

Women & *Smoking Cessation* Handbook

*A Resource
for Providers*



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Foreword

VA developed *Women & Smoking Cessation Handbook* to provide clinical guidance on evidence-based smoking cessation care targeted to meet the needs of female Veterans. Wherever possible, this resource draws upon evidence-based and gender-specific literature for information and treatment guidance. When adequate literature on gender-specific clinical guidance did not exist, general guidance from the U.S. Public Health Service Clinical Practice Guideline, *Treating tobacco use and dependence: 2008 update*, was used.

Acknowledgements

The provider-based *Women & Smoking Cessation Handbook* and the accompanying *My Smoking Cessation Workbook* were developed by the San Diego Tobacco Cessation Clinical Resource Center (TCCRC) of the Department of Veterans Affairs, led by Dr. Timothy Chen. The authors' primary goal was to develop materials promoting smoking cessation interventions, based on published principles of evidence- and consensus-based clinical practice, for use by providers treating female Veterans.

With permission from Dr. Miles McFall and Dr. Andrew Saxon, several materials used in these publications were modified from smoking cessation workbooks they developed for providers of patients with posttraumatic stress disorder as part of the Smoking Cessation Project of the Northwest Network Mental Illness Research, Education & Clinical Center of Excellence in Substance Abuse Treatment and Education at the VA Puget Sound Health Care System. The U.S. Public Health Service Clinical Practice Guideline¹ and the treatment model described by Richard Brown provided the foundation for their work and therefore indirectly ours as well.²

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¹ Fiore, M. C., Bailey, W. C., Cohen, S. J., Dorfman, S. F., Goldstein, M. G., Gritz, E. R., Heyman, R. B., Jaén, C. R., Kottke, T. E., Lando, H. A., Mecklenburg, R. E., Mullen, P. D., Nett, L. N., Robinson, L., Stitzer, M. L., Tommasello, A. C., Villejo, L., & Wewers, M. E. (2000). *Treating tobacco use and dependence*. Clinical practice guideline. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service.

² Brown, R. A. (2003). Intensive behavioral treatment. In D. B. Abrams, R. Niaura, R. Brown, K. M. Emmons, M. G. Goldstein, & P. M. Monti, *The tobacco dependence treatment handbook: A guide to best practices* (pp. 118-177). New York, NY: Guilford Press.

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I. Women and Smoking

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CHAPTER SUMMARY

Scope of the problem

- Smoking kills nearly 175,000 women in the United States annually,¹ and has been directly implicated in several life-threatening health conditions, including pulmonary disease, cardiovascular disease, various cancers, and osteoporosis
- Women who smoke during pregnancy have been shown to have increased birth complications and low birth weight babies²
- Women who smoke can have fertility difficulties²⁻³
- Chronic Obstructive Pulmonary Disease (COPD) related deaths have increased dramatically in women smokers and the disease risks are now considered similar to men³
- Female Veterans may face increased stressors and barriers to quitting, such as greater likelihood of depression, anxiety, and other mental health issues²⁻³

Benefits of smoking cessation in female Veteran smokers

- Quitting smoking can reduce and reverse many of the negative effects of tobacco use
- Smoking is the most clinically important modifiable cardiovascular risk factor
- Quitting smoking has been linked to several female-specific health benefits, such as decreased risk for cervical and breast cancer, as well as improved fertility and healthier pregnancies

About the health care provider's role

- Effectiveness starts with the clinical routine:
 - Ask about the patient's smoking status
 - Advise patients to quit and inquire about readiness
 - Monitor quit attempts and relapses
- Help patients access comprehensive care to address co-morbidities hindering their ability to quit
- Utilize an integrated model and provide a consistent message about smoking
- Greater efficacy with a team approach
- Stress the importance of using medications coupled with behavioral counseling, if possible

CHAPTER SUMMARY

Challenges to cessation in female Veteran smokers

- Higher rates of comorbidities such as posttraumatic stress disorder (PTSD), depression, other psychiatric disorders, and substance and alcohol use among smokers
- Quitting smoking may be harder for women

SCOPE OF THE PROBLEM

Women now comprise a substantial portion of the military and hold positions in nearly all branches of service. Twenty percent of female Veterans in care at VA smoke, as compared to 16.5% in the civilian population, supporting evidence that there is an increased vulnerability to smoking initiation and difficulty with cessation among female Veterans.⁴⁻⁵

While overall smoking rates among women continue to decrease (perhaps due to increased awareness of the dangers of smoking), quitting rates among women are consistently lower than those among men, indicating a greater need for cessation efforts for female smokers.⁶ Furthermore, it appears that the increase in smoking behavior among military women, as compared to civilian women, is even greater than those found between military and civilian men.⁷ Research has shown that smoking has a significant and unique impact on the health of women, with additional consequences for those serving in the military:

- Smoking is related to 90% of pulmonary disease among women. Chronic obstructive pulmonary disease (COPD) kills more women than breast cancer annually, with newly diagnosed cases of COPD increasing three times as fast in women as compared to men.^{3,8} The rate of COPD deaths are increasing in women smokers while rates are declining in male smokers.³ The risks associated with COPD complications in smokers (e.g. deaths) are considered equal between men and women smokers.³
- Smoking is directly linked to 80% of lung cancer deaths, surpassing breast cancer as the leading cause of cancer deaths among women.¹ Evidence also suggests a causal relationship between smoking and colorectal cancer and liver cancer.³ Smoking may also be associated with the development and progression of several female-specific cancers, such as cervical, ovarian, vulvar, and breast cancers.^{1,3}

- Even light smoking has been shown to triple the risk of coronary disease and stroke among women, particularly when there is concurrent use with oral contraceptives (considered a contraindication).⁹
- Studies have shown a link between smoking and premenopausal signs of osteoporosis among women, most likely due to estrogen deficiencies among female smokers.¹⁰
- Smoking has been identified as an independent risk factor for low fertility, gestational complications, birth complications, and perinatal morbidity and mortality.¹¹⁻¹²
- Studies have shown a possible association between smoking and increased rates of depression, anxiety, and substance abuse among military women, particularly those in active-duty.² Additionally, psychiatric comorbidity has been shown to be more prevalent in women with COPD.⁸
- Psychological comorbidities may complicate quitting efforts, as women may smoke as a method to cope with emotional distress; thus, these issues should be carefully assessed and treated with concurrent therapy, if necessary.

BENEFITS OF SMOKING CESSATION IN FEMALE VETERAN SMOKERS

Smoking cessation can reduce and reverse many of the negative effects of tobacco use.

- Smoking cessation reduces respiratory symptoms, including coughing, wheezing, and shortness of breath. Overall lung functioning improves within several months of smoking cessation, and risk of death from COPD decreases with continued abstinence.¹³
- Cigarette smoking continues to be the most important modifiable cardiovascular risk factor for both women and men. The risk of cardiovascular events in women is substantially reduced after 2-4 years of abstinence.¹⁴ Additionally, smoking cessation substantially reduces the risk of peripheral arterial disease, which has been shown to be especially prevalent in female smokers, independent of other known risk factors.¹⁵
- Quitting smoking has been shown to decrease the risk of developing various cancers, including lung and oral cancers as well as female-specific cancers, such as breast, cervical, vulvar, and ovarian cancers. For those with a cancer diagnosis, smoking cessation has

been shown to increase responsiveness to cancer treatments as well as reduce the risk of developing a second cancer.¹⁶

- Women who quit smoking reduce the risk of infertility, and pregnant women who quit early in their pregnancies reduce the risk of gestational complications and premature birth, low-birth weight infants, and infant death.¹⁷
- Studies have shown that female Veterans who quit smoking report significantly less depressive symptoms than current smokers.⁷

Smoking Cessation Among Women

Studies have shown that women may face additional challenges in smoking cessation than men, evidenced by lower quit rates and increased difficulty in maintaining long-term abstinence.¹⁸ These challenges include:

- Women appear to have a higher rate of nicotine metabolism, leading to increased usage⁸
- Women may be more sensitive than men to different behavioral maintaining factors of smoking, such as social influences of one's smoking community and fears of weight gain following cessation⁸
- Self-reported studies have shown a consistent pattern of lower confidence and motivation and increased stress during cessation attempts among women¹⁹⁻²⁰
- Women's menstrual cycles may impact success during a quit attempt, as studies have shown that quitting during the follicular phase (lower estrogen) may be related to higher chances of relapse²¹
- Military women in particular may have comorbidity of tobacco use and psychiatric conditions, suggesting smoking may serve as a coping mechanism⁷

Indeed, women may especially benefit from patient-centered smoking cessation therapies aimed at addressing these unique challenges.

Effective Smoking Cessation Strategies

While there is currently limited research addressing evidence-based treatment for smoking cessation specific to female Veterans, studies have shown that patient success in quitting and staying tobacco-free can be dramatically increased by the selection of appropriate interventions¹⁷⁻¹⁸ such as:

- The use of smoking cessation counseling *plus* medication

- The use of combination nicotine replacement therapy, if possible
- The consistent identification, documentation, and treatment of smokers
- The use of proactive smoking cessation quitlines to provide counseling
- Patient-centered methods to address unique maintaining factors for women, as listed on the previous page
- Better patient and staff education (increased gender-specific patient education)
- Increased training for providers in evidence-based care

ABOUT THE HEALTH CARE PROVIDER'S ROLE

What We Can Do for Female Veteran Patients Who Smoke

VA primary care clinicians and health care staff can play a key role in helping their female patients quit smoking in the following ways:

- Recommend quitting, assess readiness to quit, and monitor quit attempts and smoking relapses
- Provide education that specifically targets gender-specific motives for quitting, such as preventing deaths related to COPD, to improve reproductive health and to lower risks for cancer (e.g., lung, colorectal, and breast cancer) and osteoporosis
- Prescribe smoking cessation medications
- Make referrals to specialists (e.g., mental health, substance abuse) and otherwise help patients access comprehensive care, so they receive help in resolving co-morbidities that may affect their ability to quit smoking
- Provide information on the availability of Quit VET, the Veteran-specific telephone smoking cessation quitline, 1-855-QUIT-VET (<http://vaww.publichealth.va.gov/smoking/quitline.asp>) and VA's supportive text messaging program, SmokefreeVET (<http://smokefree.gov/VET/>)
- Provide treatment in group therapy formats when possible to foster a supportive non-smoking environment

Additionally, as female Veterans tend to have a higher incidence of co-morbidities such as PTSD, depression, and other psychiatric conditions when compared to civilian women, using an integrated care model to address smoking cessation within mental health care may result in greater quitting success.²²

CHALLENGES TO CESSATION IN FEMALE SMOKERS

There is a higher incidence of co-morbidities such as depression, anxiety, and substance abuse among military women who smoke² yet some providers are hesitant to attempt smoking cessation in patients with serious co-morbidities. Several studies suggest that smoking cessation is possible in populations with serious co-morbidities, including women smokers.

- For Veterans with PTSD who smoke, an integrated model of smoking cessation with PTSD providers and staff providing consistent care was found to be effective and superior to standard-of-care smoking cessation programs given separately from the PTSD clinic.²² Studies in populations with psychiatric disorders and depression suggest at least moderate efficacy of smoking cessation and little or no evidence of exacerbation of these disorders.²²⁻²⁴
- Approximately half of alcohol dependent individuals are daily smokers and a number of studies have evaluated concurrent treatment of nicotine dependence and alcohol use disorders.²⁵⁻²⁶ Overall, evidence indicates that smoking cessation interventions for individuals with alcohol use disorders are effective and have no detrimental effects on abstinence from alcohol.²⁷ Study results are mixed regarding optimal timing of smoking cessation interventions for individuals with alcohol use disorders.²⁸⁻²⁹

Smoking status should be addressed for all individuals with alcohol use disorders and the following recommendations have been proposed:³⁰

- Smoking cessation interventions should be offered to all alcohol use disorder patients who smoke
- A menu of options about how and when to stop should be offered
- Timing of smoking cessation interventions (concurrent versus delayed) should be based on patient preference

- Some women smokers have misconceptions about the impact of light smoking. The Surgeon General Report on how tobacco causes disease documents in great detail how both direct smoking and secondhand smoke causes damage not only to the lungs and heart, but to every part of the body.^{3,31} Researchers found that inhaling cigarette smoke from one cigarette causes immediate changes to the lining of blood vessels and that light smoking may be almost as detrimental as heavy smoking.

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II. Smoking Cessation Interventions

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CHAPTER SUMMARY

Effectiveness of smoking cessation interventions

- Effective interventions can be brief (3-5 minutes) or intensive (lasting for >10 minutes)
- Brief 3-minute interventions advising patients to quit can enhance abstinence rates
- Even without a smoking cessation program, brief counseling and medications provided as part of ongoing health care can be effective

Starting a smoking cessation program for Veterans

- Identify women's health care providers and key staff with an interest in smoking cessation
- Start small and manageable by selecting brief interventions appropriate for the setting
- Build the program by incorporating more intensive interventions when appropriate
- Monitor and track your patients' progress
- Order VA's quit strategies booklet specific to women, information at <http://vaww.publichealth.va.gov/smoking/publications.asp#women> (VA intranet)

EFFECTIVENESS OF SMOKING CESSATION INTERVENTIONS

Smoking cessation interventions can be extremely effective and providers who perform even brief interventions of advice to quit can significantly increase abstinence rates. Care providers should present a clear, concise, and consistent “quit” message to all their patients who smoke. It is important to remember that brief counseling and medications provided as part of an ongoing therapeutic relationship can be as or more effective than a referral to an outside clinic smoking cessation program or the prescribing of medication alone.

Any type of provider can be effective at increasing quit rates. Strong evidence suggests that the more intense the cessation intervention, the greater the rate of abstinence. Intervention intensity can be increased by extending the length and number of individual treatment sessions.¹ Cessation counseling lasting between 4 and 30 minutes can double a patient's chance of abstinence

whereas counseling lasting more than 30 minutes can triple a patient's chance of success.¹ Conducting 2-3 counseling sessions increases abstinence rates by 1.5 fold while conducting 4-8 sessions doubles the chance of success.¹

Self-help, proactive group counseling and telephone counseling have all been shown to significantly increase abstinence rates compared to stopping “cold turkey.”¹

STARTING A SMOKING CESSATION PROGRAM FOR FEMALE VETERANS

Implementing a sustainable and effective smoking cessation program can feel daunting, but several key strategies can be helpful when implementing such a program in your clinic.

As you start to build a program in your clinic, identify providers and staff who are interested in smoking cessation as these “local champions” can help build momentum for the program and get other providers involved. As more providers become interested, you can start to implement more intensive cessation interventions. Monitoring and tracking patients' progress over time can provide helpful feedback to staff so they can see the impact of their work.

Finally, each VA facility has a smoking cessation lead clinician who can be a valuable resource to your clinic. Please email publichealth@va.gov to obtain the name of this clinician at your VA facility.

SMOKING CESSATION BEHAVIORAL INTERVENTIONS

Described in this chapter are interventions you can use when talking with your patients about their interest in smoking cessation. These brief and intensive interventions have been used in health care settings and range from 3-10 minute conversations, to intensive counseling that can last an hour. Also addressed are challenges and opportunities for implementing these well-established interventions with your patients and making smoking cessation a routine part of the clinical care you provide.

Brief Interventions (3-10 minutes)

The most important factor in smoking cessation is engaging patients. Providing patients with information about the impact of smoking in the context of women's health, assessing their level of motivation to quit, and helping them move to the next step in cessation (i.e., provision of resources, referrals to smoking cessation programs) are critical components of brief interventions.

Outlined below the five elements of a brief smoking cessation intervention.

TABLE 1. THE 5 A'S OF BRIEF SMOKING CESSATION INTERVENTIONS¹⁻³

ASK about tobacco use*

Ask patients about tobacco use at every clinic visit

- If a patient has never used, you do not need to ask again
- If a patient quit years ago, congratulate and check in periodically

**Clinical reminders and performance measures within VHA can assist with this intervention*

ADVISE patient to quit

Provide clear, strong, and personalized suggestions

- **Clear:** *I think it is important that you quit smoking. I can help.*
- **Strong:** *Quitting smoking is one of the most important things you can do to protect your health.*
- **Personalized:** Associate smoking with something that is important to the patient, such as exposure of children/family to tobacco smoke, the expense of cigarettes, pulmonary and cardiovascular comorbidities, risk of COPD and lung cancer deaths, increased risk of osteoporosis, pregnancy complications, infertility, and impact of smoking on appearance and smell.
 - *Children often pick up smoking from modeling their parents.*
 - *Do you realize that you can save more than \$2,000 a year on cigarette expenses if you quit? What else might you be able to spend that money on?*

ASSESS readiness to quit

Assess readiness to quit within 30 days

- *Are you willing to give quitting a try in the next 30 days?*
 - If patient is ready, assist patient with the quit attempt, arrange follow-up
 - If not ready, consider using motivational interviewing to increase patient's readiness to quit (see *Table 2. Enhancing Motivation to Quit Tobacco* (p. 20)).

ASSIST patients with their quit attempt

Prepare patients for quitting using STAR

- Set a quit date. Ideally, the target quit date should be within four weeks. The quit date should be a date the patient feels comfortable with and gives them enough time to prepare.
- 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 addressing nicotine withdrawal symptoms.
- Remove tobacco products from the environment. Before quitting, avoid smoking in places where a lot of time is spent (e.g., work, home, car). Make your home smoke free.

Offer pharmacotherapy and discuss the role of medication in treatment

Provide practical counseling (problem-solving/skills training)

- Offer intensive treatment options (e.g., tobacco cessation classes, telephone clinic) within your VA facility.

Provide a supportive clinical environment while encouraging the patient in her quit attempt

Provide supplementary materials and other resources available through the VA and the community

- VA smoking cessation quitline: 1-855-QUIT VET (1-855-784-8838). Counselors are available Monday-Friday
- SmokefreeVET text program: text the word VET to 47848 or visit <http://smokefree.gov/VET>
- Stay Quit Coach, a smartphone app to help Veterans quit smoking and stay quit
- Visit www.publichealth.va.gov/smoking for an up-to-date list of all resources available through VA

ARRANGE follow-up

Arrange follow-up contact by phone or in clinic (enroll in a VHA-based smoking cessation clinic, if the patient wishes)

- Timing

- First follow-up contact should be around the target quit date or within the first week
- Second follow-up should be within the first month of the target quit date
- Actions to take during follow-up
 - Assess medication use and any adverse reactions
 - Remind patient of reasons for quitting and other resources available to them (see www.publichealth.va.gov/smoking for a complete list of resources)
 - Congratulate patient on abstinence
- Treat as a chronic disease by addressing at each clinic visit

For providers with less time or comfort, the 5 A's can be modified to **AAR: Ask → Advise → Refer**, where the patient is referred to existing smoking cessation services.

Intensive Intervention (>10 minutes)¹

The components of an intensive smoking cessation intervention consist of:

- Determining whether smokers are willing to make a quit attempt with intensive counseling
- Conducting patient assessments that may be helpful including lung function, stress level, and the Fagerström Test for Nicotine Dependence (See *Table 3. Fagerström Test for Nicotine Dependence* on p. 26)
- When possible, conducting sessions longer than 10 minutes and including ≥ 4 sessions
- Combining behavioral counseling and medication (essential to successful smoking cessation treatment)
- Including problem solving/skills training and intra-treatment social support as part of the intervention

For sample programs and examples of intensive smoking cessation counseling, please see *Appendix A*.

IDENTIFYING REASONS TO QUIT

It is important to help patients identify reasons for quitting. The following intervention, based on motivational interviewing, can help motivate patients to quit who are not quite ready and can also be used during a patient's quit attempt.

TABLE 2. ENHANCING MOTIVATION TO QUIT TOBACCO (THE 5 R'S)³⁻⁶

RELEVANCE Explain why cessation is personally relevant

- Health concerns and patient's disease status or risk
- Family situation, such as quitting for children
- Cost

RISKS Ask patients to explain their perceived potential risks of smoking; discuss these risks with them (female smokers have a particularly high risk of developing COPD, women who smoke while using oral contraception have increased risks of myocardial ischemia and stroke, smoking significantly interferes with fertility and the healthy growth of a fetus).

Explain that:

- 20 minutes after quitting, heart rate and blood pressure drop
- 2 weeks to 3 months after quitting, circulation and lung function improve by 30%
- 1 year after quitting, risk of coronary heart disease (CHD) is reduced by 50%
- 5 years after quitting, stroke risk is similar to that of someone that never smoked

REWARDS Ask patients to explain what they might gain from cessation. The clinician should highlight the rewards that are most relevant to the patient.

- Food will taste better
- Improved sense of smell
- Saving money
- Setting a good example for children
- Performing better in physical activities

- Improved appearance (reduce wrinkling, whiter teeth)
 - Decreased risk of osteoporosis, heart disease, lung disease, cancers
-

ROADBLOCKS Ask patients to identify barriers to quitting and offer options to address those barriers (see *Chapter 4. Special Topics for Female Veterans* for more ideas on how to challenge barriers).

Some common barriers include:

- Withdrawal symptoms
 - Fear of failure
 - Weight gain
 - Lack of support
 - Depression
 - Enjoyment of tobacco
 - Being around other tobacco users
 - Stress
-

REPETITION Discuss these issues with patients at each visit

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III. Real-time Scripts for Brief Smoking Cessation Interventions

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CHAPTER SUMMARY

Approaching your patients about smoking cessation

- Smoking can be a chronic, relapsing condition
- Consider tracking smoking as a vital sign
- Administer the Fagerström Test for Nicotine Dependence

Address patient concerns

- Provide factual information to address each concern

Sample scripts for brief interventions

- Assess smoking status
- Advise patients about quitting
- Assess readiness to quit
- Encourage confidence in quitting

APPROACHING YOUR PATIENTS ABOUT SMOKING CESSATION

Though women's health providers are in an excellent position to provide smoking cessation interventions with their patients who smoke, it can be difficult and sometimes uncomfortable to approach the topic. We recommend treating smoking as a vital sign so that a patient's smoking status is readily apparent upon their entrance into the exam room. This is an easy way to encourage you and your patient to integrate conversations about cigarette smoking into your clinic visit.

Smoking can be a chronic, relapsing condition that at times requires varying levels of intervention. We encourage you to go as far as you can with each patient at each visit as you help lay the groundwork for smoking cessation. In order to assess your patient's level of nicotine dependence, we suggest using *Table 3. Fagerström Test for Nicotine Dependence* (p. 26). The level of your patient's nicotine dependence has important indications for the regimen that should be suggested for treatment.

TABLE 3. FAGERSTRÖM TEST FOR NICOTINE DEPENDENCE¹⁻²

1. How soon after you wake up do you smoke your first cigarette?

Within 5 minutes (3 pts.); 6-30 minutes (2 pts.); 31-60 minutes (1 pt.);
After 60 minutes (0 pts.)

2. Do you find it difficult to refrain from smoking in the places where it is forbidden (e.g., church, library, cinema)?

Yes (1 pt.); No (0 pts.)

3. Which cigarette would you hate most to give up?

The first one in the morning (1 pt.); Any other (0 pts.)

4. How many cigarettes a day do you smoke?

10 or less (0 pts.); 11-20 (1 pt.); 21-30 (2 pts.); 31 or more (3 pts.)

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

Yes (1 pt.); No (0 pts.)

6. Do you smoke if you are so ill that you are in bed most of the day?

Yes (1 pt.); No (0 pts.)

NICOTINE DEPENDENCE SCORE (Points):

(0-2 pts.) Very low dependence

(3-4 pts.) Low dependence

(5 pts.) Medium dependence

(6-7 pts.) High dependence

(8-10 pts.) Very high dependence

Note. Adapted with permission from “The Fagerström Test for Nicotine Dependence: a revision of the Fagerström Tolerance Questionnaire,” by T. F. Heatherton, L. T. Kozlowski, R. C. Frecker & K. O. Fagerström, 1991, *British Journal of Addiction*, 86(9), 1119-1127. Copyrighted.

ADDRESSING PATIENT CONCERNS

In the following tables, you will find helpful methods for discussing cigarettes and smoking cessation with your patients. For more detailed guidance on intensive interventions, please refer to *Appendix A*.

TABLE 4. SAMPLE RESPONSES TO PATIENTS' CONCERNS ABOUT SMOKING CESSATION³⁻⁵

Patient	Provider
<p>I don't want counseling, I only want medication.</p>	<ul style="list-style-type: none">■ Counseling + medication works better than medication alone.■ Counseling will provide you with practical skills to support the behavior changes necessary to quit.
<p>I want to try acupuncture, hypnosis, or laser therapy.</p>	<ul style="list-style-type: none">■ Reinforce evidence supporting the effectiveness of counseling + medication.■ Suggest that the patient augment any substandard therapy with counseling + medication.
<p>I am concerned that I will gain weight once I quit smoking.</p>	<ul style="list-style-type: none">■ Start to increase physical activity as soon as possible.■ Consider taking a walk instead of a cigarette break.
<p>I don't understand how nicotine replacement therapies (NRTs) could be harmless if nicotine is also one of the harmful drugs in cigarettes.</p>	<ul style="list-style-type: none">■ Medicinal nicotine by itself is relatively safe.■ What is harmful in cigarettes are the 7,000 other chemicals, including 69 carcinogens.■ Medicinal nicotine in dosages approved for NRT medications are proven to greatly reduce withdrawal symptoms during smoking cessation.
<p>My life is too stressful to quit smoking.</p>	<ul style="list-style-type: none">■ Smoking is one way that many people deal with stress.

Patient	Provider
<p>I have been smoking for 30 years and I have no health problems. Plus, my grandmother smoked all her life and she lived to be 100.</p>	<ul style="list-style-type: none">■ Counseling will help you develop new and healthier ways to cope with your stress.■ Some people who smoke do not develop health consequences, however about 50% of people who smoke will die from cigarette-related consequences.■ The average smoker lives 10 years less than a non-smoker.

SAMPLE SCRIPTS FOR BRIEF INTERVENTIONS

TABLE 5. SAMPLE SCRIPTS FOR BRIEF INTERVENTIONS³⁻⁵

Approach your patients about smoking

Assess smoking status

- How many cigarettes do you smoke a day?
- Do others in your household or work environment smoke?
- Have you thought about quitting?

Advise patient about quitting smoking

Be clear

- I think it is important that you quit smoking. I can help.

Make strong statements

- Quitting smoking is one of the most important things you can do for your health.
- Smoking is much more likely to harm you than any of your other chronic diseases (examples can include diabetes).

Personalize your feedback

- You can save more than \$2,000 a year on cigarette expenses if you quit.
- Your risk of lung disease, cardiovascular disease, and other problems are much higher.
- You are at increased risk of developing lung cancer and other health problems when you smoke.
- You can reduce the risk of infertility (or low birth weight) if you quit smoking.
- You complain of shortness of breath; giving up cigarettes will improve your breathing and stamina.

Assess patient's readiness to quit

- Are you willing to give quitting a try in the next 30 days?
- Lets get specific, how much do you want to cut back by the next time I see you?

Assess and build motivation

- How confident do you feel (on a scale of 1-10) that you can do that? What would move that number further up the scale for you?
- What would have to happen for it to become much more important for you to change?
- I believe you can do this. It's a tough thing to give up. Let's think about what some of the main barriers are that might get in the way of you being able to do this.

Support self-efficacy

- So, getting support from your non-smoking friends was a helpful strategy last time you quit.
- Would you like some resources about smoking cessation that you can read on your own time while you decide?
- Can you think about another time that you dealt with a challenge that you were successful in coping with? What skills did you learn from that time that you could use to help you quit smoking?

Encouraging confidence in quitting smoking

- On a 10-point scale, how confident are you in your ability to stop smoking for good?

- What would make you more confident in your ability to stop smoking?
- What did you learn from your past quit attempts?
- How might your past relapses be able to help you with this new attempt?
- Is there anything you found helpful in previous attempts to stop smoking?

Emphasize personal choice and responsibility

- It is up to you to decide when you're ready and how to quit. I'm here to help whenever you're ready.
- It sounds like you're not ready to think about quitting. It's one of the things we consider to be a vital sign so I'll be asking about it when you come in. Just let me know when you feel ready to make a change.
- You're interested in quitting, that's an important step. Here's what we have available to help you (e.g., services, medications). What would you be interested in trying first?
- If you would like, I can tell you some strategies that will help you address those concerns.

Expressing empathy

- Lots of people worry about how they'll be able to manage without cigarettes.
 - Sounds like you're not ready to quit today, I know this is a tough decision. I'm here to help you whenever you decide you're ready to quit or start to cut down.
-

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IV. Special Topics for Female Veterans

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CHAPTER SUMMARY

As discussed in the introduction, female Veterans may face additional challenges to quitting smoking than men due to physical and psychosocial factors. Thus, in addition to broad-based intervention techniques, it is recommended that any smoking cessation programs designed for women include topics tailored towards female-specific barriers to quitting such as:

- Concerns regarding weight gain
- Smoking cessation during pregnancy
- Stress and mood management
- Social support

CONCERNS REGARDING WEIGHT GAIN

Fears of weight gain have long been identified as an important factor in maintaining smoking behavior amongst women.¹ In fact, the tobacco industry continues to advertise to women through depicting images of beauty and thinness with cigarette use.² Thus, women in smoking cessation intervention groups may express that potential weight gain is a significant barrier to quitting, or may be at risk of relapse if weight gain should occur with early abstinence. To address this concern, the following intervention strategies are recommended:

1. Provide psychoeducation regarding the average weight gain following quitting. Results of a large epidemiological study found that women on average gained only 8-9 pounds after adjusting for possibly confounding factors, such as age, race, education, alcohol use, and comorbid illnesses. Furthermore, less than 15% of those who quit smoking experienced major weight gain of more than 25 pounds.³ Informing patients that weight gain is likely to be minimal, if present, and that the health benefits of quitting smoking far outweigh the risks of minor weight gain, may allay some concern over weight gain. Smoking cessation significantly reduces cardiovascular disease events (e.g., stroke, myocardial infarction) and weight gain following smoking cessation does not change the cardiovascular benefits of quitting smoking.⁴ Weight gain for former smokers who had been quit for less than four years was less than 10% and former smokers who had been quit for more than four years had no significant change in weight compared to smokers.⁴

2. Use motivational interviewing techniques to help the patient explore the pros and cons of weight gain versus continued tobacco use on health and appearance. For example, you may reflect and validate a patient's concern about potential weight gain, and then discuss the discoloring and drying effects of smoking on skin, teeth, nails, and hair. Remember to provide advice in a nonjudgmental manner and use open-ended questions (e.g., What is your view regarding these various impacts of smoking?) to help generate a discussion with your patient.
3. Cognitive behavioral therapy techniques may also be helpful in challenging and restructuring negative thoughts regarding weight gain. Help patients explore any cognitive distortions regarding weight gain (e.g., that their significant others may not find them attractive, that they'll never be able to lose the weight) and help them to arrive at more realistic and positive self-statements.
4. Encourage patients to engage in healthful behaviors while quitting to avoid excessive weight gain. Studies have shown that engaging in a moderate exercise program helps significantly reduce the amount of weight gained following quitting to an average of 3-4 pounds.⁵ Additionally, consistent exercise has been shown to help women manage smoking cravings, withdrawal effects, and mood symptoms following cessation.⁶ Exercise recommendations include moderate intensity aerobic exercise (60-80% of maximal heart rate) for 50 minutes three times per week (*Physical Activity Guidelines for Americans*). Exercise suggestions include brisk walking, jogging, swimming, or dancing.
5. In addition to exercise, you may present healthy food alternatives to help patients manage cravings, especially crunchy foods (e.g., apples, carrot sticks, air-popped popcorn), as they may also relieve stress or frustration associated with nicotine withdrawal. Patients are also recommended to increase their water intake to create a sensation of fullness. Significant weight gain can be due to food tasting much better after quitting.
6. Stress often contributes to weight gain during the quitting process. Provide patients various stress management techniques, such as joining a social support network, exercise, meditation, and stress-balls. Patients may also be referred to therapy for stress management if more intensive intervention is needed.

7. Research has shown that offering a concurrent weight management program to overweight or obese patients looking to quit smoking improves smoking cessation participation and treatment outcome.⁷ Thus, proactively informing patients of weight management resources within the VA, such as MOVE![®], may help patients overcome weight gain concerns as a primary barrier to quitting smoking. Look at the qualifications for MOVE![®] and refer your patient if needed.

SMOKING CESSATION DURING PREGNANCY

Women who are pregnant or who are attempting to conceive may be especially motivated to quit smoking, given the known risk factors to both the mother and fetus/infant. Maternal smoking is associated with 5% of infant deaths, 10% of preterm births, and 30% of small for gestational age (growth-restricted) infants.⁸ Recent reports cite that 11.4% of women continue to smoke through pregnancy, although this rate has dropped from 38% since 1990.⁹

Smoking during pregnancy appears to be particularly prevalent among younger mothers, thus, smoking cessation intervention strategies are especially important for female Veterans under the age of 25. Additionally, lack of education regarding the benefits of smoking cessation even after conception may prevent women from trying to quit.

TABLE 6. FACTS ABOUT THE RISKS OF SMOKING PRIOR TO CONCEPTION, DURING PREGNANCY, AND POSTPARTUM

Risks to Mother	Risks to Fetus/Infant
■ Infertility/delayed conception	■ Low birth weight/small for gestational age
■ Miscarriage (heavy smoking)	■ Preterm birth
■ Placental abruption	■ Fetal death/stillbirth
■ Preterm premature rupture of membranes	■ Sudden infant death syndrome (SIDS) and other causes of neonatal death (like respiratory illnesses)
■ Placenta previa	■ Increased exposure to nicotine/cotinine if human milk fed
■ Reduced milk production during breastfeeding	■ Reduced sperm counts as adults
	■ Smoking later in life

Recommendations to help pregnant women and those hoping to conceive quit smoking include:

1. Present a menu of options to help female Veterans describe their smoking behavior

As smoking during pregnancy is highly stigmatized, women may be less forthcoming with their smoking behavior when asked directly. To make assessment somewhat easier, you may consider presenting pregnant patients with a menu of options to describe their smoking frequency, ranging from “No smoking prior to or after conception” to “Currently smoking at the same level as I was prior to conception.”¹⁰

2. Educate female Veterans about how smoking harms mothers and babies and how quitting can help

Provide education about the benefits of quitting prior to conception or as early in pregnancy as possible. Encourage patients to reduce smoking as they work toward quitting. The following are points you may wish to discuss with your patient:

- Inform women who are hoping to get pregnant that smoking can affect the ability to get pregnant. Smoking delays conception by as much as two months and some studies suggest that women who smoke experience menopause earlier.¹¹ Quitting smoking can reverse these negative effects on fertility.¹²
- For women who are already pregnant, inform them about the effects of maternal smoking on a child’s health, growth, and development. Children born to mothers who smoke during pregnancy have higher risks for low birth weight, sudden infant death syndrome (SIDS), and behavioral and cognitive deficits.¹⁰ Children exposed to smoke during pregnancy and in the home as infants and children are more likely to smoke themselves and to start at a younger age.
- Inform women that quitting during any stage of pregnancy reduces the risks of complications for both her and her baby. Women who quit during the first trimester have the least smoking-related birth complications, but studies have shown that quitting smoking at the 30th week of pregnancy decreases the effects of smoking on infant birth weight compared to women who did not quit.¹³

3. Support a non-smoking home—the smoking status of her partner and others living in the home matters

Women living with a partner or other family members who smoke

have a higher risk for continued smoking during pregnancy or relapse after delivery.¹³ Always ask your patient if her significant other or family members smoke in the home. Inform the patient that being around others who smoke increases temptation to smoke and that exposure to second hand smoke is a risk to her and her fetus/ infant. If the patient's partner is open to treatment, offer smoking cessation services within the VA if spousal support is covered at your facility, or provide referrals to programs within the community. Continue to follow up with the patient and her partner regarding cessation plans throughout pregnancy and postpartum. Women who succeed in quitting during pregnancy have a high rate of relapse postpartum, especially if others in the home smoke.

4. Offer weekly individual or group counseling sessions for smoking cessation when possible

Due to the severe risks of smoking to pregnant women, more intensive interventions are highly recommended for this population.¹⁴⁻¹⁶ When possible, offer weekly individual or group counseling sessions that meet for 30 minutes or more using behavioral intervention strategies.

5. Consider offering smoking cessation pharmacotherapy when behavioral intervention alone is not enough

Nicotine replacement therapy, bupropion, and varenicline may be used during pregnancy/lactation but risk and benefit should be discussed with patients. During pregnancy, co-management of smoking cessation medications with the maternity care provider is recommended. See *Chapter 5 subsections Pregnancy Considerations with Tobacco Cessation Medication and Lactation Considerations with Tobacco Cessation Medications*.

STRESS AND MOOD MANAGEMENT

Quitting smoking is a stressful process that is both physically and mentally draining. Given the lowered rates of smoking cessation and increased rates of relapse among women, stress and other psychological symptoms may be an especially important factor to consider. Furthermore, women in the military have been shown to have higher rates of certain psychological conditions than civilian women or men in the military.¹⁷ Recommendations to assist women with comorbid stress or mood difficulties in quitting smoking include:

1. It is important to be able to recognize observed or reported symptoms of common psychiatric conditions among female Veterans, namely PTSD and depression.

2. If it is suspected that a patient suffers from emotional distress, you may consider performing a brief assessment of mood using standardized measures, such as the Patient Health Questionnaire (PHQ-9) or PTSD Check List (PCL), which evaluate depression and PTSD symptoms, respectively (measures may be requested from mental health providers). If the patient screens positive for comorbid psychiatric conditions and is not being seen by a mental health provider, you may refer her for additional mental health treatment, if she is amenable. An integrated care approach, which would integrate smoking cessation treatment into PTSD care, would assist with some of these issues.
3. Help the patient understand the connection between her stress or mood symptoms and her smoking behavior by asking her to track her smoking frequency and notice associated emotions (e.g., does she smoke more when happy, frustrated, scared). By helping the patient recognize that smoking is often a learned behavior to cope with emotional distress, you can help her break those associations and engage in healthier coping skills.
4. If the patient expresses frustration and guilt with relapse or difficulty in quitting, inform the patient that relapse and multiple quit attempts before successful cessation is common and expected. Also, you may inform her that increased quit attempts within the past year are associated with successful long-term maintenance.
5. If there is a significant population of female Veterans with comorbid psychiatric conditions seeking a smoking cessation intervention, you may want to consider conducting a specialized smoking cessation group for these patients. Social support and peer-to-peer understanding offered through the group, in addition to behavioral intervention strategies, may help bolster attendance and effectiveness of the therapy.
6. A woman's hormonal levels may potentially influence mood and stress levels, which, in turn, impact her ability to manage withdrawal symptoms. In fact, limited research has shown that quitting during the luteal (progesterone dominant) stage yields better smoking cessation outcomes than quitting during the follicular (estrogen dominant) phase. It is thought that estrogen mediates nicotine metabolism so in the follicular phase, female smokers may be more nicotine dependent.¹⁸ This phenomenon is likely the result of increased premenstrual symptoms, thereby

magnifying craving and anger at a vulnerable time, leading to relapse.¹⁹ Thus, to increase chances at a successful quit attempt, you may recommend that premenopausal patients set their quit date about 2-3 weeks into their menstrual cycle (optional). Additionally, offer patients several additional coping skills to manage increased emotionality due to premenstrual symptoms, such as exercise, socialization, or meditation.

7. If a patient expresses difficulty in the intervention due to an inability to cope with other stressors or psychiatric issues, do not hesitate to refer the patient for counseling or more intensive psychiatric care in the appropriate specialty clinic.
8. Nicotine is a stimulant and does not relieve stress. At times smoking may worsen physical stress (i.e., increase blood pressure and heart rate) as there is the daily need of more nicotine when smoking. Suggest activities that can actually relieve stress (e.g., deep breathing, stretching, exercise, yoga).

SOCIAL SUPPORT

As previously noted, women have been shown to be more influenced by their social network when it comes to smoking initiation as well as cessation. Helping the patient obtain and maintain a supportive environment when attempting to quit may improve her chance of success. To encourage positive social support, the following strategies are recommended:

1. Ask the patient to identify both helpful and discouraging comments and/or actions made by friends and family regarding her smoking behavior. Patients may have a variety of responses for what positive-versus-negative interactions entail when it comes to their smoking behavior, so it is important to have an understanding of their preferred social support style.
2. Encourage the patient to choose several friends or family members who have been supportive in her cessation efforts to be contacts for when strong smoking urges arise. You may also encourage the patient to identify people for whom she would like to quit (e.g., her spouse, children). Suggest the patient carry these individuals' contact information in her pack of cigarettes or wallet to remind her of her support network and her motivations to quit.
3. Some patients may find quitlines, text messaging programs, tobacco

cessation groups, and online resources helpful in their quit attempt. These resources may be particularly useful for patients who have fewer supportive friends or family members. Provide patients with information about Quit VET, the VA quitline, 1-855-QUIT-VET (1-855-784-8838) and SmokefreeVET, a supportive text messaging service to help Veterans quit smoking. Patients can sign up to use SmokefreeVET by texting the word VET to 47848 or by visiting <http://smokefree.gov/VET>. Information about local tobacco cessation groups and online resources such as Smokefree Women may also be useful (<http://women.smokefree.gov/>).

4. Teach the patient assertive communication skills to help her maintain her resolve to quit when faced with negative social interactions. Encourage the patient to be open and vocal about quitting and to tell her friends and family about her quit date. Also, encourage the patient to be forthcoming with her triggers to friends and family, and to request that others be mindful of these high-risk situations. It is also helpful to teach the patient to use “I” statements when making these requests. For example, have the patient practice saying, “I am trying to quit smoking, and I would really find it helpful if _____.”
5. If the patient’s primary social network consists of smokers, help the patient brainstorm different activities she could engage in to avoid smoking with them. For example, the patient could read a magazine or a book, call friends, take a walk, or chew gum or candy in place of going on a “smoke break.”

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V. Medications for Smoking Cessation

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CHAPTER SUMMARY

Nicotine pharmacology

- Use of medications for smoking cessation result in better abstinence rates and durability
- Medications for smoking cessation are most successful when combined with other interventions (e.g., counseling, monitoring and tracking)
- Use *Table 3. Fagerström Test for Nicotine Dependence* (p. 26) to guide prescribing
- The goal of titration is to eliminate the need for nicotine replacement therapy while maintaining smoking abstinence
- Nicotine pharmacology considers the dose response and manages withdrawal symptoms, which commonly include irritability, impatience, anxiety, difficulty concentrating, restlessness, hunger, depression, insomnia, and cravings
- Selection of the smoking cessation medication should be based on the person's level of addiction to nicotine, product preference, and concomitant medical conditions
- Consider combination therapy in patients with high dependence, those who are heavier smokers, or those experiencing cravings or withdrawal symptoms while on the patch alone

Nicotine replacement therapy (NRT)

- Nicotine transdermal patch
- Nicotine polacrilex gum
- Nicotine polacrilex lozenge
- Nicotine nasal spray*
- Nicotine oral vapor inhaler*
- Consider combination therapy of nicotine patch plus polacrilex gum or lozenge for maximum management of withdrawal symptoms

Non-NRT agents

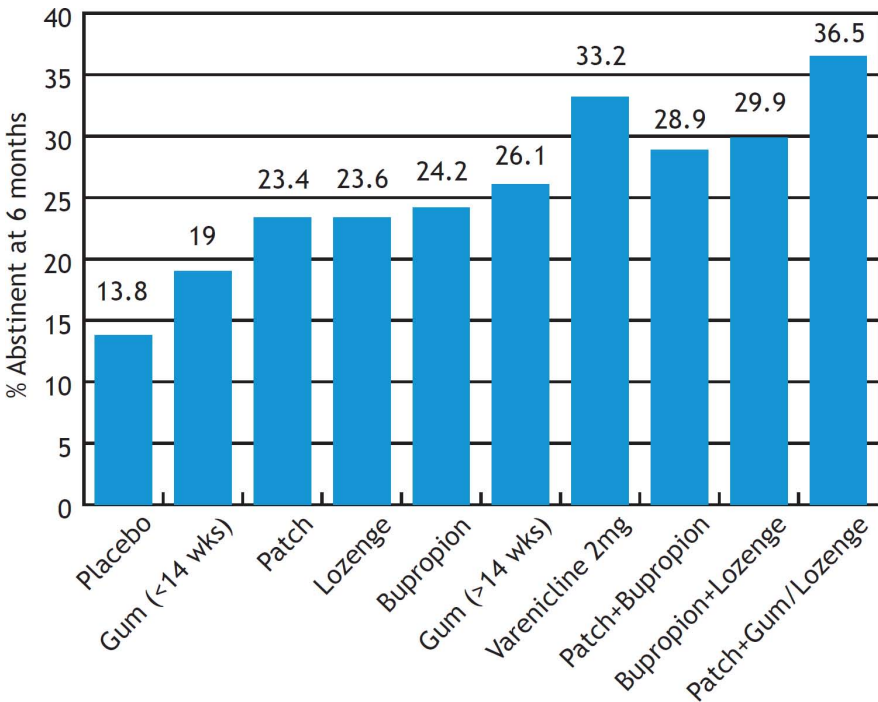
- Bupropion
- Varenicline (second-line agent within VA)

*Not on VA national formulary

NICOTINE PHARMACOLOGY

First-line agents approved for smoking cessation consist of NRT including the nicotine patch, gum, lozenge, inhaler and spray; and the non-NRT agent bupropion. Within VA, varenicline is a second-line agent for smoking cessation. Combination therapy using the nicotine patch plus either gum, lozenge, nasal spray, inhaler, or NRT plus bupropion is also recommended as a first-line treatment option.

FIGURE 1. EFFICACY OF MEDICATIONS FOR SMOKING CESSATION^{6,9,12-13}



Nicotine Withdrawal³

Once absorbed, nicotine induces a variety of central nervous system, cardiovascular, and metabolic effects.¹⁻³ Within seconds after taking a puff on a cigarette, nicotine reaches the brain and stimulates the release of various neuro-transmitters including dopamine, which induces nearly immediate feelings of pleasure and relieves nicotine-withdrawal symptoms. This rapid dose response reinforces the need to repeat the intake of nicotine, thereby perpetuating smoking behavior.

When nicotine is discontinued, individuals may develop withdrawal symptoms such as irritability, impatience, anxiety, difficulty concentrating, restlessness, hunger, depression, insomnia, and cravings. Most physical withdrawal symptoms generally manifest within 24-48 hours after quitting and gradually dissipate over 2-4 weeks; however, strong cravings for cigarettes can persist for months or even years.

NICOTINE REPLACEMENT THERAPY (NRT)

The mechanism of action of these agents, which are ganglionic (nicotinic) cholinergic-receptor agonists, is to replace nicotine that would have been obtained from smoking.³ These agents improve quit rates by reducing the symptoms of nicotine withdrawal and because the onset of action with NRT is not as rapid as that of nicotine obtained through a cigarette, patients become less accustomed to the nearly immediate reinforcing effects of tobacco.⁴ The goal is to use NRT to titrate off a patient's nicotine addiction over a few months. All NRTs are contraindicated in patients with a hypersensitivity to nicotine or components and all agents have the potential for nicotine overdose. *Table 7. Medications for Smoking Cessation Available Through the VA National Formulary* (p. 58) summarizes the dosing regimens, advantages and disadvantages, common adverse effects, and contraindications for three forms of NRT, bupropion, and varenicline.

*Nicotine transdermal patch*⁴⁻⁶

- Although the patch has the slowest onset of all the nicotine preparations, it offers more consistent levels of nicotine over a sustained period of time resulting in fewer blood level fluctuations. Plasma nicotine concentrations rise slowly over 1-4 hours and peak within 3-12 hours.
- Steady-state concentration is reached 2-3 days after placement of first patch; following removal of the transdermal patch, the apparent half-life averages 3-6 hours. Plasma nicotine levels are about 50% lower than those achieved with cigarette smoking but still alleviate symptoms of withdrawal.
- Can be applied anywhere on the upper body, including arms and back, avoiding hairy areas; rotate the patch site each time a new patch is applied.
- Available over the counter in the community without a prescription; advise patients not to combine products obtained in the community with products dispensed from VA without discussing with their providers.

*Nicotine polacrilex gum*⁶⁻⁹

- Resin complex of nicotine and polacrilin in a sugarfree chewing gum base. Gum has a distinct peppery taste and contains sodium carbonate/bicarbonate buffers to increase salivary pH thereby enhancing absorption of nicotine across the buccal mucosa. The amount of nicotine absorbed from each piece is variable (approximately 1.1 mg and 2.9 mg from the 2 mg and 4 mg formulations, respectively).
- Nicotine plasma levels peak approximately 30 minutes after chewing a piece of gum and slowly decline over 2-3 hours. Provides plasma nicotine concentrations approximately 30-64% of pre-cessation levels.
- Allows smokers to take an active coping response to nicotine withdrawal symptoms.
- Associated with less weight gain compared to placebo during treatment.
- Sticks to dentures, may dislodge fillings and inlays because of its density.
- Patients should be advised not to eat or drink for 15 minutes before, during, or after using. Acidic beverages (e.g., coffee, juice) inhibit the absorption of nicotine and should be avoided within 15-20 minutes of use.
- Available OTC in the community; advise patients not to combine products obtained in the community with products dispensed from VA without discussing with their providers.

Nicotine polacrilex lozenge^{4,6-9}

- Resin complex of nicotine and polacrilin in a flavored lozenge intended to be sucked and moved from side to side in the mouth until fully dissolved. The lozenge contains sodium carbonate/potassium bicarbonate buffers to increase salivary pH thereby enhancing absorption of nicotine across the buccal mucosa.
- Nicotine plasma levels peak in approximately 30 minutes and slowly decline over 2-3 hours. Because the lozenge dissolves completely, it delivers about 25% more nicotine than does an equivalent dose of nicotine gum.

- Allows smokers to take an active coping response to nicotine withdrawal symptoms.
- Potential to consume too quickly may cause symptoms of high nicotine levels (e.g., nausea, gastrointestinal upset).
- Patients should be advised not to eat or drink for 15 minutes before, during, or after using. Acidic beverages (e.g., coffee, juice) inhibit the absorption of nicotine and should be avoided within 15-20 minutes of use.
- Available OTC in the community; advise patients not to combine products obtained in the community with products dispensed from VA without discussing with their providers.

*Nicotine nasal spray*⁶⁻¹⁰ (not on VA national formulary)

- Aqueous solution of nicotine available in a metered-spray pump for administration to nasal mucosa. Each actuation delivers a 50 mL spray containing 0.5 mg of nicotine.
- Peak concentrations occur more rapidly than with other NRT products; plasma levels peak within 5-15 minutes resembling the kinetics of nicotine seen with cigarette use; approximately 53% is absorbed.
- Due to its faster onset, capacity for self-titration, and rapid fluctuations of nicotine levels, the nasal spray has the highest potential for developing dependence.
- Local irritant adverse effects including nasal and throat irritation, runny nose, sneezing, watery eyes, and cough may occur. These effects frequently dissipate after the first week of use.
- Not recommended for patients with known chronic nasal disorders or severe reactive airway disease.

Nicotine oral inhaler^{6-9,11} (not on VA national formulary)

- Consists of a plastic mouthpiece and cartridge that delivers nicotine as an inhaled vapor from a porous plug containing nicotine. When puffed, nicotine is vaporized and absorbed across the mucosa of the mouth and throat (not the lungs).
- Each foil sealed cartridge contains 10 mg of nicotine and 1 mg of menthol. Plastic spikes on the mouthpiece pierce the foil allowing the release of 4 mg of nicotine vapor following intensive inhalation of which about 2 mg is absorbed.

- Peak plasma concentrations occur within 15-30 minutes and then slowly decline.
- High residual level of nicotine in discarded cartridge can be dangerous to children and pets.
- High incidence of mouth and throat irritation.
- Use cautiously in patients with severe reactive airway disease.
- Delivery of nicotine from the inhaler declines significantly at temperatures below 40°F.
- Patients should be advised not to eat or drink for 15 minutes before, during, or after using. Acidic beverages (e.g., coffee, juice) inhibit the absorption of nicotine and should be avoided within 15-20 minutes of use.

Please note the nicotine oral inhaler is not the same as electronic cigarettes, which are not FDA approved for smoking cessation treatment.

Combination Nicotine Replacement Therapy^{6,9,12-14}

Monotherapy NRT may be less effective in women smokers compared to men, so combination NRT should be considered for most women smokers. Combination NRT involves the use of a long-acting formulation (e.g., nicotine patch) along with a short-acting formulation (e.g., gum, lozenge, inhaler, or nasal spray). A nicotine patch provides a passive sustained form of nicotine delivery and is used to prevent the onset of severe withdrawal symptoms.

Short-acting formulations provide an ad libitum delivery that has a faster onset and can be used to control the strong cravings or urges that occur during potential relapse situations (e.g., after meals, during times of stress, when around other smokers).

Controlled trials suggest that the nicotine patch in combination with short-acting NRT formulations significantly increases quit rates relative to placebo and nicotine patch alone. Combination therapy with the patch and either gum or lozenge is superior to monotherapy with the patch in up to one year of follow up. Using a combination of patch plus long-term nicotine gum (>14 weeks) has been shown to more than triple the likelihood of long-term abstinence (OR = 3.6, 95% CI 2.5-5.2). Similarly, studies evaluating the nicotine patch in combination with the nicotine lozenge for 12 weeks have resulted in abstinence rates of up to 40% at six months.

Example Titration Schedule

- ▶ Week 1: Nicotine 21 mg patches and 5 lozenges
- ▶ Week 2: Nicotine 21 mg patches and 4 lozenges
- ▶ Week 3: Nicotine 21 mg patches and 3 lozenges
- ▶ Week 4: Nicotine 21 mg patches and 2 lozenges
- ▶ Week 5: Nicotine 21 mg patches and 1 lozenge
- ▶ Week 6: Nicotine 14 mg patches and 4 lozenges
- ▶ Week 7: Nicotine 14 mg patches and 3 lozenges
- ▶ And so forth...

Use behavioral strategies previously listed to assist with titration

NRT Safety^{6,9,15-17}

Nicotine can increase one's heart rate, blood pressure, and myocardial contractility, and also act as a coronary vasoconstrictor. In patients with stable coronary artery disease, NRT can be initiated at intermediate doses with careful monitoring. Large randomized trials have found no significant increase in the incidence of cardiovascular events or mortality among patients with cardiovascular disease receiving NRT when compared to placebo. A large observational study of more than 33,000 patients found that NRT use was not associated with an increased risk of myocardial infarction, stroke, or death. Serum concentrations of nicotine achieved with the recommended dosages of NRT are generally much lower than those attained with smoking and most experts agree that the risks associated with NRT use in patients with cardiovascular disease are minimal relative to the risks of continued smoking.

Other conditions for which NRT should be used with caution include active temporomandibular joint (TMJ) disease (specifically, NRT gum), hyperthyroidism, peptic ulcer disease, and severe renal impairment. Although the FDA has developed a uniform warning for all NRTs because of the risks of nicotine in pregnancy, they believe that NRT is safer than smoking during pregnancy.

The safety of NRT in the elderly has not been systematically evaluated. However, one small pharmacokinetic study concluded that though there were statistically significant differences, the disposition of nicotine does not seem to be changed to a clinically important extent in the elderly.

NRT Use⁶

Treatment of nicotine dependence with NRT should adhere to the following principles:

- **Dose to effect:** The initial dose should be sufficient to provide the patient with a nicotine dose similar to that seen prior to stopping cigarettes. Providers should always assess the patient's nicotine dependence before prescribing cessation aids.
(See *Table 3. Fagerström Test for Nicotine Dependence* on p. 26)
- **Treat withdrawal symptoms:** The nicotine replacement dose should be sufficient to prevent or minimize craving for tobacco products.
- **Avoid adverse reactions:** The nicotine replacement dose should be titrated so that signs and symptoms of overmedication (e.g., headache, nausea, palpitations) do not occur.
- **Advise patient not to use cigarettes while using NRT:** Encourage the patient to report to their provider if they have severe cravings, which may indicate reevaluation of dosage and type of NRT (consider use of combination NRT, such as the patch or gum).
- **Selection of the NRT should be based on the person's level of addiction to tobacco, product preference, and concomitant medical conditions:** Consider combination therapy in patients with high dependence or in those who are heavy smokers.

BUPROPION^{6,18-21}

Bupropion (Zyban[®]) is a weak dopamine-norepinephrine reuptake inhibitor with some nicotine receptor blocking activity.¹⁸⁻¹⁹ The mechanism by which bupropion enables patients to abstain from smoking is unknown. However, it is presumed that bupropion acts by enhancing central nervous noradrenergic and dopaminergic release and antagonizes nicotinic acetylcholine receptor function. The antismoking effect of bupropion does not seem to be related to the antidepressant effect, as bupropion is equally effective as a smoking cessation therapy in smokers with or without depression.²⁰ There may not be gender differences with bupropion and it may be a good agent for female smokers.²¹

- Steady-state levels of bupropion and metabolites are reached within 5-8 days, respectively. It is best to start bupropion one week before one's target quit date.
- In patients with severe hepatic cirrhosis, extreme caution is advised since peak bupropion levels are substantially increased. For patients

with mild-to-moderate hepatic cirrhosis, a reduced frequency or dose should be considered.

- Bupropion should be used with caution in patients with renal impairment and a reduced frequency of dosing should be considered. Patients should also be closely monitored for possible adverse effects that could indicate high drug or metabolite effects.
- Bupropion has the potential to interact with other drugs that are metabolized by or which inhibit/induce the CYP2B6 isoenzyme. It can also interact with drugs metabolized by the CYP2D6 isoenzyme.
- Although the recommended duration of treatment is 7-12 weeks, bupropion is approved for use up to six months to prevent relapse to smoking.²²
- Bupropion may be associated with less weight gain.
- Bupropion *may be used in combination* with NRT (e.g., nicotine lozenge, nicotine gum and nicotine patch).^{6,23}

Bupropion Safety²⁵⁻²⁷

Bupropion is associated with a dose-dependent risk of seizures; maximum bupropion SR dose for treating smoking is 300 mg/day. Although higher doses of bupropion SR have been used for treating depression, they have not been tested for smoking cessation. Also, there is no evidence that higher doses improve quit rates.

Extreme caution is advised in patients with severe hepatic cirrhosis; all patients with hepatic impairment should be closely monitored for possible adverse effects. Caution is also advised in patients with a history of hypertension, myocardial infarction, or unstable heart disease due to risk of hypertension.

Serious neuropsychiatric symptoms have been reported in patients taking bupropion for smoking cessation. These symptoms include, but are not limited to, depression, suicidal ideation, and suicide attempt.

VARENICLINE²⁷⁻²⁹

Varenicline tartrate (CHANTIX®/Champix®) is a partial agonist that binds selectively to the α 4B2 subunit of the nicotinic acetylcholine receptor thereby reducing the symptoms of nicotine withdrawal during abstinence.²⁷⁻²⁸ Because of the significantly higher affinity of varenicline for the α 4B2 receptor subunit, it

blocks nicotine from binding to the receptor and attenuates the reinforcement and rewarding effects of nicotine (thus this is not used with NRT).

- Peak concentrations occur within 3-4 hours after oral administration. Steady-state conditions are reached within four days. Varenicline is well absorbed and levels are unaffected by food or time-of-day dosing. However, recommend to patients that they take it after eating and drink eight ounces of water in order to minimize nausea.
- Primarily eliminated via glomerular filtration with active tubular secretion. In subjects with decreased renal function, varenicline exposure increased from 1.5 to 2.7-fold compared with subjects with normal renal function. Varenicline is efficiently removed by hemodialysis.
- Dosage adjustment is necessary for patients with estimated creatinine clearance <30 ml/min.
- No clinically significant drug interactions.
- For patients who have successfully stopped smoking at the end of 12 weeks, an additional 12-week course of treatment (for a total of 24 weeks) may be beneficial in maintaining and increasing the likelihood of long-term abstinence and preventing relapse.³⁰
- To date, the safety and efficacy of varenicline in conjunction with NRT or bupropion for smoking cessation has not been studied extensively and is *not recommended*.

Varenicline for Smoking Cessation in VA

Within VA, varenicline is a second-line agent for smoking cessation and must be prescribed according to Pharmacy Benefit Management (PBM) criteria, which can be found on the PBM website (<https://vaww.cmopnational.va.gov/cmop/PBM/Clinical%20Guidance/Criteria%20For%20Use/Varenicline%20Criteria%20for%20Prescribing.doc>).³¹

Varenicline Safety^{26,32-34}

Varenicline carries a boxed warning about the risk for serious neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behaviors, and attempted suicide. All patients should be monitored closely and advised to stop treatment if any of these symptoms appear.

Health care providers should perform a careful psychiatric history prior to prescribing the drug and avoid use in smokers with a history of suicidal ideation or a current unstable psychiatric condition. Consider a temporary or permanent dose reduction in patients who cannot tolerate the adverse effects of varenicline.

Varenicline may be associated with a small, increased risk of certain cardiovascular adverse events in patients who have cardiovascular disease. Cardiovascular adverse events were infrequent overall, however, certain cardiovascular adverse events were reported in more patients treated with varenicline than patients treated with placebo. The FDA is continuing to evaluate the cardiovascular safety of varenicline.

TABLE 7. MEDICATIONS FOR SMOKING CESSATION AVAILABLE THROUGH THE VA NATIONAL FORMULARY

	BUPROPION	NICOTINE TRANSDERMAL PATCH	NICOTINE POLACRILEX GUM	NICOTINE POLACRILEX LOZENGE	VARENICLINE
Trade name and dose availability	Bupropion SR (Zyban®/Wellbutrin®) 150mg tablet	Nicoderm®/Habitrol® 7mg, 14mg, 21mg	Nicorette® Gum 2mg, 4mg	Commit® Lozenge 2mg, 4mg	CHANTIX® 0.5mg, 1mg tablets
Pregnancy category	C	D	D	D	C
Recommended regimen	Bupropion SR 150mg daily for 3d, then 150mg twice daily (8 hrs apart) Patients with cirrhosis need adjusted dose: 150mg every other day Bupropion IR 100mg daily for 3d, then 100mg three times daily Patients with cirrhosis need adjusted dose: 75mg daily	Smoking more than 10 cigarettes a day: 21mg for 4-6wks, then 14mg for 2wks, then 7mg for 2wks Smoking 10 or fewer cigarettes a day: 14mg for 6-8wks, then 7mg for 2wks	High dependence*: 4mg every 1-2 hrs for 6wks, then every 2-4hrs for 3wks, then every 4-8hrs for 3wks Low dependence: 2mg every 1-2hrs for 6wks, then every 2-4hrs for 3wks, then every 4-8hrs for 3wks No more than 24 pieces in 24hrs	High dependence*: 4mg every 1-2hrs for 6wks, then every 2-4hrs for 3wks, then every 4-8hrs for 3wks Low dependence: 2mg every 1-2hrs for 6wks, then every 2-4hrs for 3wks, then every 4-8hrs for 3wks No more than 20 pieces in 24hrs	0.5mg daily for 1-3d, then 0.5mg twice daily on days 4-7, then STOP SMOKING on quit date, then 1mg twice daily for total of 12 weeks duration CrCl<30ml/min: max dose 0.5mg twice daily ESRD or HD: 0.5mg daily
Start instructions	1-2 weeks before quit day	On quit day	On quit day	On quit day	1-2 weeks before quit day

	BUPROPION	NICOTINE TRANSDERMAL PATCH	NICOTINE POLACRILEX GUM	NICOTINE POLACRILEX LOZENGE	VARENICLINE
Administration comments	<ul style="list-style-type: none"> Continue treatment for 7-12 wks (if no progress is made by week 7, consider discontinuing therapy) If insomnia, take evening dose in afternoon Dose tapering is not required upon discontinuation Alert patients to potential for drug interactions Do not crush or chew tablets <i>Can be used in combination with nicotine patch, nicotine gum, or nicotine lozenge</i> 	<ul style="list-style-type: none"> Usually worn for 16-24 hrs Apply from shoulders to waist Rotate sites Takes 2-3 d for effect after application of first patch <i>Can be used in combination with nicotine gum or lozenge at usual dose.</i> Patch continued for 8-10 weeks with lozenge and 8-24 weeks with gum <i>Can be used in combination with bupropion</i> 	<ul style="list-style-type: none"> Chew slowly (about 10 chews) until peppery taste then "park" between cheek and gums until taste disappears. Repeat chew and park process for 30 minutes on each piece of gum Avoid acidic beverages (citrus juice, soft drinks, coffee) within 15 minutes of use Avoid eating or drinking while using the gum <i>Can be used in combination with nicotine patch or bupropion;</i> most patients will require 6-8 pieces of gum/day as needed when used in combination. Gum can be continued for 26-52 weeks when initiated as combination therapy 	<ul style="list-style-type: none"> Dissolve slowly over 20-30 minutes shifting in the mouth occasionally Do not chew or swallow (increased risk of GI side effects) Avoid acidic beverages (citrus juice, soft drinks), within 15 minutes of use Avoid eating or drinking while using the lozenge <i>Can be used in combination with nicotine patch or bupropion;</i> most patients will require 6-8 lozenges/day as needed when used in combination. Lozenges can be continued for 12 weeks duration when initiated as combination therapy 	<ul style="list-style-type: none"> Take after eating and with 8 ounces of water to minimize nausea Report depression, suicidal ideation, unusual behavior, or worsening psychiatric illness An additional 12 wks of treatment in patients who have successfully stopped smoking may increase the likelihood of long-term abstinence

	BUPROPION	NICOTINE TRANSDERMAL PATCH	NICOTINE POLACRILEX GUM	NICOTINE POLACRILEX LOZENGE	VARENICLINE
Advantages (+) and disadvantages (-)	<p>(+) better adherence; ease of use; can be combined with NRT; consistent rate of exposure; helps with withdrawal symptoms</p> <p>(-) many drug interactions; CNS side effects; must be adjusted for hepatic insufficiency; increased risk of seizures</p>	<p>(+) best adherence; easy to use; consistent rate of exposure; unobtrusive; can be combined as needed with gum, lozenge, or bupropion for better efficacy</p> <p>(-) less effective for cravings; difficult to control titration; absorption increased at elevated temperatures</p>	<p>(+) can titrate to adjust for cravings or sudden urges; oral substitute for cigarettes; can be combined with nicotine patch or bupropion for better efficacy</p> <p>(-) difficult for those with poor dentition or dentures; must use proper chewing technique; must abstain from drinking and eating during gum use; swallowing the nicotine causes GI side effects</p>	<p>(+) ease of use; discreet; higher immediate levels; can titrate to adjust for cravings; reduces self-reported withdrawal symptoms; can be combined with nicotine patch or bupropion for better efficacy</p> <p>(-) must abstain from drinking/eating during lozenge use</p>	<p>(+) better adherence; ease of use; consistent rate of exposure; superior rate of abstinence compared to bupropion and placebo</p> <p>(-) potential for serious neurologic and psychiatric side effects (esp. in those with underlying psychiatric disease); dose adjust for renal insufficiency (CrCl<30); high incidence of nausea</p>
Adverse effects	<ul style="list-style-type: none"> • Agitation • Anxiety • Dizziness • Headache • Insomnia • Constipation • Dry mouth • Nausea 	<ul style="list-style-type: none"> • Sleep disturbances • Local skin irritation • Bone pain • Headache • Nausea 	<ul style="list-style-type: none"> • Local mouth irritation • Jaw pain • Hiccups • Dyspepsia • Rhinitis • Nausea • Flatulence 	<ul style="list-style-type: none"> • Local mouth irritation and tingling • Heartburn, indigestion (if chewed) • Headache • Nausea, diarrhea • Flatulence 	<ul style="list-style-type: none"> • Dream disorders • Headache • Insomnia • Agitation • Depressed mood • Suicidal thoughts • Constipation • Flatulence

	BUPROPION	NICOTINE TRANSDERMAL PATCH	NICOTINE POLACRILEX GUM	NICOTINE POLACRILEX LOZENGES	VARENICLINE
Adverse effects (cont)	<ul style="list-style-type: none"> • Hypersensitivity reactions • Seizures (risk 1:1000) 				<ul style="list-style-type: none"> • Nausea and vomiting <p><i>Consider dose reduction in patients with nausea, insomnia, headache</i></p>
VA national formulary	Open formulary, no restrictions	Open formulary, no restrictions	Open formulary, no restrictions	Open formulary, no restrictions	Yes, must meet criteria for use.
Contraindications & relative contraindications	<ul style="list-style-type: none"> • History of seizures • Predisposition to seizures (severe head trauma, CNS tumor, 	<ul style="list-style-type: none"> • Hypersensitivity • Pregnancy category D • Use within 14 days post MI, or serious or worsening angina 			<p>Criteria available at https://www.cmpnational.va.gov/cmop/PBM/Clinical%20Guidance/Criteria%20For%20Use/Varenicline%20Criteria%20for%20Prescribing.doc</p> <p>Available to patients without active mental health disorders who have had >1 relapse on NRT or bupropion</p>
Relative & contraindications:					<p>Relative Contraindications:</p> <ul style="list-style-type: none"> • Serious neuropsychiatric disorders

	BUPROPION	NICOTINE TRANSDERMAL PATCH	NICOTINE POLACRILEX GUM	NICOTINE POLACRILEX LOZENGE	VARENICLINE
Contraindications & relative contraindications (cont.)	<ul style="list-style-type: none"> hepatic cirrhosis • Abrupt withdrawal from heavy alcohol or sedative use • MAO inhibitor within 14 d • Bulimia, anorexia nervosa • Hypersensitivity • Pregnancy category C 	<ul style="list-style-type: none"> • Patients should be encouraged to avoid smoking while on nicotine replacement therapy. If the patient has a slip, encourage them to get back on track and consider using combination therapy if on monotherapy. If patient has a relapse, then suggest patient stop using NRT and restart once they are ready to try quitting again. • TMJ syndrome (gum only) 			<ul style="list-style-type: none"> (including suicidal and homicidal ideation) • History of suicidal, homicidal, or assaultive behavior in the past 12 weeks • Untreated or unstable mental disorder • Severe renal impairment • Pregnancy category C
Comments	<ul style="list-style-type: none"> • Use with caution in patients with liver, kidney failure • Avoid in patients on MAO inhibitors • Monitor for neuro-psychiatric signs and symptoms during use 	<ul style="list-style-type: none"> • <i>May be used in combination with nicotine gum/lozenge or bupropion for significantly better abstinence rates and durability</i> • Using the 21 mg patch yields roughly 40-50% the plasma nicotine levels of smoking 1.5 packs per day 	<ul style="list-style-type: none"> • <i>May be used in combination with nicotine patch or bupropion for significantly better abstinence rates and durability</i> • Using 2 mg dose every 1-2 hours yields roughly 40% the plasma nicotine levels of smoking 1 pack per day 	<ul style="list-style-type: none"> • <i>May be used in combination with nicotine patch or bupropion for significantly better abstinence rates and durability</i> • Delivers about 25% more nicotine than does an equivalent dose of nicotine gum 	<ul style="list-style-type: none"> • Should not be used as first-line therapy • Ask about psychiatric history prior to prescribing • Monitor for signs and symptoms of psychiatric illness during use • Monitor serum creatinine; if renal function decreases dose reductions may be necessary

* High dependence = use of tobacco less than 30 minutes after awakening or greater than or equal to 20 cigarettes (one package) per day. If these criteria do not apply the patient is considered to have low dependence.

Pregnancy Considerations with Tobacco Cessation Medications

During pregnancy, co-management of smoking cessation medications with the maternity care provider is highly recommended.

- **NRT (Pregnancy Category D)^{6,9,17}**: May be considered during pregnancy for women who are unable to quit smoking with behavioral interventions alone. A 2012 review of published data on pharmacological interventions for smoking cessation during pregnancy found insufficient evidence to determine whether or not NRT is effective or safe when used to promote smoking cessation during pregnancy or to determine whether NRT has positive or negative effects on birth outcomes compared to smoking.³⁵ This review included six randomized controlled trials of 1,745 pregnant smokers.
- Nicotine has well documented adverse effects during pregnancy; however, compared with smoking, use of NRT is associated with lower maternal blood levels of nicotine. In addition, smoking results in fetal exposure to carbon monoxide and hundreds of harmful chemicals, some of which are carcinogens. The American College of Obstetrics and Gynecology states NRTs can be used during pregnancy under close supervision following a provider/patient discussion about relative risks and benefits.³⁶ NRTs with intermittent dosing (e.g., gum, lozenge, nasal spray) generally achieve lower daily exposures to nicotine than 24-hour patches.

Recommendation: Use NRT only if benefits outweigh risks. If patient can't quit smoking with behavioral interventions, consider NRT with approval from obstetrician.

- **Bupropion (Pregnancy Category C)^{6,18-19,37}**: A relatively weak norepinephrine and dopamine reuptake inhibitor that is approved as an aid to smoking cessation and for the treatment of depression. A retrospective managed care database study assessed the risk for congenital malformations overall and cardiovascular malformations following exposure of 1,213 infants to bupropion during the first trimester compared to the risk of malformations following exposure of 5,792 other infants to other antidepressants during the first trimester or bupropion later in pregnancy. The study found no greater risk for congenital malformations overall or cardiovascular malformations following first trimester bupropion exposure. There are no studies of pregnancy outcomes with bupropion exposure among women using the medication as an aid for smoking cessation.

However, slight increase in incidence of fetal malformations and skeletal variations were seen in rabbits so risk cannot be ruled out.

Recommendation: Use bupropion only if benefits outweigh risks. If patient can't quit smoking with behavioral interventions, consider bupropion in patients without contraindications with approval by obstetrician. It is highly recommended that if patient has underlying mood disorders that mental health provider should also be involved.

- **Varenicline (Pregnancy Category C)**^{26,32-34}: A nicotine receptor partial agonist that prevents nicotine from binding to its receptor. It is approved for use as an aid to smoking cessation. There are no studies on the use of varenicline during human pregnancy. Studies in two species of pregnant animals did not show any increased risk for birth defects or pregnancy loss, and effects on fetal weights did not occur until animal doses reached more than 23 times the maximum recommended human dose.

Recommendation: Use varenicline only if benefits outweigh risks. If patient can't quit smoking with behavioral interventions, consider varenicline in patients without contraindications, after failure of combination therapy and with approval by obstetrician. It is highly recommended that if patient has underlying mood disorders that mental health provider should also be involved. Mood assessments are required every 28 days for Veterans.

Lactation Considerations with Tobacco Cessation Medications

- **NRT**^{6,9,17,35,36}: Nicotine can pass freely into breast milk and an infant has the ability to clear nicotine through first pass metabolism, albeit with unclear level of efficiency. Harmful effects to infants are unknown and benefits/risks should be assessed for each case.

Recommendation: Can consider use of NRT only if benefits outweigh risk (i.e., nursing mother can only quit with NRT).

- **Bupropion**^{6,18-19,37}: It is known that bupropion and metabolites are excreted in humans. Health effects are inconclusive. The current manufacturer recommendation is to discontinue the medication or discontinue nursing.

Recommendation: Bupropion should not be used in conjunction with nursing.

- **Varenicline**^{26,32-34}: It is not known if varenicline is excreted in humans. Health effects are inconclusive. However, it is excreted in animals. The current manufacturer recommendation is to discontinue the medication or discontinue nursing.

Recommendation: Varenicline should not be used in conjunction with nursing.

Tobacco Smoke and Interactions with Medications^{18,28,38}

Smoking cessation medications (NRT, bupropion, and varenicline) are associated with minimal drug interactions. However, there are some medications that have possible interactions with tobacco smoke, specifically with the polycyclic aromatic hydrocarbons (PAHs) in the smoke. PAHs are potent hepatic cytochrome P-450 (CYP) 1A2 inducers (1A1 and 2E1 as well). Several medications (e.g. theophylline, olanzapine, clozapine, benzodiazepines) and caffeine are metabolized through CYP 1A2. When a patient smokes the clearance of caffeine and medications are faster, resulting in less drug amount and less pharmacologic effect in the body (which is why sometimes patient may be on higher doses of medications). When a patient quits smoking, there is potential for the drug level to be increased resulting in a higher pharmacological effect. This may potentially lead to increase adverse drug events.

Recommendation for caffeine: Reduce caffeine intake by 50% as increased levels of caffeine upon quitting can lead to more withdrawal symptoms, not to mention that caffeine can be a trigger to smoke.

Recommendation for medication management after quitting: Monitor symptoms closely and adjust at first signs of an adverse drug event.

- *Example: A 56 yo woman with history of tobacco use disorder, schizophrenia now tobacco free for 2 weeks doing very well and mood is also stable. She is noticing some slight tremors and is currently on olanzapine 20 mg every day. Given that tremors may be due to increased pharmacological effects of olanzapine, olanzapine dose was decreased to 15 mg every day. At next follow-up, tremors subsided and mood still stable. Patient was continued on 15 mg every day.*
- Another important interaction that is serious and a contraindication for women 35 and older is the interaction between tobacco smoke and hormonal contraceptives. The interaction between the two increases risk of cardiovascular events such as stroke and myocardial infarction.

Recommendation: Do not prescribe hormone replacement in a female smoker over the age of 35 (consider not prescribing for younger patients as well).

*****Consult your pharmacist about possible interactions*****

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VI. Relapse Prevention and Smoking Cessation Maintenance

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CHAPTER SUMMARY

- Smoking is a chronic, relapsing disorder
- Multiple quit attempts and interventions may be necessary
- Relapse is NOT uncommon
- Continue to address smoking status at every visit and provide ongoing support
- Offer re-treatment with medication and counseling
- Provide patients with options for the management of withdrawal symptoms

SMOKING: A CHRONIC, RELAPSING DISORDER

Patients who have recently quit smoking are at very high risk for relapse. Relapse is more likely to occur early in the process of quitting, but it can also occur months or years later. While there have been numerous studies attempting to identify strategies or interventions that are effective to prevent relapse, these studies have failed to identify specific interventions that are effective.¹ The most effective strategy to prevent relapse appears to be the provision of evidence-based smoking cessation treatment from the start, including a combination of smoking cessation medications and behavioral counseling, as described in previous chapters.

For patients who have recently quit smoking, continue to provide support at each visit, especially if they express concerns about relapse. Patients should receive reinforcement for their decision to quit, be congratulated on their success at quitting, and be encouraged to remain abstinent. Ask open-ended questions about noticeable benefits they have experienced since quitting. It may be helpful to talk with patients about previous quit attempts and encourage them to plan for how they will cope with challenges to quitting.

Encourage patients to identify their sources of support and if needed, refer them to a counselor or smoking cessation program for additional support. Additional support available from VA is summarized on the Tobacco & Health webpage (www.publichealth.va.gov/smoking). Options include the VA telephone quitline, which can be reached at 1-855-QUIT-VET (1-855-784-8838) Monday through Friday, and the SmokefreeVET text support program (<http://smokefree.gov/VET>). It may also be helpful to consider extending the use of smoking cessation medications to help reduce withdrawal symptoms.¹

MANAGEMENT OF WITHDRAWAL SYMPTOMS

For patients who relapse, encourage them to describe the challenges they encountered during their quit attempt and to recommit to another quit attempt. If needed, also consider referring them to a more intensive smoking cessation treatment program. If the previous quit attempt included medication, review whether the patient used it in an effective manner and determine whether the medication was helpful. Based on this assessment, re-treatment can be recommended with either the same medication or with combination NRT.²

Those who relapse often report problems that have been worsened by smoking withdrawal. These may include depression, weight gain, or withdrawal symptoms. If a patient reports prolonged cravings or other withdrawal symptoms, consider using combination therapy or extending the use of a short-acting medication (such as the gum or lozenge) to be used on an as-needed basis when acute withdrawal symptoms and urges to use cigarettes occur.¹

Please refer to the table below for guidance on counseling patients about specific withdrawal symptoms commonly associated with quitting smoking.

TABLE 8. SMOKING WITHDRAWAL SYMPTOMS* AND RECOMMENDATIONS

Withdrawal Symptoms	Recommendation
<ul style="list-style-type: none"> ■ Chest tightness (tension created by body's need for nicotine) 	<ul style="list-style-type: none"> ■ Practice relaxation techniques ■ Use nicotine replacement therapies
<ul style="list-style-type: none"> ■ Stomach pain ■ Constipation ■ Gas (decrease of intestinal movement) 	<ul style="list-style-type: none"> ■ Drink fluids ■ Eat fruits and vegetables
<ul style="list-style-type: none"> ■ Cough ■ Dry throat ■ Nasal drip (body getting rid of mucus) 	<ul style="list-style-type: none"> ■ Drink fluids ■ Avoid stress

Withdrawal Symptoms	Recommendation
<ul style="list-style-type: none"><li data-bbox="175 230 388 364">■ Cravings/urges (nicotine withdrawal/habit)	<p data-bbox="439 230 950 295"><u>DEADS Strategy</u> (Delay, Escape, Avoid, Distract, Substitute)</p> <p data-bbox="439 326 1028 668"><u>Delay:</u> The most important thing to remember is that an urge will go away if you just give it time. Waiting out an urge, especially if you begin to do something else, is easier than you may expect. Believe it or not, the urge will fade after 5-10 minutes, even if you do not smoke. It also helps if you have a positive attitude about the urge disappearing. Think "this won't last, the urge will go away," or "I would like a cigarette, but I'm not going to have one, because I don't need one."</p> <p data-bbox="439 699 1017 933"><u>Escape:</u> Another technique for dealing with an urge is to remove yourself from the situation or event which led to the urge. If you're in a room where others are smoking, and an urge hits, get up and take a short walk. You can walk around the building, or outside, until you feel ready to re-enter the situation without smoking.</p> <p data-bbox="439 965 1022 1199"><u>Avoid:</u> Avoiding situations where you'll be tempted to smoke will be particularly important in the first days and weeks after you quit. For example, if you regularly go to places where there's a lot of smoking, like coffee shops or clubs, it's best to avoid them for a little while to allow you to get used to not smoking.</p> <p data-bbox="439 1230 1030 1465"><u>Distract:</u> Another way to control urges is to get busy, get back to what you were doing before the urge hit. Also, there may be other things you enjoy doing that are incompatible with smoking such as working in the yard, reading a magazine, walking, taking a shower, or working a crossword puzzle.</p> <p data-bbox="439 1496 1013 1637"><u>Substitute:</u> When you feel that you want a cigarette, substitute something else for a cigarette. We suggest sugarfree gum, especially if you are watching your weight. You could eat</p>

Withdrawal Symptoms	Recommendation
<ul style="list-style-type: none"> ■ Cravings/urges (nicotine withdrawal/habit) <i>(cont.)</i> 	<p>a piece of fruit or drink a soft drink. You can also use something to chew on like a straw or a toothpick. The trick is to come up with something you like that can be easily substituted for a cigarette.</p>
<ul style="list-style-type: none"> ■ Depressed mood (normal process for a short period) 	<ul style="list-style-type: none"> ■ Increase pleasurable activities ■ Get support from family/friends ■ Discuss with provider
<ul style="list-style-type: none"> ■ Difficulty concentrating (body needs time to adjust to not having constant nicotine stimulation) 	<ul style="list-style-type: none"> ■ Avoid stress ■ Plan workload accordingly
<ul style="list-style-type: none"> ■ Dizziness (body is getting extra oxygen) 	<ul style="list-style-type: none"> ■ Be cautious the first few days
<ul style="list-style-type: none"> ■ Fatigue (lack of stimulation of nicotine) 	<ul style="list-style-type: none"> ■ Take naps ■ Do not push yourself ■ NRTs may help
<ul style="list-style-type: none"> ■ Hunger (cravings for cigarette can be mistaken for hunger) 	<ul style="list-style-type: none"> ■ Drink lots of water ■ Eat low-calorie snacks
<ul style="list-style-type: none"> ■ Insomnia (nicotine affects brain wave function and sleep patterns) 	<ul style="list-style-type: none"> ■ Limit caffeine (reduce by 50%) ■ Practice relaxation techniques

Withdrawal Symptoms	Recommendation
<ul style="list-style-type: none">■ Irritability (body's craving for nicotine)	<ul style="list-style-type: none">■ Exercise■ Practice relaxation techniques■ Take a hot bath
<ul style="list-style-type: none">■ Stress	<ul style="list-style-type: none">■ Exercise■ Practice relaxation techniques■ Avoid known stressful situations■ Plan workload accordingly

**Most withdrawal symptoms go away after a few days to 1-2 months at the most. Cravings/lurges are the only symptoms that can return even after one year of smoking cessation.*

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Appendices

**Appendix A. Sample Intensive
Smoking Cessation
Counseling Programs**

**Appendix B. Web and Telephone
Tobacco Cessation
Resources**

Appendix A. Sample Intensive Smoking Cessation Counseling Programs

SUMMARY

Research suggests that intensive tobacco cessation programs can double a patient's chance of quitting smoking.¹ Programs that consistently identify smokers, raise awareness of the need to quit smoking, and encourage smoking cessation have been shown to increase abstinence. Such programs can be delivered by phone, face to face, or in groups and offered by all members of the healthcare team.¹

In VA, not all clinics can provide the recommended comprehensive programs as outlined in this handbook. In light of this reality, below are examples of different levels of intensive smoking cessation counseling programs considerate of staff and time constraints. For clinics that have minimal staff, conducting brief interventions (see *Chapter 3*) and referring patients to 1-855-QUIT-VET (1-855-784-8838) will assist your patients in their cessation efforts.

The types of smoking cessation programs detailed in this section are:

- One-on-one counseling
- Group counseling
- Telephone counseling

Before initiating a program, please address the following items:

- Identify ***existing*** smoking cessation programs
- Identify the smoking cessation lead clinician (Email publichealth@va.gov to obtain the name of this clinician at your VA facility) and/or the health behavior coordinator at your facility
- Identify the process at your facility to initiate a new program (i.e., this could include adding privileges to existing scopes of practice)

- Determine time allocated for a smoking cessation program and level of intervention that will work best:
 - Brief
 - Less than three minutes
 - 3-10 minutes
 - Intensive
 - 10-30 minutes
 - More than 30 minutes

- Determine the type of program (e.g., one-on-one counseling, group counseling, telephone counseling) to offer taking into account what is the best fit for your facility, the duration of follow-up allowed (should be at least six months), and who can provide medications (e.g., physicians, pharmacists, nurse practitioners)

- Setting up the program (after facility approval process)
 - Meet with coding and billing to establish program
 - Ensure that the clinic is set up with a stop code “707” so patients will not be billed for smoking cessation counseling as ***federal policy prohibits charging co-payment to Veterans for outpatient smoking cessation counseling***
 - Use appropriate diagnostic and clinic codes for smoking cessation counseling
 - Diagnostic Code: Tobacco Use Disorder (305.1)
 - Procedure Code (CPT): Will depend on the length of appointment and discipline (discuss with local DSS expert)

- Develop clinic note templates (or adapt existing templates) specifically addressing smoking cessation so that the patient's progress and response to interventions is easily documented and tracked in the patient's medical chart

Regardless of which type of intervention you choose, smoking cessation programs for female Veterans should have the following goals in common:

- Educate providers about the risks of cigarette smoking for women
- Adopt a standard of care that includes identifying and tracking patients who smoke, and encouraging smoking cessation among them

- Identify and denote in Vista/CPRS all patients who are current cigarette smokers
- Offer every patient who is a current smoker:
 - Motivational interviewing (conducted by their primary care provider)
 - If available, enrollment in an intensive smoking cessation program at your facility
 - At the minimum, brief counseling and medication, and refer to 1-855-QUIT-VET (1-855-784-8838)
- Establish a bimonthly open house where patients who smoke can learn more about evidence-based cessation techniques and opportunities for cessation support through the clinic

EXAMPLES OF INTENSIVE SMOKING CESSATION COUSELING

ONE-ON-ONE (*INDIVIDUAL*) COUNSELING

Whether conducted in a 4-session or 8-session program, one-on-one counseling will require these common elements:

- Designate time in your schedule each week for a certain number of appointment slots
- Create a referral process to smoking cessation counseling program that is known to all providers
- Create a program flier
- Remind providers of the program
- Be proactive
- Schedule 15-30 minute counseling sessions with patients
- Discuss number of sessions available (e.g., 4-6 sessions, as many as needed)
- Discuss session spacing (e.g., biweekly, based on quit date)
- Conduct outreach and follow up
- Make sure patients know one-on-one counseling is available

- If a patient is interested in counseling, make sure to follow up (e.g., offer to remind them with calls/letters about appointments)
- Long-term follow up can increase success
- Choose a protocol that you like that uses behavioral interventions (see below for some examples)

Example of a 4-session one-on-one counseling intervention

Ideally, meet with patient for 15-30 minutes at least four times in person or by telephone.

Appointment 1: Prepare for the quit attempt

Appointment 2: (should be on or before the quit date)

- Review benefits of quitting
- Review quit plan
- Discuss concerns/fears (e.g., confidence and motivation, develop plan to address concern)
- Discuss plan for handling urges
- Introduce relaxation strategies such as diaphragmatic breathing

Appointment 3: Maintenance (approximately one week after quit date)

- Assess current cigarette use
- Discuss maintenance strategies
- Address stress management

Appointment 4: Relapse prevention (approximately one month after quit date)

- Assess current cigarette use
- Discuss positive experiences associated with quitting smoking and successful methods used to quit
- Assess and resolve problems encountered in quitting smoking and/or anticipated threats to abstinence
- Discuss the difference between a slip and a relapse
- Discuss strategies for managing and preventing relapse

Note, this program is flexible and can be condensed or expanded depending on the patient's needs. Sessions are best conducted in person, but telephone sessions can also be effective for Veterans who are not able to come in weekly.

Example of an 8-session one-on-one counseling intervention

This intervention uses a patient workbook based on McFall's model,² which is a one-on-one integrated smoking cessation program for patients with PTSD. The intervention as it appears here has been modified for female smokers. The patient workbook, *My Smoking Cessation Workbook*, consists of the following worksheets and sections:

- STEP 1: Setting My Quit Date!
- STEP 2: Identifying My Smoking Triggers and Beginning to Delink
- STEP 3: Identifying My Reasons to Quit and My Support System
- STEP 4: Talking to My Provider to Identify Smoking Cessation Medications to Use with My Quit Plan
- STEP 5: Getting Ready to Quit
- STEP 6: Developing Strategies and Skills for Quitting
- STEP 7: Planning to Cope with Smoking Triggers
- STEP 8: STOP SMOKING!
- STEP 9: My Strategies to Use Immediately After Quitting
- STEP 10: Identifying and Coping with Nicotine Withdrawal
- STEP 11: Preventing a Smoking Relapse
- STEP 12: Preventing Weight Gain After Quitting
- STEP 13: Stress and Smoking
- STEP 14: Developing an Exercise Program
- STEP 15: Deep Breathing Exercises

TABLE 9. EXAMPLE OF 8-SESSION INTERVENTION

Timeframe	Activities
MONTH 1	<p>Week 1</p> <p>Baseline assessment of level of tobacco use: Review workbook, check on other substance use and/or cravings and psychosocial stressors or issues that might interfere with quit program. Schedule quit date, assign homework to identify smoking triggers and reasons for quitting, review smoking cessation medications available, and establish next session.</p>
	<p>Week 2</p> <p>Preparing to quit: Review workbook and discuss triggers and ways to mediate, check on other substance use/cravings/stressors, assign homework on getting support and completing <i>Getting Ready to Quit Worksheet</i> and <i>My Action Plan for Coping with Smoking Triggers Worksheet</i>. Confirm quit date, order bupropion/varenicline if going to be used, and schedule next session.</p>
	<p>Week 3</p> <p>Strategies and skills for quitting: Review homework assignment, check on other substance use or cravings, assign homework on planning strategies to use after quitting and coping with nicotine withdrawal, confirm quit date, encourage abstinence, order NRT medications and provide instructions for use, and schedule next session.</p>
	<p>Week 4</p> <p>Planning ahead: This session should be conducted shortly after quit date and should focus on preventing smoking relapse, support for continued abstinence, and correct use of medications. Encourage continued abstinence and schedule next session.</p>
	<p>Week 5</p> <p>Preventing smoking relapse: Discuss cessation program and check for cravings and/or relapse and discuss interventions if present. Support continued abstinence and assign homework on weight control following smoking cessation. Schedule next session.</p>
MONTH 2	<p>Weight control after smoking cessation: Review homework assignment and encourage Veteran to adopt healthier eating habits that will assist in smoking cessation and weight control. Assign homework on benefits of physical exercise in a cessation program. Support continued abstinence and schedule next session.</p>

Timeframe	Activities
MONTH 3	<p>Physical exercise: Review homework and discuss how exercise can help the Veteran remain smoke free. Encourage establishment of an exercise regimen. Check on cravings/relapse and support continued abstinence. Schedule final visit.</p>
MONTH 4	<p>Feedback and graduation: Review homework and encourage Veteran to continue making healthier lifestyle choices to support their new smoke-free status. Support continued abstinence and provide graduation certificate.</p>

Note. Adapted with permission from Tobacco use cessation: A brief primary care intervention (A training manual for integrated primary care behavioral health providers and other tobacco cessation providers), 2010, VA Center for Integrated Healthcare.

This program is flexible and can be condensed or expanded depending on an individual Veteran's needs. These sessions are best conducted in person, but telephone sessions can also be effective for Veterans who are not able to come in weekly. Topics for each session are general guidelines and follow the patient workbook, but can be condensed into fewer sessions.

GROUP COUNSELING

Smoking cessation quit groups are generally one hour and can be conducted by any healthcare provider including physicians, pharmacists, social workers, psychologists, psychology interns, or nurses. It is important that the groups be advertised and held in or near the clinic where women Veterans receive their primary care.

Drop-in Support Groups

- Schedule a weekly, 1-hour block of time
 - Just before a women's clinic time is often most convenient for patients
- Recruit
 - Post fliers in clinic and have providers distribute to patients
 - Make sure your patients are aware that there is a drop-in group and provide reminder calls/letters if the patient requests

- Offer an open structure
 - Patients do not need to make an appointment to attend a drop-in group
 - Patients attending the group can be in any stage of quitting, including preparing to quit
 - At the group, check in with each participant about their smoking, barriers to cessation, challenges, and lessons learned
 - Prepare a group topic that can be tied into what patients are interested in discussing that day
 - Maintain an open stance by letting participants' stated needs and discussion topics drive the focus of each group session

On-going Structured Group Therapy

- Schedule a weekly, 1-hour block of time
- Recruit
 - Post fliers in clinic and have providers distribute to patients
 - Make sure your patients are aware that there is an on-going group and provide reminder calls/letters if the patient requests
- Choose a program that will fit your schedule (e.g., weekly sessions, biweekly)
- Cycle through crucial group topics every 6-8 weeks (other topics can be added):
 - Psycho education about nicotine dependence
 - Health consequences of smoking and benefits of quitting
 - Motivation to quit/setting a quit date
 - Managing withdrawal symptoms and concerns about weight gain
 - Mood and stress management
 - Coping with urges to smoke
- Address social support
 - Relapse prevention

TELEPHONE COUNSELING

Personalized telephone counseling initiated by your clinic or facility can be conducted by physicians, pharmacists, social workers, psychologists, psychology interns, or nurses.

A toolkit for a telephone counseling clinic based on a pharmacist provider is available; however, it can be modified as needed for other providers. Visit <http://vaww.publichealth.va.gov/smoking/clinical.asp> for the Pharmacy Managed Telephone Tobacco Cessation Clinic (PMTTCC) toolkit.

All telephone counseling programs should include the following components:

- Schedule your telephone clinic for a block of time each week
- Create a referral process to telephone counseling that is known to all providers
 - Create a program flier
 - Remind providers the program is available
 - Encourage active and ongoing recruitment
- Describe to patients the purpose, nature, and structure of telephone counseling
 - Include specific smoking cessation strategies from the *Clinical Practice Guidelines* and this handbook
- Conduct a program assessment, outreach, and follow up

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2. McFall, M., Saxon, A. J., Thompson, C. E., Yoshimoto, D., Malte, C., Straits-Troster, K., Kanter, E., Zhou, X. H., Dougherty, C. M., & Steele, B. (2005). Improving the rates of quitting smoking for veterans with posttraumatic stress disorder. *The American Journal of Psychiatry*, 162(7), 1311-1319. Retrieved from <http://ajp.psychiatryonline.org/article.aspx?volume=162&page=1311>

Appendix B. Web and Telephone Tobacco Cessation Resources

VA INTRANET RESOURCES

Provide your women Veterans with resources to stop smoking such as the *I QUIT: Strategies to Help Women Quit Smoking* booklet and pocket guide. You can also order posters for display in your facility about the health effects of secondhand smoke. Print publications and ordering information can be found at: <http://vaww.publichealth.va.gov/smoking/publications.asp>

WEB AND TELEPHONE RESOURCES

- VHA Tobacco and Health
www.publichealth.va.gov/smoking
- Quit VET, Veterans Smoking Quitline.
1-855-QUIT-VET (1-855-784-8838)
Monday-Friday
Counseling is available in English and Spanish
- SmokefreeVET Text Message Program
Text the word VET to 47848
www.smokefree.gov/VET

SmokefreeVET en Español
Envie la palabra VETesp al 47848
www.smokefree.gov/VETespanol
- Stay Quit Coach smartphone app
www.ptsd.va.gov/public/materials/apps/index.asp
- Women.smokefree.gov
www.women.smokefree.gov
- Womenshealth.gov
www.womenshealth.gov/smoking-how-to-quit
- Pregnancy and smoking
www.cdc.gov/Features/PregnantDontSmoke/
www.cdc.gov/reproductivehealth/TobaccoUsePregnancybetobaccofree.hhs.gov/health-effects/pregnancy/index.html
women.smokefree.gov/pregnancy-motherhood.aspx

- SmokefreeMOM Text Message Program
Text the word MOM to 222888
<http://women.smokefree.gov/smokefreemom.aspx>
- My HealtheVet
www.myhealth.va.gov
- Spit Tobacco Resources
 - Spit Tobacco: A Guide to Quitting
www.nidcr.nih.gov/OralHealth/Topics/SmokelessTobacco/SmokelessTobaccoAGuideforQuitting.htm
 - U.S. Food and Drug Administration
www.fda.gov/TobaccoProducts/ucm173429.htm
- Centers for Disease Control and Prevention
www.cdc.gov/tobacco and
www.cdc.gov/tobacco/data_statistics/sgr/2010/consumer_booklet
- U.S. Department of Health and Human Services
<http://www.ahrq.gov/professionals/clinicians-providers/guideline-recommendations/tobacco/clinicians/tearsheets/helpsmokers.html>
- Office of the Surgeon General
www.surgeongeneral.gov/tobacco
- Healthfinder Tobacco Resources Page
www.healthfinder.gov/scripts/SearchContext.asp?topic=860

WEB RESOURCES AND ONLINE TRAININGS FOR HEALTH CARE PROVIDERS

- VHA Smoking and Tobacco Use Cessation intranet
<http://vaww.publichealth.va.gov/smoking>
- VHA Model of Pharmacy Managed Telephone Tobacco Cessation Clinic (PMTTCC)
vaww.publichealth.va.gov/PUBLICHEALTH/docs/smoking/pmttc-toolkit.pdf
- National Institutes of Health – National Institute of Drug Abuse – Smoking Cessation
<http://health.nih.gov/topic/SmokingCessation>
- Health Resources and Services Administration
www.hrsa.gov/stopsmoking

- Centers for Disease Control and Prevention – Smoking and Tobacco Use
www.cdc.gov/tobacco
- American Lung Association
www.lung.org
- American Cancer Society
www.cancer.org
- American Heart Association
www.heart.org
- Surgeon General’s Report
How Tobacco Causes Disease: The Biological and Behavioral Basis for Smoking-Attributable Disease (2010)
<http://www.ncbi.nlm.nih.gov/books/NBK53017/>
- U.S. Department of Health and Human Services, Public Health Service
Treating Tobacco Use and Dependence: 2008 Update (Clinical Practice Guideline)
<http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/index.html>

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