

Tobacco Use Guideline

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Last guideline approval: February 2015

Guidelines are systematically developed statements to assist patients and providers in choosing appropriate health care for specific clinical conditions. While guidelines are useful aids to assist providers in determining appropriate practices for many patients with specific clinical problems or prevention issues, guidelines are not meant to replace the clinical judgment of the individual provider or establish a standard of care. The recommendations contained in the guidelines may not be appropriate for use in all circumstances. The inclusion of a recommendation in a guideline does not imply coverage. A decision to adopt any particular recommendation must be made by the provider in light of the circumstances presented by the individual patient.

Major Changes as of February 2015

- Information has been added on alternative nicotine products (such as e-cigarettes and hookahs), including talking points for prevention counseling.
- A table of tobacco cessation resources, including web and mobile apps, has been added.
- Varenicline and bupropion are now equal options as monotherapy for adults. Varenicline no longer requires prior authorization.
- Nicotine replacement therapy (NRT) plus varenicline, and bupropion plus varenicline are now second-line options for combination therapy. Neither combination was recommended in the previous edition.
- A new section on lung cancer screening has been added.

Tobacco Use Prevalence and Patterns

Nationwide, 18% of adults are current cigarette smokers, a rate that has remained constant over the past 10 years. Almost 90% of adults who smoke started before the age of 18 (2012 Surgeon General's Report). In 2012, the smoking prevalence rate among high school students nationwide was 23.3%.

Alternative Nicotine Products

Among adults and adolescents, the use of alternative nicotine products (including e-cigarettes, hookahs, and smokeless tobacco) has been on the rise. The 2014 Surgeon General's Report [LINK] found that nicotine use in any form can have adverse effects.

Electronic cigarettes

Electronic cigarettes mimic conventional cigarettes by producing a vapor from heated liquid nicotine for inhalation. In the 2013 National Youth Tobacco Survey results, 3% of middle school and 11.9% of high school students reported ever using e-cigarettes. The 2013 National Adult Tobacco Survey reported an even higher percentage, with 14.1% of adults reporting that they had ever used e-cigarettes.

Use of these devices—also known as e-cigarettes, e-cigs, or electronic nicotine delivery systems (ENDS)—is called “**vaping**.” Most e-cigs contain an electronic heating element, a battery, and a cartridge that contains a liquid solution of propylene glycol and/or glycerol and nicotine. E-cigs are either disposable, to be discarded once the liquid is gone, or rechargeable. The liquid cartridges come in a wide variety of flavors such as tobacco, strawberry, and chocolate, many of which appeal to children.

The FDA currently allows e-cigarettes to be sold as tobacco products. However, **it does not allow these devices to be marketed for smoking cessation**. In April 2014, the FDA announced that it would expand its authority over e-cigarettes. At present, the sale and manufacture of these devices is unregulated.

Washington state currently prohibits the sale of e-cigs to anyone under age 18. King County has banned use in public places. The current literature does not specifically address the long-term impacts of e-cigarette use. Inhalant exposures associated with e-cigarettes and their health effects are the subject of ongoing study.

Hookahs

A hookah is a water pipe used to smoke a tobacco product called “**shisha**.” As traditional cigarette smoking decreases in young people, hookah use is on the rise. Almost 20% of high school students have tried it, as have 40% of college students. Hookah lounges are accessible locations for young people below the legal drinking age to meet. The tobacco comes in colorful packaging and in fruit, chocolate, and other flavors that appeal to youth.

An important aspect of the hookah's appeal is the mistaken belief that hookah use is safer than cigarette smoking.

Smokeless tobacco

Approximately 5% of high school students use chewing tobacco, snuff, or dip. Moist snuff now comes in flavors designed to appeal to youth, such as mint and a variety of fruits. Two percent use “**snus**,” small, teabag-like pouches containing tobacco and other flavorings that users place between their upper gum and lip. Because snus does not require spitting, its use can be easily concealed.

Smokeless tobacco causes tooth decay, oral lesions, and cancer of the mouth, esophagus and pancreas, contains addictive nicotine, and increases the user’s likelihood of becoming a cigarette smoker.

Prevention

Because approximately 90% of tobacco users start before the age of 21, it is important to begin prevention counseling at an early age ([2012 Surgeon General’s Report](#)).

Non-smokers – adolescents	Counsel children and adolescents (aged 11–21) at all visits to avoid tobacco experimentation and note that alternative nicotine methods are also unsafe. (See “Talking points for prevention counseling in adolescents,” below.) The USPSTF recommends using behavioral counseling interventions such as face-to-face or phone interactions with a health care provider, print materials, and computer applications to reduce the risk for smoking initiation in school-aged children and adolescents.
Non-smokers – all ages	Counsel all non-smokers to avoid secondhand tobacco smoke.
Smokers	Advise current smokers that parental, sibling, or peer tobacco use and experimentation are major risk factors for the initiation of smoking among adolescents. Counsel current smokers about the dangers to others of secondhand smoke, especially for children.

Talking points for prevention counseling in adolescents

General tobacco and nicotine use

(Source: www.cdc.gov/tobacco/data_statistics/sgr/2012/pdfs/physician_card508.pdf)

Ask your teen patients what they know about tobacco/nicotine use and health, and help them fill in the gaps. Key points include:

- Teens are more susceptible to nicotine addiction than adults. While fewer than one out of five high school students smoke, nearly four out of five who do smoke continue into adulthood, even if they plan to quit after a few years.
- As a group, teen smokers are no thinner than their non-smoking peers.
- It’s much easier to say “no” in the first place than to quit later.

E-cigarettes and other “vaping” devices

- All tobacco products, even the smokeless ones, contain nicotine and can cause addiction.
- Because e-cigarettes are unregulated, their contents vary widely. In some cases, the products contain materials not included on the label. Some samples contain carcinogens and toxic chemicals such as diethylene glycol—an ingredient in antifreeze.
- Reports of **accidental poisonings** through exposure to the liquid nicotine, particularly among children, have soared in the past several years as e-cigs have become more popular.

Hookahs

- Although hookah smoke might have reduced nicotine levels compared to cigarettes, it has higher levels of many carcinogens, including arsenic and lead. Hookah smoke contains high levels of toxic agents known to:
 - Cause cancer of the lung, bladder, stomach, and mouth,
 - Clog arteries,
 - Cause heart disease,
 - Reduce lung function, and
 - Decrease fertility.
- Tobacco-containing shisha delivers the addictive drug nicotine, and the more frequently it is smoked the more likely it is to cause addiction.
- Sharing the mouthpiece of a hookah places the user at risk for infections like herpes and hepatitis A.
- A typical 1-hour hookah session consists of 200 puffs compared to fewer than 20 puffs in an average cigarette, and the amount of smoke inhaled is well over 100 times greater (90,000 mL compared to 600 mL). Because water pipe use also leads to deeper and longer inhalation of tobacco, hookah users may actually absorb more of the toxic substances than cigarette smokers.

Smokeless tobacco

Smokeless tobacco, including snus, is known to:

- Cause cancer of the mouth, esophagus and pancreas, and tooth decay and oral lesions
- Contain addictive nicotine
- Increase your likelihood of becoming a cigarette smoker.

Screening

Screening for tobacco use

Every patient must have smoking history documented in Epic.

Table 2. Recommendations for tobacco use screening		
Eligible population	Screening ¹	Recommended frequency
Adults, including pregnant women	Ask about tobacco use.	Every visit. ²
Adolescents	Ask about tobacco use.	Every visit.
Children	Ask about exposure to secondhand smoke and tobacco use by parents or caregivers.	

¹ The screening question “Have you ever used tobacco (smoke, chew, e-cigarettes) or vapor products?” is included on the well visit questionnaires for ages 10 and older.

² For adults who have never smoked, less frequent screening may be considered, but should be done at a minimum at all Well Visits. The [2012 U.S. Surgeon General's Report](#) found that virtually all adult smokers started smoking before the age of 26.

Screening for lung cancer

Patients who are current smokers or have quit within the past 15 years should be assessed to determine whether they are eligible for lung cancer screening. See the Lung Cancer Screening Guideline for more information.

Lung cancer screening with low-dose computed tomography (LDCT) is recommended for patients who meet **all of the following criteria**:

- Are ages 55 through 74,
- Have at least a 30-year pack history,
- Currently smoke or quit less than 15 years ago, **and**
- Have no significant comorbidities that would preclude surgical treatment or limit life expectancy.

While screening with LDCT can prevent some lung cancer deaths, it is important to emphasize to patients that the single most effective way to reduce lung cancer risk is smoking cessation. For every year patients don't smoke, their risk for lung cancer goes down.

Interventions

All tobacco users should be strongly urged to quit.

Tobacco dependence is a chronic condition that often requires repeated interventions. At a minimum, provide brief cessation messages repeatedly over an extended period of time. Motivational interviewing may be more effective than brief advice. Also, success in quitting tobacco depends less on any specific intervention modality than on the delivery of personalized cessation advice to patients, repeated in different forms by several sources over a long period (Kottke 1988).

Internet-based and mobile phone-based interventions can be effective for smoking cessation in adults when they are interactive and individually tailored. Treatment effect may vary according to individuals' socioeconomic status and level of motivation to quit.

Electronic cigarettes are *not* an intervention

Although the FDA does not allow e-cigs to be marketed as smoking cessation aids, they are frequently promoted as such. However, available evidence does not support use of these devices for cessation, and some evidence suggests that their use may encourage continued smoking by reinforcing smokers' reliance on nicotine and the behavioral habit of "smoking."

1. Former Tobacco Users Who Recently Quit

Goal

Prevent relapse.

Counseling interventions

Arrange for follow-up contacts, either in person or via telephone. The first two follow-ups are recommended within 1 week and 1 month of the quit date, respectively. Relapse is most common in the first 1–2 weeks after quitting.

The former tobacco user should receive repeated congratulations on any success (even if only brief) and strong encouragement to remain abstinent or make a new quit attempt, if necessary. Relapse remains common within the first year of cessation.

For recent quitters, use open-ended questions relevant to the topics below:

- The benefits, including potential health benefits that derive from cessation.
- Any success the patient has had in quitting (duration of abstinence, reduction in withdrawal, etc.).
- The problems encountered and dangers to maintaining abstinence.
- A medication check-in, including adherence and side effects.

Recognize danger situations that increase the risk of relapse:

- Depression
- Being around other smokers
- Drinking alcohol
- Experiencing urges
- Time pressure
- Life stressors

Provide basic information about smoking and successful quitting:

- Tobacco use is addictive.
- Withdrawal symptoms include negative mood, urges to smoke, and difficulty concentrating.
- Withdrawal typically peaks within 1–3 weeks after quitting.
- Any smoking (even a single puff) increases the likelihood of full relapse.

- Use of pharmacotherapies can reduce withdrawal symptoms. See “Pharmacologic options,” p. 10.
- Odds of successful quitting are significantly increased with combination use of medication and counseling compared to either counseling or medication alone (Stead 2012).

2. Former Tobacco Users with Lapses

Goal

Encourage another quit attempt or a recommitment to total abstinence.

Counseling interventions

- Suggest continued use of medications, which can reduce the likelihood that a lapse will lead to a full relapse.
- Reassure the patient that quitting may take multiple attempts, and use the lapse as a learning experience.
- Refer the patient to the Quit For Life® Program.

3. All Current Tobacco Users

Goal

Quit all tobacco use.

Counseling interventions

Urge every tobacco user to quit in a clear, strong, and personalized manner.

- "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."
- Tie tobacco use to the patient's current health or illness, social and economic costs, impacts on children, pets, and others in the household.

Assess the patient's readiness to attempt to quit using tobacco. Ask, "Are you willing to make a quit attempt within the next 30 days?"

- If **yes**, see "Tobacco users who are ready to quit," below.
- If **no**, acknowledge the patient's choice, let the patient know that effective treatments are available when they are ready to quit, and follow up at subsequent visits.

Strategies for engaging patients and enhancing their motivation to quit tobacco can include:

- Encouraging them to indicate why quitting is personally relevant, being as specific as possible.
- Asking them to identify potential benefits of stopping tobacco use.
- Using a "readiness ruler." Patients can be asked the following questions at every engagement visit:

On a scale from 0 to 10:

1. How **IMPORTANT** do you feel it would be to change your tobacco use?
2. How **CONFIDENT** do you feel that you can change your tobacco use?

Ask follow-up questions about the patient's self-rating. Asking, "Why not a higher number?" gives the patient an opportunity to explore and articulate current **barriers** to quitting tobacco, while "Why not a lower number?" can elicit the patient's **motivations** to change or their self-efficacy. The actual number patients assign themselves is not important, but the discussion that follows can help increase a smoker's readiness to quit.

4. Current Tobacco Users Who Are Ready to Quit

Goals

Develop a quit plan with the patient. Discuss smoking cessation programs, clinic-based counseling (Primary Care or Adolescent Center), web- or mobile phone-based interventions, drug treatment, and follow-up.

Counseling interventions

Option 1: Refer the patient to a tobacco cessation counseling program.

For patients aged 18 years and older:

- The Quit For Life® Program, a comprehensive tobacco cessation program. Members are eligible to participate in the program at no cost. Quit For Life® provides individual telephone counseling sessions with coaches who screen participants for medication appropriateness, contraindications or precautions; make initial dosing recommendations; and provide follow-up and support for medication use. Participants can also access the program coaches online. Have the patient call 1-800-462-5327 for more information, or use the Quit For Life® e-referral in Epic.
- Some patients may also be eligible for services through the Washington State Quitline, but certain restrictions apply. All Washington state residents may also get online information and resources to help in quitting from Washington’s Department of Health at www.quitline.com or by calling 1-800-QUIT-NOW. In Idaho, use www.quitnow.net/idaho.

For patients under age 18 years:

- Teens can be referred to the Washington State Quitline at 1-800-QUIT-NOW. In Idaho, use www.quitnow.net/idaho.

Table 3. Tobacco cessation resources for ADULTS	
In-person	Primary Care team
Phone	Quit For Life® Program: 1-800-462-5327 Washington State Quitline: 1-800-QUIT-NOW Available in English, Spanish, Chinese, Korean, Vietnamese
Web	Patient information Quit For Life® Program Web Coach® Washington State Quitline Smokefree (NCI) Interactive quizzes, social media connections, health information
Mobile app	Quit For Life® app Tips and reminders through quit and after; savings calculator NCI QuitPal Users can track cravings/mood, monitor progress, identify triggers, and upload personalized “pick-me-ups” and reminders. QuitGuide (NCI) SmokefreeTXT (text messaging)

Table 4. Tobacco cessation resources for ADOLESCENTS

In-person	Primary Care team Adolescent Center
Phone	Washington State Quitline: 1-800-QUIT-NOW
Web	Patient information Smokefree Teen (NCI) Interactive quizzes, social media connections, health information
Mobile app	SmokefreeTXT (text messaging) QuitSTART app Users can track cravings/mood, monitor progress, identify triggers, and upload personalized “pick-me-ups” and reminders.

Option 2: Deliver counseling at clinic visits.

For teens, consider referral to the Adolescent Center for counseling.

Help patients with a quit plan by instructing them to:

- Set a quit date. Ideally, the quit date should be within 2 weeks.
- Tell family, friends, and coworkers about quitting and request their understanding and support.
- Anticipate challenges to planned quit attempt, particularly during the critical first few weeks. These include nicotine withdrawal symptoms.
- Remove tobacco products from their environment. Prior to quitting, avoid smoking in places where they spend a lot of time (e.g., work, home, car).

Provide practical counseling by addressing:

- Abstinence. Total abstinence is essential, including "not even a single puff after the quit date."
- Past quit experiences. Review past quit attempts, including identification of what helped during the quit attempt and what factors contributed to relapse.
- Potential triggers or challenges in the upcoming attempt. Discuss challenges/triggers and how the patient will successfully overcome them.
- Alcohol use. Because alcohol can cause tobacco relapse, the patient should consider limiting/abstaining from alcohol while quitting.
- Other smokers in the household. Quitting is more difficult when there is another smoker in the household. Patients should encourage housemates to quit with them or not smoke in their presence.

Pharmacologic options

Criteria for medication treatment for current tobacco users:

- Motivated and ready to quit.
- Agrees to 100% cessation as a goal, quit date, and follow-up.
- Smokes more than one-half pack per day or uses smokeless tobacco regularly.
- Requests drug therapy.
- Over-the-counter nicotine replacement therapy (NRT) products—including patches, gum, and lozenges—are covered for most but not all members; questions about individual coverage should be directed to Member Services. While Quit For Life® enrollment is not required for coverage of NRT products, nor for bupropion or varenicline, medications are more effective when paired with behavioral intervention. Encourage all members to enroll in Quit For Life® or a similarly comprehensive counseling program to improve their chances of quitting.

Monotherapy

There is good evidence that NRT (e.g., nicotine patch, gum, or lozenges), bupropion, varenicline, and nortriptyline are all effective at increasing smoking cessation rates. There is fair evidence that there is no significant benefit of one type of therapy over another. Based on cost and the potential for side effects, the order of preference of these medications is:

- First-line: NRT
- Second-line: bupropion or varenicline
- Third-line: nortriptyline

For patients who experience significant adverse effects with NRT or who have tried NRT in the past without success, consider using a second-line monotherapy.

For patients who have not achieved cessation with NRT alone and have not experienced any adverse effects, consider moving towards combination therapy.

Combination therapy

Combination therapy may be considered for patients who have not achieved cessation with any form of monotherapy or are highly dependent on nicotine. The order of preference of combination therapies is:

- First-line: Nicotine patch (for sustained control) plus nicotine gum or lozenge (for breakthrough cravings), or NRT (any form) plus bupropion
- Second-line: Nicotine patch plus varenicline, or bupropion plus varenicline

The Quit For Life® Program encourages selected participants to try the following combination therapies: two forms of NRT or NRT plus bupropion.

Adults

All of these therapies are options for adults (see Tables 5 and 6, pp. 12–13).

Adolescents

At this time NRT alone is the only pharmacologic option recommended for adolescents (see Table 5, p. 12). *Note:* Medication treatment is recommended only for patients who are nicotine dependent (i.e., who smoke 10 or more cigarettes per day or are regular users of alternative nicotine products). Because many teens who smoke use fewer than 10 cigarettes per day or are occasional users of alternative nicotine products, NRT would actually increase the amount of nicotine they consume.

FDA black box warnings for bupropion and varenicline

Bupropion

Effective July 2009, the FDA issued a boxed warning regarding the use of bupropion for smoking cessation. This is in addition to the existing class warning for all antidepressants related to the increase in risk of suicidality in children, adolescents, and young adults with major depression. The newer warning is based on post-marketing adverse event reports that suggest a possible association between bupropion and serious neuropsychiatric symptoms, both in patients with a previous history of psychiatric illness and in those without. Inform patients that serious neuropsychiatric symptoms have been reported in patients taking bupropion for smoking cessation. Also, advise patients to stop taking bupropion and contact a

health care provider immediately if they experience agitation, depressed mood, and any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. Monitor patients taking bupropion for smoking cessation, particularly in the first 2–4 weeks of therapy.

Varenicline

Effective July 2009, the FDA issued a boxed warning that serious neuropsychiatric symptoms have been reported in patients taking varenicline. These symptoms include changes in behavior, agitation, depressed mood, and suicidal ideation and behavior. (Note that some of these symptoms are also characteristic of nicotine withdrawal.) Symptoms have occurred in patients both with and without a history of psychiatric illness (current or past). In October 2014 the FDA met to discuss a filed application by Pfizer to remove the boxed warning on varenicline due to meta-analyses of randomized controlled trials showing no significant difference between varenicline and placebo, NRT, or bupropion with regard to neuropsychiatric events. The FDA upheld the boxed warning, stating that although no significant difference was seen, there is not reassuring evidence of an absence of risk for neuropsychiatric events. The FDA is awaiting the completion of a randomized controlled trial prospectively designed to evaluate the risk of neuropsychiatric events before reconsidering removal of the warning. Because of this safety concern, the FDA recommends that health care providers monitor **all** patients taking varenicline for serious neuropsychiatric symptoms.

Monotherapy treatment options

Table 5. Monotherapy treatment options					
Eligible population	Line	Medication	Initial dose	Maximum dose	
Adults and adolescents	1st	Nicotine transdermal patch	Tapering schedule ¹		
			> 1 pack per day ² (> 20 cigarettes)		
			Weeks 1–4: 21 mg patch per day Weeks 5–6: 14 mg patch per day Weeks 7–8: 7 mg patch per day	—	
			½–1 pack per day (10–20 cigarettes)		
			Start with 14 mg patch; can increase to 21 mg if needed and taper as above.	—	
			< ½ pack per day (< 10 cigarettes)		
			Patient can try quitting with 7 mg patch per day or no patch.	—	
			Nicotine gum	2 mg up to 24 pieces per day (dosing schedule same as for lozenge)	4 mg each ³ up to 24 pieces per day
			Nicotine lozenge	Tapering schedule	
				Time from waking to first cigarette ≤ 30 minutes	
	Use 4 mg lozenge. Weeks 1–6: 1 lozenge every 1–2 hours (at least 9 per day) Weeks 7–9: 1 lozenge every 2–4 hours Weeks 10–12: 1 lozenge every 4–8 hours	24 lozenges per day			
	Time from waking to first cigarette > 30 minutes				
	Same schedule as above with 2 mg lozenge	24 lozenges per day			
Adults only	2nd	Bupropion sustained release (SR)	Bupropion SR 150 mg b.i.d. after an initial 3-day titration period of bupropion SR 150 mg daily	300 mg per day	
		Varenicline	Begin 1 week before the quit date. Day 1–3: 0.5 mg once daily Day 4–7: 0.5 mg b.i.d. Day 8 through week 12: 1 mg b.i.d.	1 mg b.i.d.	
	3rd	Nortriptyline	Begin 10–28 days before quit date and continue for 12 weeks after quitting: 25 mg once daily, increasing gradually to a target dose of 75–100 mg once daily	150 mg per day	
<p>¹ The manufacturer of Nicoderm recommends a 10-week schedule. Most patients don't require this length of treatment.</p> <p>² Conversion to chewing tobacco: For more than two tins per week, use dosing and tapering schedule displayed for > 1 pack per day of cigarettes. For less than two tins per week, use 14 mg patch for 4 weeks, then taper with 7 mg patch for 4 weeks.</p> <p>³ The 4 mg dose is for highly dependent tobacco users or those who have failed the 2 mg dose.</p>					

Combination therapy treatment options

Table 6. Combination therapy treatment options			
Eligible population	Line	Medication	Initial dose
Adults only	1 st	Nicotine patch + nicotine gum or lozenge	Dose according to schedules in Table 5 for individual therapies; do not need to decrease doses when using two NRTs together.
		NRT (any form) + bupropion	Dose NRT and bupropion according to schedules in Table 5.
	2 nd	Nicotine patch + varenicline	Start 14 mg nicotine patch 2 weeks before quit date and continue for 12 weeks. Start varenicline 1 week before quit date and dose according to schedule in Table 5.
		Bupropion + varenicline ¹	Dose varenicline and bupropion according to schedules in Table 5.
¹ Bupropion in combination with varenicline showed greater efficacy in patients with high nicotine dependence (Fagerstrom Test for Nicotine Dependence score ≥ 6) or high cigarette consumption (≥ 20 cigarettes per day). One study also found greater efficacy in males versus females (Rose 2014).			

Treatment options that are *not* recommended

The following medications have more adverse effects and are less affordable compared to recommended NRT options. In addition, they are not on the formulary:

- Nicotine inhaler
- Nicotine nasal spray

The following combination therapy is not recommended due to evidence that the combination is not better than NRT alone:

- NRT + nortriptyline

Medication monitoring

Table 7. Recommendations for periodic medication monitoring		
Eligible population	Recommended tests	Recommended frequency¹
Nicotine replacement users	<ul style="list-style-type: none"> • Test heart rate and blood pressure periodically during therapy; discontinue therapy if signs of nicotine toxicity occur, such as: <ul style="list-style-type: none"> ○ Severe headache ○ Dizziness ○ Mental confusion ○ Disturbed hearing and vision ○ Abdominal pain ○ Rapid, weak, and irregular pulse ○ Excessive salivation ○ Nausea ○ Vomiting ○ Diarrhea ○ Cold sweat ○ Weakness • Therapy should be discontinued if rash develops. • Discontinuation may be considered if other adverse effects of patch occur, such as: <ul style="list-style-type: none"> ○ Myalgia ○ Arthralgia ○ Abnormal dreams ○ Insomnia ○ Nervousness ○ Dry mouth ○ Sweating 	Periodically
Varenicline users	If a patient or their family or caregivers notice agitation, depressed mood, or changes in behavior that are not typical for the patient or if the patient has suicidal thoughts or actions, the patient should stop taking varenicline and contact their health care professional.	2–4 weeks after treatment initiation ²
Bupropion users	If a patient or their family or caregivers notice agitation, depressed mood, or changes in behavior that are not typical for the patient or if the patient has suicidal thoughts or actions, the patient should stop taking bupropion and contact their health care professional.	2–4 weeks after treatment initiation ²
Nortriptyline users	Blood pressure and pulse rate (ECG, cardiac monitoring) prior to and during initial therapy in older adults; weight; blood levels are useful for therapeutic monitoring.	Periodically
¹ No studies have evaluated the optimal intervals for monitoring. ² The FDA advises that serious side effects have occurred when patients were taking varenicline or bupropion or after they stopped. While the optimal timing of monitoring is not known, it is recommended that primary care providers follow up 2–4 weeks after starting varenicline or bupropion for changes in behavior, agitation, depressed mood, and suicidal ideation. Patients with use precautions may need more intensive follow-up.		

Evidence Summary

The Tobacco Use Screening and Intervention Guideline was developed using an evidence-based process, including systematic literature search, critical appraisal, and evidence synthesis.

Potential benefits and harms of treatment

According to the U.S. Preventive Services Task Force (2013), there is moderate-level evidence to recommend that primary care clinicians provide interventions, including education or brief counseling, to prevent initiation of tobacco use in school-aged children and adolescents.

Counseling

- There is good evidence from meta-analyses of randomized controlled trials (RCTs) that group counseling is more effective for smoking cessation than self-help advice or no intervention (Stead 2005).
- There is good evidence from a pooled analysis of randomized controlled trials that group counseling is **not** more effective for smoking cessation than individual counseling (Stead 2005).
- There is good evidence from a pooled analysis of randomized controlled trials that individual face-to-face counseling is more effective for smoking cessation than a minimal behavioral intervention (Lancaster 2005).
- There is insufficient evidence that motivational interviewing (MI) by trained providers is more effective for smoking cessation than brief advice. There was one RCT with positive findings (Soria 2006) and one lower-quality RCT with negative findings (Wakefield 2004). In the trial conducted by Soria, the MI intervention had more sessions, so it is difficult to disentangle the effects of intervention length versus type of intervention.
- There is insufficient evidence that any particular type of counseling is superior to another type of counseling, of similar intensity.
- There is insufficient evidence on the optimal intensity of counseling. One RCT did not find a significant difference in the quit rate at 2 years (the primary outcome) among groups assigned to pharmacotherapy plus up to two counseling calls every 6 months, pharmacotherapy plus up to six counseling calls every 6 months, and pharmacotherapy alone (Ellerbe 2009).

Nicotine replacement therapy

There is good evidence from three meta-analyses of randomized controlled trials that the nicotine patch, nicotine tablets, nicotine gum, and intranasal spray are all effective at increasing smoking cessation rates (Moore 2009, Stead 2012, Eisenberg 2008).

Type of NRT	No. studies	Pooled RR (95% CI)
Gum	56	1.49 (1.40–1.60)
Patch	43	1.64 (1.52–1.78)
Inhaler	4	1.90 (1.36–2.67)
Tablet/Lozenge	7	1.95 (1.61–2.36)

The Moore study pooled results of nine placebo-controlled studies of NRT with or without motivational support in smokers who were not motivated to stop smoking. There was a significantly higher rate of sustained abstinence at 6 months in the NRT group, but smoking cessation rates in this population were low overall (6.75% for NRT and 3.28% for placebo).

Other medications

Bupropion

- Another RCT found that treatment with bupropion in combination with a group counseling program was superior to behavioral support alone. However, medication alone was as effective as medication plus group counseling (Hall 2002).
- In a trial at Group Health, the 12-month quit rate was higher among participants in the Free & Clear program compared to a less intensive behavioral intervention, regardless of whether patients received 150 mg or 300 mg of bupropion (Swan 2003).

Nortriptyline

A meta-analysis of six RCTs found that at least 6 months of treatment with nortriptyline, in the absence of NRT, increased quit rates compared to placebo. Doses were in the range of up to 75–100 mg daily, titrated to therapeutic levels (Hughes 2014).

Varenicline

- An RCT found that treatment of adult smokers with cardiovascular disease (CVD) using varenicline is well tolerated and effective for smoking cessation (Rigotti 2010).
- Two double-blind RCTs found that 12 weeks of varenicline was more effective than placebo at increasing the quit rate at the end of treatment (Jorenby 2006, Tsai 2007). The effect of varenicline was maintained at the final follow-up (an additional 12 weeks in the Tsai study and 1 year in the Jorenby study). The number needed to treat (NNT) = 8 to achieve one additional quitter at 1 year.

Combination therapy

- There is good evidence from two meta-analyses of RCTs (Shah 2008, Stead 2012) that combination therapy is more effective than single-agent therapy at promoting smoking cessation. A pooled analysis of nine studies in the Stead (2012) meta-analysis found RR = 1.34 (95% CI, 1.18–1.51). All of the trials evaluated the combination of two types of NRT, and findings may not apply to NRT plus a different agent.
- There is fair evidence from one RCT that the combination of NRT and bupropion SR is more effective at promoting smoking cessation than NRT alone (Jorenby 1999).
- There is fair evidence from one RCT that the combination of NRT and varenicline is more effective at promoting smoking cessation than varenicline alone (Koegelenberg 2014).
- One RCT conducted among medically ill smokers found a significantly higher quit rate at 26 weeks in the group receiving triple therapy (nicotine patch, nicotine inhaler, and bupropion) than the nicotine patch alone (Steinberg 2009). The evidence supporting triple therapy is insufficient: The RCT had a relatively small sample size and a high drop-out rate; long-term safety and efficacy could not be determined; and generalizability to otherwise healthy smokers is unclear.
- An RCT found that treatment with bupropion SR alone or in combination with the NRT patch resulted in significantly higher long-term quit rates (Jorenby 1999).

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Guideline Development Process and Team

Development process

The Tobacco Use Guideline was developed using an evidence-based process, including systematic literature search, critical appraisal, and evidence synthesis. For details, see Evidence Summary and References.

This edition of the guideline was approved for publication by the Guideline Oversight Group in February 2015.

Team

The Tobacco Use Guideline development team included representatives from the following specialties: adolescent medicine, family medicine, medical support services, pharmacy, and preventive care.

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Disclosure of conflict of interest

Kaiser Permanente requires that team members participating on a guideline team disclose and resolve all potential conflicts of interest that arise from financial relationships between a guideline team member or guideline team member's spouse or partner and any commercial interests or proprietary entity that provides or produces health care-related products and/or services relevant to the content of the guideline.

Team members listed above have disclosed that their participation on the Tobacco Use Guideline team includes no promotion of any commercial products or services, and that they have no relationships with commercial entities to report.