence, dentures when considering the gum, or dermatitis when considering the patch.
Is a patient's prior experience with a medication relevant?	Prior successful experience (sustained abstinence with the medication) suggests that the medication may be helpful to the patient in a subsequent quit attempt, especially if the patient found the medication to be tolerable and/or easy to use. However, it is difficult to draw firm conclusions from prior failure with a medication. Some evidence suggests that retreating relapsed smokers with the same medication produces small or no benefit while other evidence suggests that it may be of substantial benefit.
What medications should a clinician use with a patient who is highly nicotine dependent?	The higher dose preparations of nicotine gum, patch, and lozenge have been shown to be effective in highly dependent smokers. Also, there is evidence that combination NRT therapy may be particularly effective in suppressing tobacco withdrawal symptoms. Thus it may be that NRT combinations are especially helpful to highly dependent smokers or those with a history of severe withdrawal.

<p>Is gender a consideration in selecting a medication?</p>	<p>There is evidence that NRT can be effective with both sexes; however, evidence is mixed as to whether NRT is less effective in women than men. This may encourage the clinician to consider use of another type of medication with women such as bupropion SR or varenicline.</p>
<p>Are cessation medications appropriate for light smokers (i.e., <10 cigarettes/day)?</p>	<p>As noted above, cessation medications have not been shown to be beneficial to light smokers. However, if NRT is used with light smokers, clinicians may consider reducing the dose of the medication. No adjustments are necessary when using bupropion SR or varenicline.</p>
<p>Which medications should be considered with patients particularly concerned about weight gain?</p>	<p>Data show that bupropion SR and nicotine replacement therapies, in particular 4 mg nicotine gum and 4 mg nicotine lozenge, delay, but do not prevent, weight gain.</p>
<p>Are there medications that should be especially considered in patients with a past history of depression?</p>	<p>Bupropion SR and nortriptyline appear to be effective with this population, but nicotine replacement medications also appear to help individuals with a past history of depression.</p>
<p>Should nicotine replacement therapies be avoided in patients with a history of cardiovascular disease?</p>	<p>No. The nicotine patch in particular has been demonstrated as safe for cardiovascular patients. See individual medication tables below and FDA package inserts for more complete information.</p>
<p>May tobacco dependence medications be used long-term (e.g., up to 6 months)?</p>	<p>Yes. This approach may be helpful with smokers who report persistent withdrawal symptoms during the course of medications, who have relapsed in the past after stopping medication, or who desire long-term therapy. A minority of individuals who successfully quit smoking use ad libitum NRT medications (gum, nasal spray, inhaler) long-term. The use of these medications for up to 6 months does not present a known health risk and developing dependence on medications is uncommon. Additionally, the FDA has approved the use of bupropion SR, varenicline and some NRT medications for 6 month use.</p>
<p>Is medication adherence important?</p>	<p>Yes. Patients frequently do not use cessation medications as recommended (e.g., they don't use them at recommended doses or for recommended durations) and this may reduce their effectiveness.</p>
<p>May medications ever be combined?</p>	<p>Yes. Only the combination of nicotine patch plus bupropion is currently approved by the FDA for smoking cessation. However, evidence exists that combining the nicotine patch long-term (> 14 weeks) with either nicotine gum or nicotine nasal spray, the nicotine patch with the nicotine inhaler, or the nicotine patch with bupropion SR, increases long-term abstinence rates.</p>
<p>Can medications be used <i>before</i> the quit attempt?</p>	<p>Yes. For those willing to try it, NRT medications (patch, gum, or inhaler) may be used for up to 6 months before the quit date. Patients should develop a smoking reduction plan, cutting down on number of cigarettes per day or smoking in certain contexts (e.g., while in the car or watching TV.)</p>

Suggestions for the clinical use of bupropion SR

	Clinical use of bupropion SR 150 (FDA approved)
Patient selection	Appropriate as a first-line medication for treating tobacco use.
Precautions, warnings, contraindications and side effects (see FDA package insert and website for complete list and updates)	<p><i>Pregnancy</i>-- Pregnant smokers should be encouraged to quit without medication. Bupropion has not been shown to be effective for tobacco dependence treatment in pregnant smokers. (Bupropion is an FDA pregnancy Class C agent.) Bupropion has not been evaluated in breast-feeding patients.</p> <p><i>Cardiovascular diseases</i>-- Generally well-tolerated; occasional reports of hypertension.</p> <p><i>Side effects</i>-- The most common reported side effects were insomnia (35-40%) and dry mouth (10%).</p> <p><i>Contraindications</i>-- Bupropion SR is contraindicated in individuals who have a history of seizures or eating disorder, who are taking another form of bupropion, or who have used an MAO inhibitor in the past 14 days.</p> <p><i>Warning</i>-- In February, 2008, the FDA added a warning regarding the use of bupropion. Specifically, it noted that depressed mood, agitation, changes in behavior, suicidal ideation, and suicide have been reported in patients attempting to quit smoking while using bupropion. The FDA recommends that patients should tell their healthcare provider about any history of psychiatric illness prior to starting this medication and clinicians should monitor for changes in mood and behavior when prescribing this medication. In light of these FDA recommendations, clinicians should consider eliciting information on their patients' psychiatric history. For further information, see FDA websites for black-box warning: Bupropion FDA black-box warning Bupropion FDA Press Announcement</p>
Dosage	Patients should begin bupropion SR treatment 1-2 weeks before they quit smoking. Patients should begin with a dose of 150 mg every morning for 3 days, then increase to 150 mg twice daily. Dosage should not exceed 300 mg per day. Dosing at 150 mg twice daily should continue for 7-12 weeks. For long-term therapy, consider use of bupropion SR 150 mg for up to 6 months post-quit.
Availability	Prescription only
Prescribing instructions	<p><i>Stopping smoking prior to quit date</i>-- Recognize that some patients may lose their desire to smoke prior to their quit date, or will spontaneously reduce the amount they smoke.</p> <p><i>Dosing information</i>-- If insomnia is marked, taking the PM dose earlier (in the afternoon, at least 8 hours after the first dose) may provide some relief.</p> <p><i>Alcohol</i>-- Use alcohol only in moderation.</p>

Suggestions for the clinical use of nicotine gum

	Clinical Use of Nicotine Gum (FDA Approved)
Patient selection	Appropriate as a first-line medication for treating tobacco use.
Precautions, warnings, contraindications and side effects (see FDA package insert and website for complete list and updates)	<p>Pregnancy -- Pregnant smokers should be encouraged to quit without medication. Nicotine gum has not been shown to be effective for treating tobacco dependence in pregnant smokers. (Nicotine gum is an FDA pregnancy Class D agent.) Nicotine gum has not been evaluated in breast-feeding patients.</p> <p>Cardiovascular diseases -- NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) post-myocardial infarction period, those with serious arrhythmias, and those with unstable angina pectoris.</p> <p>Side effects -- Common side effects of nicotine gum include mouth soreness, hiccups, dyspepsia, and jaw ache. These effects are generally mild and transient, and often can be alleviated by correcting the patient's chewing technique (see <i>prescribing instructions</i> below).</p>
Dosage	<p>Nicotine gum (both regular and flavored) is available in 2 mg and 4 mg (per piece) doses. The 2 mg gum is recommended for patients who smoke their first cigarette <i>more than 30 minutes after waking</i>, while the 4 mg gum is recommended for patients who smoke their first cigarette <i>within 30 minutes of waking</i>. Smokers should use at least 1 piece every 1 to 2 hours for the first six weeks. The gum should be used for up to 12 weeks post-quit with no more than 24 pieces used per day.</p> <p>Pre-quit - Patients may begin using nicotine gum up to 6 months <i>before</i> the quit date along with reducing the number of cigarettes smoked per day.</p>
Availability	OTC only
Prescribing instructions	<p>Chewing technique -- Gum should be chewed slowly until a "peppery" or "flavored" taste emerges, then "parked" between cheek and gum to facilitate nicotine absorption through the oral mucosa. Gum should be slowly and intermittently "chewed and parked" for about 30 minutes or until the taste dissipates.</p> <p>Absorption -- Acidic beverages (e.g., coffee, juices, soft drinks) interfere with the buccal absorption of nicotine, so eating and drinking anything except water should be avoided for 15 minutes before or during chewing.</p> <p>Dosing information -- Patients often do not use enough prn NRT medicines to obtain optimal clinical effects. Instructions to chew the gum on a fixed schedule (at least one piece every 1-2 hours) for at least 1-3 months may be more beneficial than <i>ad libitum</i> use.</p>

Suggestions for the clinical use of the nicotine inhaler

Clinical Use for the Nicotine Inhaler (FDA Approved)	
Patient selection	Appropriate as a first-line medication for treating tobacco use.
Precautions, warnings, contraindications and side effects (see FDA package insert and website for complete list and updates)	<p><i>Pregnancy</i> -- Pregnant smokers should be encouraged to quit without medication. The nicotine inhaler has not been shown to be effective for treating tobacco dependence in pregnant smokers. (The nicotine inhaler is an FDA pregnancy Class D agent.) The nicotine inhaler has not been evaluated in breast-feeding patients.</p> <p><i>Cardiovascular diseases</i> -- NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) post-myocardial infarction period, those with serious arrhythmias, and those with unstable angina pectoris.</p> <p><i>Local irritation reactions</i> -- Local irritation in the mouth and throat was observed in 40% of patients using the nicotine inhaler. Coughing (32%) and rhinitis (23%) also were common. Severity was generally rated as mild, and the frequency of such symptoms declined with continued use.</p>
Dosage	<p>A dose from the nicotine inhaler consists of a puff or inhalation. Each cartridge delivers a total of 4 mg of nicotine over 80 inhalations. Recommended dosage is 6-16 cartridges/day. Recommended duration of therapy is up to 6 months. Instruct patient to taper dosage during the final 3 months of treatment. Partially used cartridges can be saved for the next day.</p> <p><i>Pre-quit</i> - Patients may begin using the nicotine inhaler up to 6 months before the quit date along with reducing the number of cigarettes smoked per day.</p>
Availability	Prescription only
Prescribing instructions	<p><i>Ambient temperature</i> -- Delivery of nicotine from the inhaler declines significantly at temperatures below 40°F. In cold weather, the inhaler and cartridges should be kept in an inside pocket or other warm area.</p> <p><i>Absorption</i> -- Acidic beverages (e.g., coffee, juices, soft drinks) interfere with the buccal absorption of nicotine, so eating and drinking anything except water should be avoided for 15 minutes before or during use of the inhaler.</p> <p><i>Dosing information</i> -- Patients often do not use enough prn NRT medicines to obtain optimal clinical effects. Use is recommended for up to 6 months with gradual reduction in frequency of use over the last 6-12 weeks of treatment. Best effects are achieved by frequent puffing of the inhaler and using at least 6 cartridges/day.</p>

Suggestions for the clinical use of the nicotine lozenge

	Clinical use of nicotine lozenge (FDA approved)
Patient selection	Appropriate as a first-line medication for treating tobacco use.
Precautions, warnings, contraindications and side effects (see FDA package insert and website for complete list and updates)	<p><i>Pregnancy</i> -- Pregnant smokers should be encouraged to quit without medication. The nicotine lozenge has not been shown to be effective for treating tobacco dependence for pregnant smokers. The nicotine lozenge has not been evaluated in breast-feeding patients. Because the lozenge was approved as an over-the-counter agent, it was not evaluated by the FDA for teratogenicity.</p> <p><i>Cardiovascular diseases</i> -- NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) post-myocardial infarction period, those with serious arrhythmias, and those with unstable angina pectoris.</p> <p><i>Side effects</i> -- The most common side effects of the nicotine lozenge are nausea, hiccups, and heartburn. Individuals on the 4 mg lozenge also had increased rates of headache and coughing (less than 10% of participants).</p>
Dosage	Nicotine lozenges are available in 2 mg and 4 mg (per piece) doses. The 2 mg lozenge is recommended for patients who smoke their first cigarette more than 30 minutes after waking, while the 4 mg lozenge is recommended for patients who smoke their first cigarette within 30 minutes of waking. Generally, smokers should use at least 9 lozenges per day in the first six weeks. The lozenge should be used for up to 12 weeks with no more than 20 lozenges/day.
Availability	OTC only
Prescribing instructions	<p><i>Lozenge use</i> -- The lozenge should be allowed to dissolve in the mouth rather than chewing or swallowing it.</p> <p><i>Absorption</i> -- Acidic beverages (e.g., coffee, juices, soft drinks) interfere with the buccal absorption of nicotine, so eating and drinking anything except water should be avoided for 15 minutes before or during use of the nicotine lozenge.</p> <p><i>Dosing information</i> -- Patients often do not use enough prn NRT medicines to obtain optimal clinical effects. Generally, patients should use one lozenge every 1-2 hours during the first six weeks of treatment, using a minimum of 9 lozenges/day, then decrease lozenge use to one lozenge every 2-4 hours during Weeks 7-9, and then to one lozenge every 4-8 hours for Weeks 10-12.</p>

Suggestions for the clinical use of the nicotine nasal spray

Clinical Use for Nicotine Nasal Spray (FDA Approved)	
Patient selection	Appropriate as a first-line medication for treating tobacco use.
Precautions, warnings, contraindications and side effects (see FDA package insert and website for complete list and updates)	<p><i>Pregnancy</i> -- Pregnant smokers should be encouraged to quit without medication. Nicotine nasal spray has not been shown to be effective for treating tobacco dependence in pregnant smokers. (Nicotine nasal spray is an FDA pregnancy Class D agent.) Nicotine nasal spray has not been evaluated in breast-feeding patients.</p> <p><i>Cardiovascular diseases</i> -- NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) post-myocardial infarction period, those with serious arrhythmias, and those with unstable angina pectoris.</p> <p><i>Nasal/airway reactions</i> -- Some 94% of users report moderate to severe nasal irritation in the first 2 days of use; 81% still reported nasal irritation after 3 weeks, although rated severity was typically mild to moderate. Nasal congestion and transient changes in sense of smell and taste also were reported. Nicotine nasal spray should not be used in persons with severe reactive airway disease.</p> <p><i>Dependency</i> -- Nicotine nasal spray produces higher peak nicotine levels than other NRTs and has the highest dependence potential of the nicotine replacement therapies. About 15-20% of patients report using the active spray for longer periods than recommended (6-12 months), and 5% used the spray at a higher dose than recommended.</p>
Dosage	A dose of nicotine nasal spray consists of one 0.5 mg dose delivered to each nostril (1 mg total). Initial dosing should be 1-2 doses per hour, increasing as needed for symptom relief. Minimum recommended treatment is 8 doses/day, with a maximum limit of 40 doses/day (5 doses/hr). Each bottle contains approximately 100 doses. Recommended duration of therapy is 3-6 months. Taper at end of treatment.
Availability	Prescription only
Prescribing instructions	<i>Dosing information</i> -- Patients should not sniff, swallow, or inhale through the nose while administering doses as this increases irritating effects. The spray is best delivered with the head tilted slightly back.

Suggestions for the clinical use of the nicotine patch

Clinical Use for the Nicotine Patch (FDA Approved)	
Patient selection	Appropriate as a first-line medication for treating tobacco use.
Precautions, warnings, contraindications and side effects (see FDA package insert and website for complete list and updates)	<p>Pregnancy -- Pregnant smokers should be encouraged to quit without medication. The nicotine patch has not been shown to be effective for treating tobacco dependence treatment in pregnant smokers. (The nicotine patch is an FDA pregnancy Class D agent.) The nicotine patch has not been evaluated in breast-feeding patients.</p> <p>Cardiovascular diseases -- NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) post-myocardial infarction period, those with serious arrhythmias, and those with unstable angina pectoris.</p> <p>Skin reactions -- Up to 50% of patients using the nicotine patch will experience a local skin reaction. Skin reactions are usually mild and self-limiting, but occasionally worsen over the course of therapy. Local treatment with hydrocortisone cream (1%) or triamcinolone cream (0.5%) and rotating patch sites may ameliorate such local reactions. In less than 5% of patients, such reactions require the discontinuation of nicotine patch treatment.</p> <p>Other side effects -- insomnia and/or vivid dreams.</p>
Dosage	<p>Patch comes in doses of 7 mg., 14 mg., or 21 mg. Patients should start the patch on the quit date and use one patch per day for up to 12 weeks post-quit. If patient smokes <i>more</i> than 10 cigarettes per day, dosing schedule should be 21 mg. patch for first 4 weeks; then 14 mg patch for the next 2 to 4 weeks; then 7 mg. patch for 2 to 4 weeks.</p> <p>Pre-quit: Patch may be used up to 6 months before quit date along with smoking reduction.</p>
Availability	OTC or prescription
Type	Duration
Step-Down Dosage	4 weeks then 2 weeks then 2 weeks

Suggestions for the clinical use of varenicline

	Clinical Use of Varenicline (FDA Approved)
Patient selection	Appropriate as a first-line medication for treating tobacco use.
Precautions, warnings, contraindications and side effects (see FDA package insert and website for complete list and updates)	<p>Pregnancy-- Pregnant smokers should be encouraged to quit without medication. Varenicline has not been shown to be effective for treating tobacco dependence in pregnant smokers. (Varenicline is an FDA pregnancy Class C agent.) Varenicline has not been evaluated in breast-feeding patients.</p> <p>Cardiovascular diseases -- Not contraindicated.</p> <p>Precautions-- Use with caution in patients with significant kidney disease (creatinine clearance < 30mL/min) or who are on dialysis. Dose should be reduced with these patients. Patients taking varenicline may experience impairment of the ability to drive or operate heavy machinery.</p> <p>Warning-- In February, 2008, the FDA added a warning regarding the use of varenicline. Specifically, it noted that depressed mood, agitation, changes in behavior, suicidal ideation, and suicide have been reported in patients attempting to quit smoking while using varenicline. The FDA recommends that patients should tell their healthcare provider about any history of psychiatric illness prior to starting this medication and clinicians should monitor for changes in mood and behavior when prescribing this medication. In light of these FDA recommendations, clinicians should consider eliciting information on their patients' psychiatric history. For further information, see FDA websites for black-box warning: Varenicline FDA black-box warning Varenicline FDA Press Announcement</p> <p>Side effects-- Nausea, trouble sleeping, abnormal/vivid/strange dreams.</p>
Dosage	Start varenicline one week before the quit date at 0.5 mg once daily for 3 days followed by 0.5 mg twice daily for 4 days followed by 1 mg twice daily for 3 months. Varenicline is approved for a maintenance indication for up to 6 months. Note: patient should be instructed to quit smoking on day 8 when dosage is increased to 1 mg twice daily. Alternatively, patient may begin varenicline and then quit between day 8 and day 35.
Availability	Prescription only
Prescribing instructions	<p>Stopping smoking prior to quit date-- Recognize that some patients may lose their desire to smoke prior to their quit date, or will spontaneously reduce the amount they smoke.</p> <p>Dosing information-- To reduce nausea, take on a full stomach. To reduce insomnia, take second pill at supper rather than bedtime.</p>

These medications have all been approved by the FDA for smoking cessation and have been shown to significantly improve abstinence rates. Choice of a specific first-line pharmacotherapy must be guided by factors such as

Not since the polio vaccine has this nation had a better opportunity to make a significant impact in public health”

clinician familiarity with the medications, contraindications for selected patients, patient preference, previous patient experience with a specific pharmacotherapy (positive or negative), and patient characteristics (e.g., history of depression, concerns about weight gain).

-- David Satcher, MD, PhD, Former U.S. Surgeon General

Combination medications

Four combinations of first-line medications have been shown to be effective smoking cessation treatments. Clinicians should consider using these combinations of medications with their patients who are willing to quit. However, only the nicotine patch and bupropion SR combination has been approved by the FDA for smoking cessation.

Combination Medications for Smoking Cessation

- **The nicotine patch + bupropion SR (FDA-approved)**
- **Long-term (> 14 weeks) nicotine patch + nicotine gum**
- **Long-term (> 14 weeks) nicotine patch + nicotine nasal spray**
- **The nicotine patch + the nicotine inhaler**
- **The nicotine patch + bupropion SR**

Decisions about using medication combinations can be based on considerations other than abstinence. Evidence indicates, for instance, that a combination of medications may suppress withdrawal symptoms better than a single medication. Patient preferences should also be considered since some combinations of medications may produce more side effects and cost more than single medications.

Addressing Smoking Lapses, Relapses, and Weight Gain

Smoking Lapses

All lapses back to smoking do not result in relapse. If a patient experiences a brief lapse, the clinician should help to reestablish abstinence.

Strategies to Help the Patient Who Has Experienced a Brief Lapse Back to Smoking

Suggest continued use of medications, which can reduce the likelihood that a lapse will lead to a full relapse.

Encourage another quit attempt or a recommitment to total abstinence.

Reassure that quitting may take multiple attempts, and use the lapse as a learning experience.

Provide or refer for intensive counseling.

Relapse

Clinicians and healthcare professionals should remain aware that relapse is likely and that it reflects the chronic nature of dependence. Most relapse begins early in a quit attempt, but can occur months and even after years of abstinence. Most smokers who ultimately quit smoking experience episodes of relapse along the way to success. Relapse should not discourage the clinician or the tobacco user from renewed quit attempts.

Evidence suggests that treatment can be effective despite the presence of risk factors for relapse, but abstinence rates in smokers with these characteristics tend to be lower than rates in those without these characteristics.

Factors Associated With Lower Abstinence Rates and Greater Chance of Relapse

Factor	Examples
High nicotine dependence	Tobacco user smokes heavily (=20 cigarettes/day), and/or has first cigarette of the day within 30 minutes after waking in the morning.
Psychiatric comorbidity and substance use	Tobacco user has currently elevated depressive symptoms, active alcohol abuse, or schizophrenia.
High stress level	Stressful life circumstances and/or recent or anticipated major life changes (e.g., divorce, job change).
Exposure to other smokers	Other smokers in the household.
Premature discontinuation of use of medicine	Discontinuing medication use after a few days of abstinence or after a slip or relapse.

Patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt. If they are currently motivated to make another quit attempt, clinicians may wish to increase the intensity of psychosocial treatment or refer the patient to a tobacco dependence specialist or program for more intensive treatment. In addition, medication should be offered to the patient, if appropriate. If the previous quit attempt included medication, the clinician should review if the patient used the medication in an effective manner, for the recommended length of time, and if it was helpful. Based on this assessment, the clinician should recommend retreatment with the same medication, another medication, or a combination of medications.

Because relapse results in continuing lifetime exposure to tobacco, clinicians should provide brief, effective relapse prevention treatment to all patients who have recently quit tobacco use. With the extraordinarily high rates of relapse to smoking, clinicians must assist their patients in staying quit.

Clinicians should:

1. Reinforce the patient's decision to quit,
2. Review the benefits of quitting,
3. Assist the patient in resolving any residual problems arising from quitting.

Minimal relapse prevention consists of:

1. Congratulating success
2. Encouraging continued abstinence
3. Discussing with the patient the benefits of quitting, the problems encountered during quitting and the anticipated challenges to staying quit (e.g., alcohol, weight gain, stress, and other tobacco users in the household).

How do I help prevent a former tobacco user from relapsing?



Individualize Relapse Prevention

A more intensive relapse prevention intervention, individualized to address the particular challenges and concerns of the individual patient, can also be utilized by clinicians.

Challenge or Concern	Suggested Responses
Lack of support from family, friends, or associates	<ul style="list-style-type: none">▪ Schedule follow-up visits or phone calls▪ Refer to organizations that offer counseling or support▪ Help patient identify possible support persons within his or her environment.
Negative mood, sadness, depression	<ul style="list-style-type: none">▪ Provide counseling▪ If appropriate, prescribe medication or refer patient to a specialist.
Long-lasting or severe withdrawal symptoms (craving)	<ul style="list-style-type: none">▪ Consider extending the use of approved medications or combining medications to reduce nicotine withdrawal.
Weight gain	<ul style="list-style-type: none">▪ Inform patient that some weight gain is common; but it is self-limiting (usually about 10 pounds) and much less of a health risk than continued tobacco use.▪ Emphasize importance of healthy diet and moderate exercise.▪ Encourage patient to limit alcohol consumption.▪ Consider using medications known to delay (but not prevent) weight gain (bupropion SR, and nicotine replacement therapies, particularly 4 mg nicotine gum or 4 mg nicotine lozenge).
Flagging motivation, feelings of deprivation	<ul style="list-style-type: none">▪ Reassure patients that these are common feelings during withdrawal from nicotine and will pass with continued abstinence.▪ Recommend engaging in rewarding activities.▪ Caution against beginning to smoke since even a single puff will increase urges and make quitting more difficult.

Relapse is common in treating tobacco dependence and often is followed by successful cessation.

Weight Gain After Stopping Smoking

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

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

For some smokers, especially women, concerns about weight or fears about weight gain are motivators to start smoking or continue smoking. Adolescents, even as young as junior high school age, who are concerned about their weight initiate smoking more often than do other adolescents.

Recommendations to clinicians when addressing weight gain

How should the clinician deal with concerns about weight gain? First, the clinician should neither deny the likelihood of weight gain nor minimize its significance to the patient. Rather, the clinician should inform the patient about the likelihood of weight gain. The clinician should also counter exaggerated fears about weight gain given the relatively moderate weight gain that typically occurs.

Clinician Statements to Help a Patient Prepare for, and Cope With, Post-cessation Weight Gain

Clinician Statements

The great majority of smokers gain weight once they quit smoking. However, even without special attempts at dieting or exercise, weight gain is usually 10 lbs or less.

Some medications including bupropion SR and nicotine replacement medicines may delay weight gain.

There is evidence that smokers often gain weight once they quit smoking, even if they do not eat more. However, there are medications that will help you quit smoking and limit or delay weight gain. I can recommend one for you.

The amount of weight you will likely gain from quitting will be a minor health risk compared with the risks of continued smoking.

I know that you don't want to gain a lot of weight. However, let's focus on strategies to get you healthy rather than on weight. Think about eating plenty of fruits and vegetables, getting regular exercise, getting enough sleep, and avoiding high-calorie foods and beverages. Right now, this is probably the best thing you can do for both your weight and your health.

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

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

Effective Treatments for Specific Populations

The interventions found to be effective in this Guideline have been shown to be effective in a variety of populations. Therefore, interventions identified as effective in the PHS Guideline Update are recommended for all individuals who use tobacco, except when medication use is contraindicated or with specific populations in which medication has not been shown to be effective (pregnant women, smokeless tobacco users, light smokers [less than 10 cigarettes per day], and adolescents).

Clinical Issues for Treating Specific Populations

Issue	Approach
Language	<ul style="list-style-type: none">▪ Ensure that interventions are provided in a language the patient understands. Most quitlines provide counseling in Spanish, and some provide counseling in other languages.▪ All textual materials used (e.g., self-help brochures) should be written at an appropriate reading level.▪ This is particularly important given epidemiological data showing that tobacco use rates are markedly higher among individuals of lower educational attainment.
Culture	<ul style="list-style-type: none">▪ Interventions should be culturally appropriate to be relevant and acceptable to the patient.▪ Clinicians should remain sensitive to individual differences and spiritual and health beliefs that may affect treatment acceptance, use, and success in all populations.
Medical comorbidity	<ul style="list-style-type: none">▪ Examine the possibility of medication interactions.▪ Address how exposure to tobacco can alter the liver's ability to metabolize different medications (HIV-positive patients).

HIV-Positive Smokers

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

Hospitalized Smokers

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

Hospitalized patients may be particularly motivated to make a quit attempt and clinicians should take advantage of this "teachable moment".

Suggested Interventions for Hospitalized Patients

Ask each patient on admission if he or she uses tobacco and document tobacco use status.

For current tobacco users, list tobacco use status on the admission problem list and as a discharge diagnosis.

Use counseling and medications to help all tobacco users maintain abstinence and to treat withdrawal symptoms.

Provide advice and assistance on how to quit during hospitalization and remain abstinent after discharge.

Arrange for follow-up regarding smoking status. Supportive contact should be provided for at least a month after discharge.

Lesbian/Gay/Bisexual/Transgender (LGBT) Smokers

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

Low SES/Limited Formal Education Smokers

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

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

Tobacco users with comorbid medical conditions such as cancer, cardiac disease, COPD, diabetes, and asthma are important to target for tobacco use treatments, given the role that smoking plays in exacerbating these conditions. Likewise, the American Dental Association urges its members to become fully informed about tobacco cessation interventions to effectively educate their patients to overcome their addiction to tobacco. Clinicians treating smokers with these conditions have an ideal "teachable moment" in that they are treating a disease that may have been caused or exacerbated by smoking and that can be ameliorated by quitting but not by cutting down. Using chronic disease management programs to integrate tobacco dependence interventions into treatment may be an effective and efficient way to deliver tobacco use interventions to these populations.

Older Smokers

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

Psychiatric Disorders, Including Substance Use Disorders

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

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

Racial and Ethnic Minority Populations

Some racial and ethnic minority populations in the United States -- African Americans, American Indians and Alaska Natives, Asians and Pacific Islanders, Hispanics -- experience higher mortality in a number of disease categories compared with others. For example, African Americans experience substantial excess mortality from cancer, cardiovascular disease, and infant death, all of which are directly affected by tobacco use. Moreover, they experience greater exposure to tobacco advertising. American Indian and Alaska Natives have some of the highest documented rates of infant mortality caused by SIDS, which also is affected by tobacco use and exposure to secondhand smoke. Therefore, the need to deliver effective tobacco dependence interventions to ethnic and racial minority smokers is critical. Unfortunately, evidence indicates that large proportions of some racial/ethnic groups lack adequate access to primary care providers and are more likely to have low SES. These populations may be less aware of Medicaid or other available benefits and more likely to harbor misconceptions about tobacco dependence treatments. Finally, these populations may be less likely to receive advice to stop smoking or use tobacco dependence treatment than are other individuals. This suggests that special efforts and resources should be provided to meet the treatment needs of these underserved populations. The differences between racial and ethnic minorities and whites in smoking prevalence, smoking patterns, pharmacokinetics of nicotine, and quitting behavior in the United States are well documented. In addition, smoking prevalence and patterns vary substantially across and within minority subgroups (e.g., gender, level of acculturation, tribal communities). Racial and ethnic minority groups also differ from whites in awareness of the health effects of smoking and awareness of the benefits of proven treatments, and some racial and ethnic minority populations report a greater sense of fatalism that may affect disease prevention efforts. On the other hand, both tobacco dependence and desire to quit appear to be prevalent across varied racial and ethnic groups. In fact, smokers in several racial and ethnic groups attempt to quit as often as or more often than nonminority smokers, but use effective treatments less often and have lower success rates.

Women

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

Children and Adolescents

Clinicians should ask pediatric and adolescent patients about tobacco use and provide a strong message regarding the importance of totally abstaining from tobacco use. Counseling has been shown to be effective in treatment of adolescent smokers. Therefore, adolescent smokers should be provided with counseling interventions to aid them in quitting smoking.

Secondhand smoke is harmful to children. Cessation counseling delivered in pediatric settings has been shown to be effective in increasing abstinence among parents who smoke. Therefore, to protect children from secondhand smoke, clinicians should ask parents about tobacco use and offer them cessation advice and assistance.

Tobacco use is a pediatric concern. In the United States, about 4,000 children and adolescents under age 18 smoke their first cigarette each day, and an estimated 1,200 children and adolescents become daily cigarette smokers each day. Because of the importance of primary prevention, clinicians should ensure that they deliver tobacco prevention and cessation messages to pediatric patients and their parents. Because tobacco use often begins during preadolescence, clinicians should routinely assess and intervene with this population. Young people vastly underestimate the addictive potential of nicotine. Adolescents are very interested in quitting. Adolescent quit attempts are rarely planned, and adolescents tend to choose unassisted rather than assisted quit methods, even though young people who enroll in a tobacco cessation program are twice as likely to succeed in their quit attempt.

Counseling provided to parents during the pediatric visit

Recent research suggests that tobacco use interventions provided to parents in pediatric clinics or during child hospitalizations increase parents' interest in stopping smoking, parents' quit attempts and parents' quit rates. Children and adolescents also benefit if parents are given information on secondhand smoke exposure. The American Medical Association has a guide to help clinicians address environmental tobacco smoke and that guide can be found at: <http://www.ama-assn.org/resources/doc/public-health/environmental-tobacco-smoke.pdf>

Tobacco use medications with adolescents

Not recommended.

Current evidence is insufficient to suggest that the use of tobacco cessation medications increases long-term abstinence among adolescents. Therefore, the use of cessation medications is not recommended for this population.

Light Smokers

Light smokers (less than 10 cigarettes per day) should be identified, strongly urged to quit, and provided counseling cessation interventions.

Light smoking is becoming more common, perhaps due to smoking restrictions and increases in the price of cigarettes.

Many light smokers want to quit but have difficulty doing so. Light smokers should be provided effective counseling treatments. One study found that health education was more effective than motivational interviewing for African-American light smokers.

Tobacco use medications with light smokers

Not recommended.

Current evidence is insufficient to suggest that the use of tobacco cessation medications increases long-term abstinence among light smokers. Therefore, the use of cessation medications is not recommended for this population.

Noncigarette Tobacco Users

Smokeless tobacco users should be identified, strongly urged to quit, and provided counseling cessation interventions.

Clinicians delivering dental health services should provide brief counseling interventions to all smokeless tobacco users.

Users of cigars, pipes, and other noncigarette forms of smoking tobacco should be identified, strongly urged to quit, and offered the same counseling interventions recommended for cigarette smokers.

Like cigarette smoking, the use of smokeless tobacco, such as chewing tobacco, snuff, or moist snuff, produces addiction to nicotine and has serious health consequences. The use of smokeless tobacco is not a safe alternative to smoking, nor is there evidence to suggest that it is effective in helping smokers quit. Evidence shows that counseling treatments are effective in treating smokeless tobacco users. Therefore, clinicians should offer quitting advice and assistance to their patients who use tobacco, regardless of the formulation of the tobacco product. Dentists and hygienists delivering brief advice to quit using smokeless tobacco, in the context of oral hygiene feedback, can increase abstinence rates. Clinicians should be aware of and address the use of other noncigarette tobacco products, including pipes, water pipes (also known as hookahs and narghile), cigarillos, loose tobacco, bidis, and betel quid.

Tobacco use medications with users of noncigarette tobacco

Not recommended.

Current evidence is insufficient to suggest that the use of tobacco cessation medications increases long-term abstinence among users of smokeless tobacco. Therefore, the use of cessation medications is not recommended for this population.

Pregnant Smokers

Because of the serious risks of smoking to the pregnant smoker and the fetus, whenever possible pregnant smokers should be offered person-to-person psychosocial interventions that exceed minimal advice to quit. Although abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in pregnancy can yield benefits. Therefore, clinicians should offer effective tobacco dependence interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy.



Examples of effective psychosocial interventions with pregnant patients

Physician advice regarding smoking-related risks (2-3 minutes); videotape with information on risks, barriers, and tips for quitting; midwife counseling in one 10-minute session; self-help manual; and followup letters. Pregnancy-specific self-help materials and one 10-minute counseling session with a health educator. Counselor provided one 90-minute counseling session plus bimonthly telephone followup calls during pregnancy and monthly telephone calls after delivery.

Cigarette smoking during pregnancy is the greatest modifiable risk factor for pregnancy-related morbidity and mortality in the United States. Smoking in pregnancy imparts risks to both the woman and the fetus. Cigarette smoking by pregnant women has been shown to cause adverse fetal outcomes, including stillbirths, spontaneous abortions, decreased fetal growth, premature births, low birth-weight, placental abruption, and sudden infant death syndrome (SIDS); and has been linked to cognitive, emotional, and behavioral problems in children. Many women are motivated to quit during pregnancy, and health care professionals can take advantage of this motivation by reinforcing the knowledge that cessation will reduce health risks to the fetus and that there are postpartum benefits for both the mother and child.

Clinical Practice Suggestions for Assisting a Pregnant Patient in Stopping Smoking

Clinical practice	Rationale
<p>Assess pregnant woman's tobacco use status using a multiple-choice question to improve disclosure.</p>	<p>Many pregnant women deny smoking, and the multiple-choice question format improves disclosure. For example: Which of the following statements best describes your cigarette smoking?</p> <ul style="list-style-type: none"> ▪ I smoke regularly now; about the same as before finding out I was pregnant. ▪ I smoke regularly now, but I've cut down since I found out I was pregnant. ▪ I smoke every once in a while. ▪ I have quit smoking since finding out I was pregnant. ▪ I wasn't smoking around the time I found out I was pregnant, and I don't currently smoke cigarettes.
<p>Congratulate those smokers who have quit on their own.</p>	<p>To encourage continued abstinence.</p>
<p>Motivate quit attempts by providing educational messages about the impact of smoking on both maternal and fetal health.</p>	<p>These are associated with higher quit rates.</p>
<p>Give clear, strong advice to quit as soon as possible.</p>	<p>Quitting early in pregnancy provides the greatest benefit to the fetus.</p>
<p>Use problem-solving counseling methods and provide social support and pregnancy-specific self-help materials.</p>	<p>Reinforces pregnancy-specific benefits and increases cessation rates.</p>
<p>Arrange for followup assessments throughout pregnancy, including further encouragement of cessation.</p>	<p>The woman and her fetus will benefit even when quitting occurs late in pregnancy.</p>
<p>In the early postpartum period, assess for relapse and be prepared to continue or reapply tobacco cessation interventions, recognizing that patients may minimize or deny smoking.</p>	<p>Postpartum relapse rates are high, even if a woman maintains abstinence throughout pregnancy.</p>

Tobacco use medication for pregnant smokers

Not recommended.

Current evidence is insufficient to suggest that the use of tobacco cessation medications increases long-term abstinence among pregnant women. Therefore, the use of cessation medications is not recommended for this population.