



**CONTINUING EDUCATION**



# **A Pharmacist's Guide for Smoking Cessation**

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## PROGRAM OBJECTIVES

1. Recognize the impact of smoking cessation counseling on healthcare
2. Discuss the use of the 5 “A’s” approach to efficiently counsel on smoking cessation
3. Discuss the 5 “R’s” for patients unwilling to quit and ways to improve adherence
4. Review pharmacological treatment options that can be individually tailored for each patient’s needs.
5. Compare and contrast various smoking cessation medications for the management of smoking cessation.
6. Understand the role of new developments in smoking cessation.

## BACKGROUND

Each year nearly a half-million people die from smoking or exposure to cigarette smoke.<sup>1</sup> In the United States, cigarette smoking is the leading cause of preventable death, accounting for one in five preventable deaths yearly.<sup>1,2</sup> In Alabama, over 20% of adults are smokers, ranking the state 42nd and 40th in number of adults and adolescents who smoke, respectively.<sup>3</sup> The state also ranks 44th in smoking-related mortality. Almost 70% of patients in the country who smoke would like to quit, and more than half have tried and failed.<sup>4</sup> Less than half of smokers were advised by their healthcare provider to quit. One in three smokers will eventually quit, while one of the remaining two smokers will develop smoking-related complications, leading to death.<sup>2</sup> While Alabama has passed legislation restricting the use of tobacco products in many public areas, pharmacists in the state can also play an important role in counseling patients to quit. Although some patients are able to stop without any other intervention, additional tools are available to help those who need the assistance to quit successfully. Patients can be counseled on various areas of their behavior. There are also products available including nicotine replacement and other pharmacological agents. While both options are effective, studies have shown that patients are more likely to quit when they receive both counseling and pharmacological treatment.<sup>5</sup> Despite this fact, almost 70% of patients who tried to quit between 2001 and 2010 did not receive counseling or medication.<sup>4</sup> Medical costs related to cigarette smoking amount to \$96 billion in the United States, with another \$97 billion in lost work productivity.<sup>2</sup> Utilization of these programs will have the most impact on smoking cessation while decreasing healthcare costs, such as hospitalizations, physician visits, and prescription medications required for the treatment of smoking-related conditions.

In the past twenty years, our nation has made progress toward a smoke-free society. In an effort to decrease the prevalence of tobacco use, the 1998 Master Settlement Agreement stopped all advertising of tobacco products including billboards and transit advertisements.<sup>2</sup> As tobacco products’ prices and taxes have increased over the years, there has been a decline in the number of users. For every 10% price increase in cigarettes, there is a 4% decrease in the total number of cigarettes consumed.<sup>6</sup> Prevention programs and education on smoking cessation and adverse effects of tobacco have also helped decrease the rate of use. Federal budget cuts have decreased funding of anti-tobacco programs by 12%

in the past year and 36% over the last four years, making it difficult to educate youth and continue the much needed decline in the number of users.<sup>7</sup>

Tobacco use usually starts at an early age.<sup>2</sup> Eighty percent of adult smokers begin by 18 years of age with 99% of tobacco users starting by age 26. Also, smokeless tobacco users are more likely to transition to cigarette use at some point in their lifetime. Initial tobacco users typically do not consider health consequences that accompany long-term tobacco use. Early education is key to promoting adherence, improving patient commitment, and influencing on how addiction affects everyday life in hopes of preventing future addiction.

## HEALTH BENEFITS FROM SMOKING CESSATION:

Quitting smoking can provide immediate and long-term health benefits.<sup>8</sup> Immediate reductions in heart rate and blood pressure can be observed, and patients may notice decreased phlegm and improved breathing within one month. Long-term benefits include a reduction in smoking-related mortality of greater than 90% if patients quit before age 30, and 50% when patients quit before age 50. Additional health risk reductions are outlined in Table 1.

Health Risk Reductions <sup>8,9,10</sup>
<ul style="list-style-type: none"><li>• Cancer, especially lung cancer</li><li>• Cardiovascular complications such as stroke, myocardial infarction, coronary heart disease, and peripheral vascular disease</li><li>• Respiratory complications and diseases such as emphysema, chronic obstructive pulmonary disease, coughing, wheezing, and shortness of breath</li><li>• Rate of decline in lung function</li><li>• Infertility risk in women during the reproductive years, and also reduces the odds of delivering a low birth weight baby</li></ul>

## ROLE OF THE PHARMACIST IN COUNSELING STRATEGIES:

Every patient at each visit should be asked if they smoke and are interested in quitting.<sup>9</sup> Pharmacists may elect to use the motivational interviewing strategy, which is a “patient-centered” approach with the goal of helping the patient make informed decisions about their health. Whether it is the first intervention or a follow-up session, a mixture of closed-ended and open-ended questions is a necessary counseling tool for evoking a patient’s own motivations to change. Asking closed-ended questions allows the pharmacist to gather relevant information needed for further

counseling.<sup>11</sup> Common closed-ended questions begin with words such as “what”, “where”, “how”, “have”, “when”, and “does.” Once specific information is obtained, the pharmacist can then move to open-ended questions gauge how the patient is feeling and assess information that may not have been previously discussed. Open-ended questions make the patient explore why smoking cessation can benefit them, and therefore can evoke their own motivations to make a change. “How has therapy been working for you?” or “Tell me your thoughts on this whole process” are common open-end questions that are designed to yield more than a one word answer. It induces the patient to discuss good reasons for making a behavioral change to move them away from their status quo.

Community pharmacists are usually time limited, so detailed counseling strategies may be difficult to achieve. According to the Public Health Service’s Clinical practice guidelines on smoking cessation, brief interventions should occur in 10 minutes or less.<sup>9</sup> The “5 A’s” is a counseling strategy used to assess patients new to the quitting process and also patients who have previously quit and are attempting cessation again (Table 2). The key components to this step-wise process are “Ask”, “Advise”, “Assess”, “Assist”, and “Arrange.” Not all pharmacists will have time to approach each step of the 5 A’s, so trying to ask one or two questions from each category should be encouraged. Successful treatment takes time, but pharmacists can provide support, compassion, and resources in order for the patient to obtain a smoke-free lifestyle. Patients may not know all of the health concerns that accompany smoking (see table 2 on page 52).

**PREPARING FOR A QUIT DATE: THE “STAR” METHOD**

The “STAR” method is a preparation process that should be used for patients actively seeking help to quit smoking.<sup>9</sup> This allows the patient to start their initiative with a plan to transition to a non-smoking state.

• Set a quit date
• Tell friends, family, and co-workers
• Anticipate adherence challenges
• Remove tobacco products to prevent easy accessibility

The first step in this series is to “set” a quit date. Two weeks is the preferred time to allot a sufficient preparation period for the upcoming quit date. The next step is informing the patient to “tell” their family members, friends, and co-workers about their proposal to quit smoking.<sup>9,10</sup> An outside support group will help the patient adhere to their designated non-smoking treatment plan and keep the patient on track. “Anticipate” adherence challenges is the third step.<sup>9</sup> Forewarn the patient about withdrawal symptoms that could make treatment arduous. Even though commitment challenges may occur at any stage of the cessation process, patients should especially be educated about withdrawal symptoms that typically peak in the first 2 weeks of quitting smoking. This is a challenging time since the patient may experience symptoms such as mood changes, smoking urgency, and concentration difficulties. The final step is to communicate the importance of “removing” all tobacco products from the patient’s home, car, work, and other

common smoking areas. Easy accessibility to tobacco products can make treatment adherence difficult when cravings and withdrawal symptoms occur.

**When to Follow-up**

Follow-up visits allow the pharmacist an opportunity to explore a patient’s non-adherence challenges. These should be scheduled during the first week of the patient’s quit date to address any arising issues.<sup>9</sup> The earlier these problems are corrected, the easier it will be for the patient to combat the situation. Keep the patient focused on their goal and assess how their treatment is working. The second follow-up date should occur within the first month of the patient’s quit date. Continuous follow-up increases the likelihood of successful quit rates by identifying withdrawal symptoms, triggers and other obstacles that need correcting. Depending on the type of obstacles presented, pharmacists can improve a patient’s abstinence by making appropriate changes or recommendations to their current therapy.

**STRATEGIES FOR THE UNWILLING PATIENT**

Not all patients are willing to stop smoking at the time of their first visit. Educating the patient about different quitting options can help them decide whether they feel comfortable in setting a quit date or they need a longer preparation period.<sup>9</sup> For patients not ready to set a quit date, providing information on different cessation opportunities can make a significant difference when they are contemplating whether or not to quit. Actively engage ambivalent patients to explore reasons to make a change.<sup>11</sup>

The “5 R’s” refer to areas that should be discussed during an interview to enhance motivation in an unwilling patient.<sup>9</sup> The first is “*relevance*”, in which the pharmacist should ask the patient why smoking cessation is relevant to them. Patients are more likely to go through with a quit attempt if they can make the connection between smoking and their health, family, disease status, and other characteristics.

The second is “*risks*.”<sup>9</sup> Ask the patient to identify possible consequences of smoking then repeat those that apply most to the patient. If the patient is unaware of the risks associated with smoking, this is a good opportunity to share valuable information.

The third is “*rewards*.”<sup>9</sup> Ask the patient about benefits of smoking cessation, and echo those that apply specifically to the patient. Patients may know that quitting can improve their respiratory function, but could be unaware of other benefits. Communicate possible advantages, such as saving money, smelling better, feeling better, aging better, and having whiter teeth. Other benefits include improved taste, sense of smell, and a healthier environment.

The fourth is “*roadblocks*.”<sup>9</sup> Ask the patient what is hindering him from quitting. This will help select proper treatment for patients who may need medication to assist in their quit attempts. Also, the pharmacist may be able to provide suggestions to overcome a certain roadblock.

The last is “*repeat*.”<sup>9</sup> At each meeting with the unwilling patient, the “5 R’s” should be discussed to determine the patient’s readiness and willingness to quit. If resistance develops, reflect back on their previous comments to reinforce their motivations for quitting.

Summary of the 5 “A’s” <sup>9,11</sup>	
Ask	<p>Ask the patient about current and past tobacco use at every patient visit and follow-up, i.e.</p> <ul style="list-style-type: none"> <li>• What types of tobacco products do you use?</li> <li>• How many cigarettes do you smoke each day?</li> <li>• What time of the day do you start smoking?</li> <li>• What are your triggers for smoking?</li> <li>• Have you tried quitting before, and if so, tell me about how those particular smoking cessation treatments worked for you.</li> </ul>
Advise	<p>Advise all patients to quit using tobacco by educating them about health benefits that will affect them personally along with their loved ones. Examples of health issues to discuss are improving blood pressure control, decreasing risk for cardiovascular disease, decreasing cancer risk, etc.</p> <ul style="list-style-type: none"> <li>• i.e. “Let me tell you about some immediate and long-term benefits of smoking cessation.”</li> </ul>
Assess	<p>For new patients who have never tried smoking cessation, assess the patient’s willingness to quit.</p> <ul style="list-style-type: none"> <li>• i.e. How would you describe your interest in quitting smoking at this time?</li> </ul> <p>For patients who have previously tried smoking cessation therapy and failed, assess what went wrong in their therapy in order to guide the patients to either a new treatment strategy or ways to correct old habits.</p> <ul style="list-style-type: none"> <li>• i.e. “If you would like, we can discuss some ways that can help improve treatment adherence.”</li> </ul> <p>For patients who are currently being treated, assess how their current therapy is working for them, i.e.</p> <ul style="list-style-type: none"> <li>• “How is your current therapy working for you?”</li> <li>• “In what ways have you noticed a positive change in your life since quitting?”</li> </ul>
Assist	<p>In the assisting process, each patient should give a detailed medical history. Some medications may be contraindicated in select patient populations.</p> <ul style="list-style-type: none"> <li>• In patients ready to quit smoking, assist the patient with selecting an appropriate treatment medication or plan.</li> <li>• For patients unwilling to quit right now, assist by letting the patient know they have an emotional support partner in this difficult process.</li> </ul>
Arrange	<p>Arrange a follow-up. Follow-ups should occur even if the patient is not actively seeking to quit smoking at this time.</p>

## PHARMACOLOGICAL TREATMENT AGENTS

There are seven FDA-approved agents that can be considered first line therapies for smoking cessation, including both over-the-counter products as well as prescription options.<sup>9</sup> These agents are nicotine replacement therapies (gum, lozenge, patch, nasal spray, and inhaler), Chantix® (varenicline), and Zyban/Wellbutrin® (bupropion SR). There are also two non-FDA-approved therapies, clonidine and nortriptyline, which are second-line options for patients who are intolerant or contraindicated to first-line treatment choices. Each of these agents has been shown to significantly increase the rate of long-term smoking avoidance. Dosages and duration vary depending on the product chosen and the patient’s current nicotine dependence status. Heavier smokers require higher doses and longer durations of therapies, while for light smokers (i.e. less than 10 cigarettes per day), cessation methods have shown little benefit. However, some lighter smokers may still choose a smoking cessation medication to assist in their quit attempt. Keep in mind that healthcare professionals should consider starting the patient on a lower dose of nicotine

replacement therapy, but prescription medications such as bupropion SR and varenicline do not require a dose adjustment.

### Nicotine Replacement Therapies (NRT)

There are several nicotine replacement therapies to choose from. Each product offers different delivery methods which cater to a wide patient population. Some products are offered over-the-counter while others are offered as prescription only. Each product has been shown to work effectively via substitution of tobacco with a nicotine-containing product.<sup>9</sup> All nicotine-containing products should be used with caution in patients with cardiovascular complications such as arrhythmias and angina. Caution should particularly be exercised in those recovering from a recent myocardial infarction occurring in the last 2 weeks. To enhance absorption of orally administered NRT medications, patients should be notified to avoid the consumption of foods and acidic beverages (i.e. juice, soft drinks, caffeinated drinks) for 15 minutes before and during NRT administration.

Nicotine gum is available as an over-the-counter product that is manufactured in two strengths: 2 mg and 4 mg pieces.<sup>9,12,13</sup> Abstinence is achieved in approximately 19% of smokers when gum is used.<sup>14</sup> The gum comes in a variety of flavors, and the dose is chosen based on the number of cigarettes smoked in a day.<sup>9,12,13</sup> Patients who smoke less than 25 cigarettes per day should start at a lower dose of 2 mg while reserving the higher dose nicotine gum (4 mg) for those who smoke 25 or more cigarettes per day. Each piece of gum usually lasts approximately 30 minutes. Counseling on the chewing technique is essential for maximal benefit. It should not be constantly chewed like regular chewing gum. When the gum is slowly chewed, it causes a “peppery” or tingle-like sensation. This sensation signifies the timing of when to “park” the gum piece between the gum and cheek, allowing for nicotine absorption. Advise the patient to rotate the gum in different “parked” areas of the mouth. Once the tingling sensation subsides, the patient should begin slowly chewing the gum to re-activate the nicotine release. The gum should be discarded after about 30 minutes, or after loss of sensation with continued chewing. Patients may repeat use every 1 to 2 hours daily, but should not exceed 24 pieces per day.<sup>9</sup> The expected duration of therapy can last up to 12 weeks. Common side effects include headaches, cough, mouth irritation, hiccups, jaw pain, and dyspepsia.<sup>13</sup>

Nicotine lozenges are an effective alternative for patients who do not desire to chew nicotine gum or for patients who are unable to chew due to temporomandibular joint disease.<sup>9</sup> It is also offered in the same doses as nicotine gum: 2 mg and 4 mg lozenges; however, the recommended starting dose differs from that of the nicotine gum.<sup>13</sup> For smokers who generally start smoking within the first 30 minutes after waking, a higher starting dose of 4 mg nicotine lozenge is recommended. For patients who smoke their first cigarette 30 minutes or longer after waking, treatment can be initiated with the 2 mg lozenge. The 2 mg lozenges led to abstinence in 24.2% of smokers who tried them.<sup>14</sup> During the first six weeks of treatment, 9 lozenges per day are recommended without exceeding a total of 20 daily.<sup>9</sup> Absorption occurs when the lozenges are dissolved and rotated throughout the oral cavity; chewing or swallowing is discouraged. The expected duration of therapy can last up to 12 weeks. For patients concerned with weight gain that often accompanies smoking cessation, the 4 mg lozenge has an extra benefit of preventing weight gain.<sup>15</sup> Common side effects include nausea, hiccups, cough, headache and dyspepsia.<sup>12,13</sup>

Nicotine inhalers are available to consumers as prescription only, and are offered at a single dose of 4 mg cartridges.<sup>16</sup> Each cartridge may provide about 80 inhalations to deliver a total of 4 mg of nicotine.<sup>9</sup> It is estimated that 24.8% of patients remain abstinent after using the inhaler.<sup>14</sup> Patients are recommended to consume between 6 to 16 cartridges daily for therapy treatment, but may taper the dose down after the first 3 months of use.<sup>12</sup> Treatment may last up to 6 months. Common side effects include mouth and throat irritation, rhinitis and coughing.

Nicotine nasal spray is a non-oral method of nicotine delivery.<sup>9,16</sup> It is only available to patients by prescription and is effective in an estimated 26.7% of patients trying to quit.<sup>9,14,16</sup> It

is not recommended for individuals with reactive airway diseases. This product produces higher peak nicotine levels compared to other NRT products, which leads to the possibility of developing dependence. Over 90% of users report nasal irritation after only 2 days of use, with over 80% of patients reporting irritation 3 weeks after use.<sup>9</sup> This can be minimized by counseling the patient to not inhale, sniff, or swallow the medication after administration. Slightly tilting the head backwards during instillation is needed for adequate nicotine absorption. The device delivers a 0.5 mg dose with each spray, and should be administered every 1 to 2 hours in each nostril. It is recommended to administer 8 doses per day, but not to exceed more than 40 doses daily. The expected duration of therapy can last up to 3 to 6 months.

The nicotine patch offers patients an alternative route of nicotine delivery, and is available over-the-counter. Since a single patch is applied to the skin once daily, it offers a better adherence profile compared to multi-dose medications.<sup>9,13</sup> An estimated 23.4% of patients are abstinent when using the nicotine patch.<sup>14</sup> The patch is manufactured in different dosages providing a 3-step method.<sup>16,17</sup> The Nicoderm CQ® patches are offered as step one (21 mg/day), two (14 mg/day), and three (7 mg/day). The initial treatment dose and duration depends on the amount of cigarettes smoked daily. For example, heavier smokers (i.e. more than 10 cigarettes per day) should start with a 6 week regimen of step one, followed by step two for 2 weeks, and then step three for an additional 2 weeks. For lighter smokers (10 cigarettes per day or less), treatment should begin at step two for a 6 week duration followed by step three for another 2 weeks. The patch should be applied to a hairless area of skin between the neck and waist and rotated to a different site daily. Patches should not be cut into smaller pieces. Common side effects include abnormal dreams, insomnia, and skin irritation.<sup>16,14</sup>

### **Non-nicotine Based Pharmacological Options**

Varenicline (Chantix®) acts as a partial nicotine receptor antagonist, thereby blocking a portion of nicotine’s activity but also helps reduce withdrawal symptoms.<sup>12</sup> By this mechanism, if patients choose to smoke, the pleasurable effects of the nicotine are diminished. Multiple clinical trials have shown patients treated with varenicline to be more successful at quitting smoking than those given placebo, and some have demonstrated superiority to treatment with bupropion SR (Zyban®).<sup>18,19,20,21</sup> A study showed 44% of patients were able to quit smoking and remain abstinent during weeks 9 - 12, compared with 18% of patients who received placebo.<sup>22</sup> The most common side effects seen during therapy include nausea, insomnia, headache, and vivid dreams.<sup>12,13</sup> Serious adverse reactions have included suicidal thoughts and even suicide attempts. These have occurred in patients with or without pre-existing neuropsychiatric diagnoses. Varenicline is available in starting and continuing monthly packages, and doses are titrated over a one week period. Patients should begin taking the medication one week prior to their predetermined “quit date”, although therapy may begin up to one month before the last cigarette. The recommended starting dose is 0.5 mg by mouth once daily on days 1-3 which is then titrated up to 0.5 mg twice daily

on days 4-7. By day 8, another dose increase to 1 mg twice daily should be initiated, and the patient should be expected to continue this dose until the completion of therapy. Treatment duration is generally continued for a total of 12 weeks; however, an additional 12 weeks of therapy may be recommended for patients who successfully completed the previous three month treatment in order to increase their chances of remaining abstinent. If the patient's first attempt is unsuccessful, a second attempt should be made once inhibiting factors have been addressed. Varenicline should not be used in combination with nicotine replacement therapies due to its partial nicotine antagonist mechanism.<sup>9</sup>

Bupropion sustained-release (SR) is believed to help patients quit smoking by two non-nicotine based methods.<sup>12</sup> It inhibits neuronal reuptake of norepinephrine and dopamine, thereby reducing withdrawal symptoms, nicotine cravings, and the urge to smoke. Its secondary action deals with blocking nicotinic acetylcholine-dependent receptors; however, the implications of this activity are not well understood.<sup>9</sup> A past medical history of seizures or eating disorders, MAOI use within the last 14 days, and the concurrent use of similar bupropion medications are all contraindications. Two of the most common side effects that may affect patient compliance are insomnia (~40%) and dry mouth (~10%).<sup>9,13</sup> Other common adverse events to consider include headache, nausea, and tachycardia.<sup>13</sup> Bupropion may also cause weight loss, which can amount to five pounds or more.<sup>17</sup> Since effects begin after one week, patients should commence therapy approximately one to two weeks prior to their desired quit date and continue for 7 - 12 weeks.<sup>9,12,13</sup> If necessary, some therapy durations may even last up to 6 months in heavier smokers. Initial treatment calls for bupropion SR 150 mg by mouth once daily for three days, followed by an up-titration to 150 mg twice daily for the remainder of the treatment period. Doses should be separated by a minimum of 8 hours.<sup>9</sup> In patients who experience insomnia with bupropion SR, an earlier administration time is recommended starting in the mid-afternoon, but still recognizing an eight hour interval between both daily doses. About 30% of patients have been able to achieve a smoke-free lifestyle by 9 - 12 weeks of therapy, as compared to 18% of patients receiving placebo.<sup>22</sup> Patients who have not been able to stop smoking after seven weeks of treatment are generally considered non-responsive, warranting a change in therapy.<sup>12</sup> If cost is a concern to the patient, the product is available as a generic. Patients may continue to use nicotine replacement products while taking bupropion, and one FDA-approved regimen involves the combination of bupropion SR with a nicotine patch.

## **FUTURE DEVELOPMENTS IN SMOKING CESSATION**

There are two new key developments for potentially treating patients with nicotine addiction. The first is the "electronic cigarette," which works by providing a nicotine vapor without the harmful by-products of smoking a cigarette.<sup>23</sup> At this time they are commonly used by smokers in environments where smoking is prohibited. There are concerns at this time with widespread use of the electronic cigarette. One is that nonsmokers may become addicted to nicotine after using these products. Those that are

marketed also have inconsistent nicotine content in separate inhalations. There are no long-term studies on the efficacy of the products for smoking cessation, and they are not currently FDA approved for this purpose. Due to this lack of evidence, patient counseling and other first line medications are preferred.<sup>24</sup> The electronic cigarette is a good option for patients who are unable to quit by conventional methods. While there is no information about long-term harmful effects, the electronic cigarette seems to be a safer alternative to smoking.

The other development is a vaccine against nicotine addiction which is not yet available.<sup>25</sup> This product is still being developed by researchers at Weill Cornell Medical College. The vaccine has currently been tested in mice causing their livers to produce antibodies against nicotine. Once the nicotine enters the bloodstream, the antibodies will bind the nicotine and prevent it from reaching the brain, thereby preventing nicotine addiction. Researchers are hopeful the vaccine will not only prevent development of nicotine addiction, but also treat patients who are already addicted. Other nicotine vaccines have been unsuccessful because they simply introduce nicotine antibodies into the host. Even though testing in primates has not occurred, the results are promising. Due to the continual antibody generation in mice, its efficacy may be achieved with a single lifetime vaccination. Approval for use in humans is years away as more studies are needed.

## **CONCLUSION**

The pharmacist has the potential to play a crucial role in assisting patients in smoking cessation. While Americans have decreased tobacco use over the last decade, many still smoke and have not been advised to quit by their healthcare providers. Through counseling and assisting with product selection, pharmacists can help patients quit smoking successfully. There is clear benefit to this strategy in reducing healthcare costs, as well as improving overall health status. By implementing smoking cessation strategies into daily patient interactions, pharmacists can greatly impact the lives of their patients. 🍷



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