

Smith Seminars
Continuing Education Credits
AARC-Approved for 2 CRCE
Smoking Cessation

Objectives

1. Learn the factors of tobacco dependency
2. Become familiar with the treatment options for smoking cessation
3. Identify medications used for tobacco dependency
4. Learn motivational interviewing techniques

Tobacco dependence displays many features of a chronic disease. Only a minority of tobacco users achieve permanent abstinence in an initial quit attempt. Users persist in tobacco use for many years and typically cycle through multiple periods of remission and relapse. A failure to appreciate the chronic nature of tobacco dependence may impede assessment and treatment of the tobacco user over time.

Data suggest that more than 70 percent of the 45 million smokers in the United States today report that they want to quit, and approximately 44 percent report that they try to quit each year. Unfortunately, most of these efforts are both unaided and unsuccessful. For example, among the 19 million adults who attempted to quit in 2005, only 4 to 7 percent were likely successful. These statistics may discourage both smokers and clinicians.

Modern approaches to treating tobacco use and dependence should reflect the chronic nature of tobacco dependence. A chronic disease model recognizes the long-term nature of the disorder with an expectation that patients may have periods of relapse and remission. If tobacco dependence is recognized as a chronic disease, clinicians will better understand the relapsing nature of the condition and the requirement for ongoing, rather than just acute, care. The existence of numerous effective treatments gives the clinician and patient many options should repeated quit attempts be needed.

A chronic disease model emphasizes for clinicians the importance of continued patient education, counseling, and advice over time. Although most clinicians are comfortable in counseling their patients about other chronic diseases such as diabetes, hypertension, or hyperlipidemia, many believe that they are less effective in providing counseling to patients who use tobacco. As with these other chronic disorders, clinicians should be encouraged to provide tobacco-dependent patients with brief advice, counseling, and appropriate medication. It is important for clinicians to know that assessing and treating tobacco use generally leads to greater patient satisfaction with health care. Policy changes, such as tax increases and smoke-free ordinances, often lead smokers to seek treatment for this chronic disease.

At least 70 percent of smokers see a physician each year, and almost one-third see a dentist. Other smokers see physician assistants, nurse practitioners, nurses, physical and occupational therapists, pharmacists, counselors, and other clinicians. Therefore, virtually all clinicians are in

a position to intervene with patients who use tobacco. Also, 70 percent of smokers report wanting to quit, and almost two-thirds of smokers who relapse, want to try quitting again within 30 days. Finally, smokers cite a physician's advice to quit as an important motivator for attempting to stop smoking. Data suggest that most smokers are interested in quitting, clinicians and health systems are in frequent contact with smokers, and clinicians have high credibility with smokers.

The first step in treating tobacco use and dependence is to identify tobacco users. The identification of smokers itself increases rates of clinician intervention. Effective identification of tobacco use status not only opens the door for successful interventions, such as clinician advice and treatment, but also guides clinicians to identify appropriate interventions based on patients' tobacco use status and willingness to quit. It is recommended that clinicians and health care systems use each healthcare visit for implementing universal assessment and intervention. Specifically, ask every patient who presents to a health care facility if he or she uses tobacco (Ask), advise all tobacco users to quit (Advise), and assess the willingness of all tobacco users to make a quit attempt at this time (Assess). This represents the first 3 of the 5 A's.

Screening for current or past tobacco use will result in four possible responses:

- the patient uses tobacco and is willing to make a quit attempt at this time
- the patient uses tobacco but is not willing to make a quit attempt at this time
- the patient once used tobacco but has since quit
- the patient never regularly used tobacco

Providing brief interventions (less than 10 minutes), can be provided by all clinicians but are most relevant to clinicians who see a wide variety of patients and are bound by time constraints (e.g., physicians, nurses, physician assistants, nurse practitioners, medical assistants, dentists, hygienists, respiratory therapists, mental health counselors, pharmacists, etc.).

In making the treatment of tobacco use a priority, there is evidence that is compelling:

- clinicians can make a difference with even a minimal (less than 3 minutes) intervention
- a relation exists between the intensity of intervention and tobacco cessation outcome
- even when patients are not willing to make a quit attempt at this time, clinician-delivered brief interventions enhance motivation and increase the likelihood of future quit attempts
- tobacco users are being primed to consider quitting by a wide range of societal and environmental factors (e.g., public health messages, policy changes, cessation marketing messages, and family members)
- there is growing evidence that smokers who receive clinician advice and assistance with quitting report greater satisfaction with their health care than those who do not
- tobacco use interventions are highly cost effective
- tobacco use has a high case fatality rate (up to 50% of long-term smokers will die of a smoking-caused disease).

The goal of these strategies is clear: to change clinical culture and practice patterns to ensure that every patient who uses tobacco is identified, advised to quit, and offered scientifically sound treatments. The strategies underscore a central theme: it is essential to provide at least a brief

intervention to every tobacco user at each health care visit. Responsibility lies with both the clinician and the health care system to ensure that this occurs. Several observations are relevant to this theme. First, although many smokers are reluctant to seek intensive treatments, they can receive a brief intervention every time they visit healthcare. Institutional support is necessary to ensure that all patients who use tobacco are identified and offered appropriate treatment. Third, the time limits on primary care physicians in the United States today (median visit = 12–16 minutes), as well as reimbursement restrictions, often limit providers to brief interventions, although more intensive interventions would produce greater success. Finally, given the growing use of electronic patient databases, smoker registries, and real-time clinical care prompts, brief interventions may be easier to fit into a busy practice and may be implemented in a variety of ways.

With brief interventions there are three types of patients:

- current tobacco users willing to make a quit attempt at this time
- current tobacco users unwilling to make a quit attempt at this time
- former tobacco users who have recently quit

Patients who have never used tobacco or who have been abstinent for an extended period should be congratulated on their status and encouraged to maintain their tobacco-free lifestyle.

The five major components, 5 A's, of a brief intervention in the primary care setting are:

- ask the patient if he or she uses tobacco
- advise him or her to quit
- assess willingness to make a quit attempt

If the patient is willing to make a quit attempt:

- assist him or her in making a quit attempt by offering medication and providing or referring for counseling or additional treatment
- arrange for follow-up contacts to prevent relapse

If the patient is unwilling to make a quit attempt, the provision of a motivational intervention and arrange to address tobacco dependence.

The strategies to deliver the 5 A's are designed to be brief and require 3 minutes or less of direct clinician time. These intervention components constitute the core elements of a tobacco intervention.

The effectiveness of tobacco intervention may reflect not only the contributions of the individual clinician, but also the systems and other clinical resources available to him or her.

The clinical situation may suggest delivering these intervention components in an order or format different from that presented, however. For example, clinical interventions such as: Ask/Assess, Advise, Agree on a goal, Assist, Arrange follow-up; Ask and Act; and Ask, Advise, and Refer have been proposed.

When "Assisting" smokers, in addition to counseling, all smokers making a quit attempt should be offered medication, except when contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents).

5 A's in Action

ASK

Implement a system that ensures that, for every patient at every clinic visit, tobacco use status is queried and documented.

VITAL SIGNS: Blood Pressure: _____ Pulse: _____ Weight: _____ Temperature: _____ Respiratory Rate: _____ Tobacco Use (circle one): Current Former Never

ADVISE

In a clear, strong, and personalized manner, urge every tobacco user to quit.

Advice should be:

Clear—"It is important that you quit smoking (or using chewing tobacco) now, and I can help you." "Cutting down while you are ill is not enough." "Occasional or light smoking is still dangerous."

Strong—"As your clinician, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you."

Personalized—Tie tobacco use to current symptoms and health concerns, and/or its social and economic costs, and/or the impact of tobacco use on children and others in the household.

"Continuing to smoke makes your asthma worse, and quitting may dramatically improve your health." "Quitting smoking may reduce the number of ear infections your child has."

ASSESS

Assess every tobacco user's willingness to make a quit attempt at the time.

Assess patient's willingness to quit: "Are you willing to give quitting a try?"

If the patient is willing to make a quit attempt at the time, provide assistance.

If the patient will participate in an intensive treatment, deliver such a treatment or link/refer to an intensive intervention. If the patient clearly states that he or she is unwilling to make a quit attempt at the time, provide an intervention shown to increase future quit attempts.

ASSIST

Help the patient with a quit plan.

A patient's preparations for quitting:

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

Recommend the use of approved medication, except when contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). Explain how these medications increase quitting success and reduce withdrawal symptoms. The first-line medications include: bupropion SR, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, nicotine patch, and varenicline; second-line medications include: clonidine and nortriptyline. There is insufficient evidence to recommend medications for certain populations (e.g., pregnant women, smokeless tobacco users, light smokers, adolescents).

Provide practical counseling (problemsolving/skills training).

Abstinence - Striving for total abstinence is essential. Not even a single puff after the quit date.

Past quit experience - Identify what helped and what hurt in previous quit attempts. Build on past success.

Anticipate triggers or challenges in the upcoming attempt - Discuss challenges/triggers and how the patient will successfully overcome them (e.g., avoid triggers, alter routines).

Alcohol - Because alcohol is associated with relapse, the patient should consider limiting/abstaining from alcohol while quitting. (Note that reducing alcohol intake could precipitate withdrawal in alcohol-dependent persons.)

Other smokers in the household - Quitting is more difficult when there is another smoker in the household. Patients should encourage housemates to quit with them or to not smoke in their presence.

Provide intratreatment social support.

Provide a supportive clinical environment while encouraging the patient in his or her quit attempt. "My office staff and I are available to assist you." "I'm recommending treatment that can provide ongoing support."

Provide supplementary materials, including information on quitlines.

Sources: Federal agencies, nonprofit agencies, national quitline network (1-800-QUIT-NOW), or local/state/tribal health departments/quitlines.

Type: Culturally/racially/educationally/age-appropriate for the patient.

Location: Readily available at every clinician's workstation.

ARRANGE

Arrange for follow-up contacts, either in person or via telephone.

Timing: Follow-up contact should begin soon after the quit date, preferably during the first week.

A second follow-up contact is recommended within the first month.

Actions during follow-up contact: For all patients, identify problems already encountered and anticipate challenges in the immediate future. Assess medication use and problems.

Remind patients of quitline support (1-800-QUIT-NOW). Address tobacco use at next clinical visit (treat tobacco use as a chronic disease). For patients who are abstinent, congratulate them on their success. If tobacco use has occurred, review circumstances and elicit recommitment to total abstinence; consider use of or link to more intensive treatment.

Medications

All smokers trying to quit should be offered medication, except when contraindicated or for specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). All seven of the FDA-approved medications for treating tobacco use are recommended: bupropion SR, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, 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 nicotine replacement therapy (NRT). Unfortunately, there are no well-accepted algorithms to guide optimal selection among the first-line medications. All seven FDA-approved medications have specific contraindications, warnings, precautions, other concerns, and side effects. Factors that may influence selection include insurance coverage, out-of-pocket patient costs, likelihood of adherence, dentures when considering the gum, or dermatitis when considering the patch. 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 re-treating relapsed smokers with the same medication produces small or no benefit, whereas other evidence suggests that it may be of substantial benefit. 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 for highly dependent smokers or those with a history of severe withdrawal. 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. 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.

Second-line agents (clonidine and nortriptyline) are for patients unable to use first-line medications because of contraindications or for patients for whom the group of first-line medications has not been helpful. Assess patients for the specific contraindications, precautions, other concerns, and side effects of the second-line agents. 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. Bupropion SR and nortriptyline appear to be effective with a past history of depression, but nicotine replacement medications also appear to help in these individuals. The nicotine patch in particular has been demonstrated as safe for cardiovascular patients. Long-term treatment, up to 6 months, 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, and 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. Among first-line medications, evidence exists that combining the nicotine patch long-term (> 14 weeks) with 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 relative to placebo treatments. Combining varenicline with NRT agents has been associated with higher rates of side effects (e.g., nausea, headaches).

Patients frequently do not use cessation medications as recommended (e.g., they do not use them at recommended doses or for recommended durations); this may reduce their effectiveness.

Bupropion SR - Appropriate as a first-line medication for treating tobacco use

Precautions, warnings, contraindications, and side effects: Pregnancy – 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 has not been evaluated in breastfeeding patients. Cardiovascular diseases – It is generally well-tolerated; occasional reports of hypertension.

Side effects – The most common reported side effects were insomnia (35–40%) and dry mouth (10%).

Contraindications – Bupropion SR is contraindicated in individuals who have a history of seizures or eating disorders, who are taking another form of bupropion, or who have used an MAO inhibitor in the past 14 days.

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 after quitting smoking. Availability is by prescription only.

Prescribing instructions - Some patients may lose their desire to smoke prior to their quit date or will spontaneously reduce the amount they smoke.

Dosing information – If insomnia is marked, taking the PM dose earlier (in the afternoon, at least 8 hours after the first dose) may provide some relief.

Alcohol – Use alcohol only in moderation.

Approximate cost - a 1 box of 60 tablets, 150 mg = \$97 per month (generic); \$197 to \$210 (Brand name)

Nicotine gum - Appropriate as a first-line medication for treating tobacco use.

Precautions, warnings, contraindications, and side effects: 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 has not been evaluated in

breastfeeding patients. 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.

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.

Dosage - 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 smoking less than 25 cigarettes per day; the 4-mg gum is recommended for patients smoking 25 or more cigarettes per day. Smokers should use at least one piece every 1 to 2 hours for the first 6 weeks; the gum should be used for up to 12 weeks with no more than 24 pieces to be used per day.

Availability is by over-the-counter (OTC) only.

Prescribing instructions: 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. 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.

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 ad libitum use.

Approximate cost - a 2 mg (packaged in different amounts), boxes of 100–170 pieces = \$48 (quantity used determines how long supply lasts) 4 mg (packaged in different amounts), boxes of 100–110 pieces = \$63 (quantity used determines how long supply lasts).

Nicotine inhaler - Appropriate as a first-line medication for treating tobacco use.

Precautions, warnings, contraindications, and side effects: Pregnancy – 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 has not been evaluated in breastfeeding patients. 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. Local irritation reactions – 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.

Dosage - 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.

Availability is by prescription only.

Prescribing instructions - Ambient temperature – 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.

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 use of the inhaler.

Dosing information – 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 six cartridges per day.

Approximate cost - a 1 box of 168 10-mg cartridges = \$196 (quantity used determines how long supply lasts)

Nicotine lozenge - Appropriate as a first-line medication for treating tobacco use.

Precautions, warnings, contraindications, and side effects: 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 breastfeeding patients. Because the lozenge was approved as an OTC agent, it was not evaluated by the FDA for teratogenicity. 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.

Side effects – 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).

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, and the 4-mg lozenge is recommended for patients who smoke their first cigarette within 30 minutes of waking. Generally, smokers should use at least nine lozenges per day in the first 6 weeks; the lozenge should be used for up to 12 weeks, with no more than 20 lozenges to be used per day.

Availability is OTC only.

Prescribing instructions: Lozenge use – The lozenge should be allowed to dissolve in the mouth rather than chewing or swallowing it. 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 use of the nicotine lozenge.

Dosing information – Patients often do not use enough prn NRT medicines to obtain optimal clinical effects. Generally, patients should use 1 lozenge every 1–2 hours during the first 6 weeks of treatment, using a minimum of 9 lozenges/day, then decrease lozenge use to 1 lozenge every 2–4 hours during weeks 7–9, and then decrease to 1 lozenge every 4–8 hours during weeks 10–12.

Approximate cost - a 2 mg, 72 lozenges per box = \$34 (quantity used determines how long supply lasts) 4 mg, 72 lozenges per box = \$39 (quantity used determines how long supply lasts).

Nicotine nasal spray - Appropriate as a first-line medication for treating tobacco use.

Precautions, warnings, contraindications, and side effects: Pregnancy – 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 has not been evaluated in breastfeeding patients. 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.

Nasal/airway reactions – 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 typically was 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.

Dependency – Nicotine nasal spray produces higher peak nicotine levels than other NRTs and has the highest dependence potential.

Approximately 15–20% of patients report using the active spray for longer periods than recommended (6–12 months); 5% used the spray at a higher dose than recommended.

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/hour). Each bottle contains approximately 100 doses. Recommended duration of therapy is 3–6 months.

Availability is by prescription only.

Prescribing instructions: Dosing information – 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.

Approximate cost - a \$49 per bottle (quantity used determines how long supply lasts).

Nicotine patch - Appropriate as a first-line medication for treating tobacco use.

Precautions, warnings, contraindications, and side effects: 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 has not been evaluated in breastfeeding patients. 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. Skin reactions – Up to 50% of patients using the nicotine patch will experience a local skin reaction. Skin reactions usually are 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 fewer than 5% of patients, such reactions require the discontinuation of nicotine patch treatment. Other side effects – insomnia and/or vivid dreams Dosage Treatment of 8 weeks or less has been shown to be as efficacious as longer treatment periods. Patches of different doses sometimes are available as well as different recommended dosing regimens. The dose and duration recommendations in this table are examples. Clinicians should consider individualizing treatment based on specific patient characteristics, such as previous experience with the patch, amount smoked, degree of dependence, etc.

Availability is OTC or prescription.

Dosage - Step-Down Dosage, 4 weeks - 21 mg/24 hours; then 2 weeks -14 mg/24 hours; then 2 weeks - 7 mg/24 hours.

Single Dosage - Both a 22 mg/24 hours and an 11 mg/24 hours (for lighter smokers) dose are available in a one-step patch regimen.

Prescribing instructions: Location – At the start of each day, the patient should place a new patch on a relatively hairless location, typically between the neck and waist, rotating the site to reduce local skin irritation. Activities – No restrictions while using the patch. Dosing information – Patches should be applied as soon as the patient wakes on the quit day. With patients who experience sleep disruption, have the patient remove the 24-hour patch prior to bedtime, or use the 16-hour patch (designed for use while the patient is awake).

Approximate cost - a 7 mg, box = \$37 (quantity used determines how long supply lasts); 14 mg, box = \$47 (quantity used determines how long supply lasts); 21 mg, box = \$48 (quantity used determines how long supply lasts).

Varenicline - Appropriate as a first-line medication for treating tobacco use.

Precautions, warnings, contraindications, and side effects: 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 has not been evaluated in breastfeeding patients. Cardiovascular diseases – Not contraindicated

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.

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 health care provider about any history of psychiatric illness prior to starting this medication, and clinicians should monitor patients 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. Side effects include nausea, trouble sleeping, abnormal, vivid and/or strange dreams.

Dosage - Start varenicline 1 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.

Availability is by prescription only.

Prescribing instructions: 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.

Dosing information –To reduce nausea, take on a full stomach. To reduce insomnia, take second pill at supper rather than bedtime.

Approximate cost - a 1 mg, box of 56 = \$131 (about 30-day supply).

Clonidine (not FDA approved for smoking cessation) - Appropriate as a second-line medication for treating tobacco use.

Precautions, warnings, contraindications, and side effect: Pregnancy – Pregnant smokers should be encouraged to quit without medication. Clonidine has not been shown to be effective for tobacco cessation in pregnant smokers. Clonidine has not been evaluated in breastfeeding patients. Activities – Patients who engage in potentially hazardous activities, such as operating machinery or driving, should be advised of a possible sedative effect of clonidine. Side effects – Most commonly reported side effects include dry mouth (40%), drowsiness (33%), dizziness (16%), sedation (10%), and constipation (10%). As an antihypertensive medication, clonidine can be expected to lower blood pressure in most patients. Therefore, clinicians should monitor blood pressure when using this medication.

Rebound hypertension – When stopping clonidine therapy, failure to reduce the dose gradually over a period of 2–4 days may result in a rapid increase in blood pressure, agitation, confusion, and/or tremor.

Dosage - Doses used in various clinical trials have varied significantly, from 0.15–0.75 mg/day by mouth and from 0.10–0.20 mg/day transdermal (TTS), without a clear dose-response relation to treatment outcomes. Initial dosing is typically 0.10 mg b.i.d. PO or 0.10 mg/day TTS,

increasing by 0.10 mg/day per week if needed. The dose duration also varied across the clinical trials, ranging from 3–10 weeks.

Availability of oral and transdermal is by prescription only.

Prescribing instructions: Initiate clonidine shortly before (up to 3 days), or on the quit date.

Dosing information – If the patient is using transdermal clonidine, at the start of each week, he or she should place a new patch on a relatively hairless location between the neck and waist. Users should not discontinue clonidine therapy abruptly.

Approximate cost - Oral – .1 mg, box of 60 = \$13 (daily dosage determines how long supply lasts); Transdermal – 4-pack TTS = \$106

Nortriptyline (not FDA approved for smoking cessation) - Appropriate as a second-line medication for treating tobacco use.

Precautions, warnings, contraindications, and side effects: Pregnancy – Pregnant smokers should be encouraged to quit without medication. Nortriptyline has not been shown to be effective for tobacco cessation in pregnant smokers. Nortriptyline has not been evaluated in breastfeeding patients.

Side effects – Most commonly reported side effects include sedation, dry mouth (64–78%), blurred vision (16%), urinary retention, lightheadedness (49%), and shaky hands (23%).

Activities – Nortriptyline may impair the mental and/or physical abilities required for the performance of hazardous tasks, such as operating machinery or driving a car; therefore, the patient should be warned accordingly. Cardiovascular and other effects: Because of the risk of arrhythmias and impairment of myocardial contractility, use with caution in patients with cardiovascular disease. Do not co-administer with MAO inhibitors.

Dosage - Doses used in smoking cessation trials have initiated treatment at a dose of 25 mg/day, increasing gradually to a target dose of 75–100 mg/day. Duration of treatment used in smoking cessation trials has been approximately 12 weeks, although clinicians may consider extending treatment for up to 6 months.

Availability of Nortriptyline HCl is by prescription only.

Prescribing instructions: Therapy is initiated 10–28 days before the quit date to allow nortriptyline to reach steady state at the target dose. Therapeutic monitoring – Although therapeutic blood levels for smoking cessation have not been determined, therapeutic monitoring of plasma nortriptyline levels should be considered under American Psychiatric Association Guidelines for treating patients with depression. Clinicians may choose to assess plasma nortriptyline levels as needed.

Dosing information – Users should not discontinue nortriptyline abruptly because of withdrawal effects. Overdose may produce severe and life-threatening cardiovascular toxicity, as well as seizures and coma. Risk of overdose should be considered carefully before using nortriptyline.

Approximate cost - a 25 mg, box of 60 = \$24 (daily dosage determines how long supply lasts).

Motivation Interviewing for the Patient Unwilling To Quit

The four general principles that underlie Motivational Interviewing are: (1) express empathy, (2) develop discrepancy, (3) roll with resistance, and (4) support self-efficacy. Because this is a specialized technique, it may be beneficial to have a member of the clinical staff receive training in motivational interviewing. The content areas that should be addressed in a motivational counseling intervention can be captured by the “5 R’s”: relevance, risks, rewards, roadblocks, and repetition. Research suggests that the “5 R’s” enhance future quit attempts.

Motivational interviewing strategies:

Express empathy.

Use open-ended questions to explore:

- The importance of addressing smoking or other tobacco use (e.g., “How important do you think it is for you to quit smoking?”)
- Concerns and benefits of quitting (e.g., “What might happen if you quit?”)

Use reflective listening to seek shared understanding:

- Reflect words or meaning (e.g., “So you think smoking helps you to maintain your weight.”).
- Summarize (e.g., “What I have heard so far is that smoking is something you enjoy. On the other hand, your boyfriend hates your smoking, and you are worried you might develop a serious disease.”).

Normalize feelings and concerns (e.g., “Many people worry about managing without cigarettes.”).

Support the patient’s autonomy and right to choose or reject change (e.g., “I hear you saying you are not ready to quit smoking right now. I’m here to help you when you are ready.”).

Develop discrepancy.

Highlight the discrepancy between the patient’s present behavior and expressed priorities, values, and goals (e.g., “It sounds like you are very devoted to your family. How do you think your smoking is affecting your children?”).

Reinforce and support “change talk” and “commitment” language:

- “So, you realize how smoking is affecting your breathing and making it hard to keep up with your kids.”
- “It’s great that you are going to quit when you get through this busy time at work.”

Build and deepen commitment to change:

- “There are effective treatments that will ease the pain of quitting, including counseling and many medication options.”
- “We would like to help you avoid a stroke like the one your father had.”

Roll with resistance.

Back off and use reflection when the patient expresses resistance:

- “Sounds like you are feeling pressured about your smoking.”

Express empathy:

– “You are worried about how you would manage withdrawal symptoms.”

Ask permission to provide information:

– “Would you like to hear about some strategies that can help you address that concern when you quit?”

Support self-efficacy.

Help the patient to identify and build on past successes:

– “So you were fairly successful the last time you tried to quit.”

Offer options for achievable small steps toward change:

– Call the quitline (1-800-QUIT-NOW) for advice and information.

– Read about quitting benefits and strategies.

– Change smoking patterns (e.g., no smoking in the home).

– Ask the patient to share his or her ideas about quitting strategies.

Enhancing Motivation to Quit Tobacco—The “5 R’s”

Relevance

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

Risks

The clinician should ask the patient to identify potential negative consequences of tobacco use.

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

Acute risks: Shortness of breath, exacerbation of asthma, increased risk of respiratory infections, harm to pregnancy, impotence, and infertility.

Long-term risks: Heart attacks and strokes, lung and other cancers (e.g., larynx, oral cavity, pharynx, esophagus, pancreas, stomach, kidney, bladder, cervix, and acute myelocytic leukemia), chronic obstructive pulmonary diseases (chronic bronchitis and emphysema), osteoporosis, long-term disability, and need for extended care.

Environmental risks: Increased risk of lung cancer and heart disease in spouses; increased risk for low birth-weight, sudden infant death syndrome (SIDS), asthma, middle ear disease, and respiratory infections in children of smokers.

Rewards

The clinician should ask the patient to identify potential benefits of stopping tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient. Examples of rewards follow: Improved health; Food will taste better; Improved sense of smell; Saving money; Feeling better about oneself; Home, car, clothing, breath will smell better; Setting a good example for children and decreasing the likelihood that they will smoke; Having healthier babies and children; Feeling better physically; Performing better in physical activities; Improved appearance, including reduced wrinkling/aging of skin and whiter teeth.

Roadblocks

The clinician should ask the patient to identify barriers or impediments to quitting and provide treatment (problemsolving counseling, medication) that could address barriers. Typical barriers might include: Withdrawal symptoms; Fear of failure; Weight gain; Lack of support; Depression; Enjoyment of tobacco; Being around other tobacco users; Limited knowledge of effective treatment options.

Repetition

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

Patient Who Has Recently Quit

The former tobacco user should receive congratulations on any success and strong encouragement to remain abstinent.

When encountering a recent quitter, use open-ended questions relevant to the topics below to discover if the patient wishes to discuss issues related to quitting:

The benefits, including potential 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:

Lack of support for cessation

Schedule follow-up visits or telephone calls with the patient.

Urge the patient to call the national quitline network (1-800-QUITNOW) 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

If significant, provide counseling, prescribe appropriate medication, or refer the patient to a specialist.

Strong or prolonged withdrawal symptoms

If the patient reports prolonged craving or other withdrawal symptoms, consider extending the use of an approved medication or adding/combining medications to reduce strong withdrawal symptoms.

Weight gain

Recommend starting or increasing physical activity.

Reassure the patient that some weight gain after quitting is common and usually is 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

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.

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