Tobacco Cessation: Behavioral Counseling and Pharmacotherapy

(a three-hour continuing education program)

This program provides an overview of behavioral counseling techniques for facilitating tobacco cessation and all FDA-approved medications for cessation (nicotine patch, lozenge, gum, inhaler, nasal spray and bupropion SR and varenicline). Skills are acquired through role-playing with case scenarios.

Goal

To provide clinicians with the knowledge and skills necessary to assist patients in the proper counseling and selection and use of pharmacotherapy for smoking cessation.

Learning Objectives

Upon completion of this Rx for Change continuing education program, participants will be able to:

1	List five health risks associated with chronic tobacco use.
2	List the 5 A's for promoting tobacco cessation among patients.
3	Counsel a tobacco user on the proper use of the following first-line pharmacologic agents (including dosing, instructions on use, potential side effects, and precautions): • Nicotine polacrilex gum • Nicotine polacrilex lozenge • Nicotine transdermal patch • Nicotine nasal spray • Nicotine inhaler • Bupropion SR • Varenicline
4	Compare the efficacy of the various pharmacologic aids for cessation.
5	Demonstrate proficiency in providing comprehensive tobacco cessation counseling.

♪ **NOTE:** This file is formatted for printing double-sided.

TOBACCO CESSATION: Behavioral Counseling and Pharmacotherapy

"CIGARETTE SMOKING…

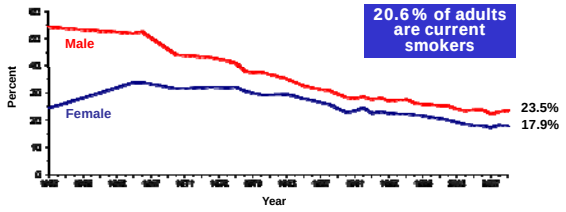
is the chief, single, avoidable cause of death in our society and the most important public health issue of our time."

C. Everett Koop, M.D., former U.S. Surgeon General

All forms of tobacco are harmful.

TRENDS in ADULT SMOKING, by SEX—U.S., 1955–2009

Trends in cigarette current smoking among persons aged 18 or older



70% want to quit

Graph provided by the Centers for Disease Control and Prevention. 1955 Current Population Survey; 1965–2005 NHIS. Estimates since 1992 include some-day smoking.

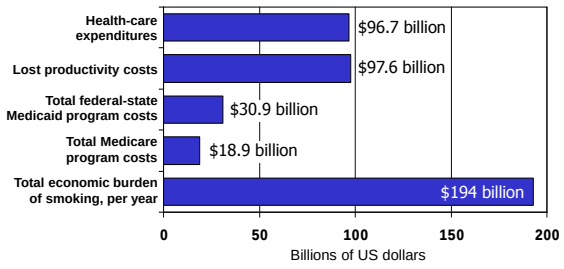
ANNUAL U.S. DEATHS ATTRIBUTABLE to SMOKING, 2000–2004

		Percent of all smoking-attributable deaths
Cardiovascular diseases	128,497	29%
Lung cancer	125,522	28%
Respiratory diseases	103,338	23%
Second-hand smoke	49,400	11%
Cancers other than lung	35,326	8%
Other	1,512	<1%

TOTAL: 443,595 deaths annually

Centers for Disease Control and Prevention (CDC). (2008). *MMWR* 57:1226–1228.

ANNUAL SMOKING-ATTRIBUTABLE ECONOMIC COSTS



Societal costs: $10.28 per pack of cigarettes smoked

Centers for Disease Control and Prevention (CDC). (2008). *MMWR* 57:1226–1228.

2004 REPORT of the SURGEON GENERAL: HEALTH CONSEQUENCES OF SMOKING

FOUR MAJOR CONCLUSIONS:

- Smoking harms nearly every organ of the body, causing many diseases and reducing the health of smokers in general.
- Quitting smoking has immediate as well as long-term benefits, reducing risks for diseases caused by smoking and improving health in general.
- Smoking cigarettes with lower machine-measured yields of tar and nicotine provides no clear benefit to health.
- The list of diseases caused by smoking has been expanded.

U.S. Department of Health and Human Services (USDHHS). (2004). *The Health Consequences of Smoking: A Report of the Surgeon General*.

QUITTING: HEALTH BENEFITS

Time Since Quit Date

- **2 weeks to 3 months:** Circulation improves, walking becomes easier; Lung function increases up to 30%
- **1 to 9 months:** Lung cilia regain normal function; Ability to clear lungs of mucus increases; Coughing, fatigue, shortness of breath decrease
- **1 year:** Excess risk of CHD decreases to half that of a continuing smoker
- **5 years:** Risk of stroke is reduced to that of people who have never smoked
- **10 years:** Lung cancer death rate drops to half that of a continuing smoker; Risk of cancer of mouth, throat, esophagus, bladder, kidney, pancreas decrease
- **after 15 years:** Risk of CHD is similar to that of people who have never smoked

TOBACCO DEPENDENCE: A 2-PART PROBLEM

Tobacco Dependence

Physiological	Behavioral
The addiction to nicotine	The habit of using tobacco
↓ Treatment	↓ Treatment
Medications for cessation	Behavior change program

Treatment should address the physiological **and** the behavioral aspects of dependence.

CLINICAL PRACTICE GUIDELINE for TREATING TOBACCO USE and DEPENDENCE

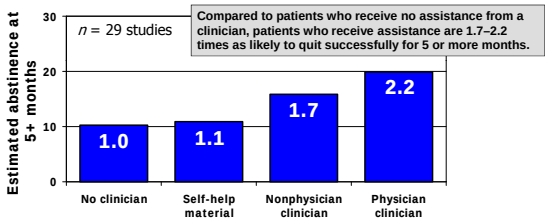
- Update released May 2008
- Sponsored by the U.S. Department of Health and Human Services, Public Heath Service with:
  - Agency for Healthcare Research and Quality
  - National Heart, Lung, & Blood Institute
  - National Institute on Drug Abuse
  - Centers for Disease Control and Prevention
  - National Cancer Institute

www.surgeongeneral.gov/tobacco/

HANDOUT

EFFECTS of CLINICIAN INTERVENTIONS

With help from a clinician, the odds of quitting approximately doubles.



Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

WHY SHOULD CLINICIANS ADDRESS TOBACCO?

- Tobacco users expect to be encouraged to quit by health professionals.
- Screening for tobacco use and providing tobacco cessation counseling are positively associated with patient satisfaction (Barzilai et al., 2001).

Failure to address tobacco use tacitly implies that quitting is not important.

Barzilai et al. (2001). *Prev Med* 33:595–599.

The 5 A's

- ASK
- ADVISE
- ASSESS
- ASSIST
- ARRANGE

HANDOUT

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

The 5 A's (cont'd)

- **ASK** about tobacco use
  - "Do you ever smoke or use any type of tobacco?"
    - "I take time to ask all of my patients about tobacco use—because it's important."
  - "Condition X often is caused or worsened by smoking. Do you, or does someone in your household smoke?"
  - "Medication X often is used for conditions linked with or caused by smoking. Do you, or does someone in your household smoke?"

The 5 A's (cont'd)

- **ADVISE** tobacco users to quit (clear, strong, personalized)
  - "It's important that you quit as soon as possible, and I can help you."
  - "Cutting down while you are ill is not enough."
  - "Occasional or light smoking is still harmful."
  - "I realize that quitting is difficult. It is the most important thing you can do to protect your health now and in the future. I have training to help my patients quit, and when you are ready, I will work with you to design a specialized treatment plan."

The 5 A's (cont'd)

- **ASSESS** readiness to make a quit attempt
- **ASSIST** with the quit attempt
  - Not ready to quit: provide motivation (the 5 R's)
  - Ready to quit: design a treatment plan
  - Recently quit: relapse prevention

The 5 A's (cont'd)

- **ARRANGE** follow-up care

Number of sessions	Estimated quit rate*
0 to 1	12.4%
2 to 3	16.3%
4 to 8	20.9%
More than 8	24.7%

* 5 months (or more) postcessation

Provide assistance throughout the quit attempt.

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

The 5 A's: REVIEW

ASK	about tobacco USE
ADVISE	tobacco users to QUIT
ASSESS	READINESS to make a quit attempt
ASSIST	with the QUIT ATTEMPT
ARRANGE	FOLLOW-UP care

The (DIFFICULT) DECISION to QUIT

- Faced with change, most people are not ready to act.
- Change is a process, not a single step.
- Typically, it takes multiple attempts.

HOW CAN I LIVE WITHOUT TOBACCO?

HELPING PATIENTS QUIT IS a CLINICIAN'S RESPONSIBILITY

TOBACCO USERS DON'T PLAN TO FAIL. MOST FAIL TO PLAN.

Clinicians have a professional obligation to address tobacco use and can have an important role in helping patients plan for their quit attempts.

THE DECISION TO QUIT LIES IN THE HANDS OF EACH PATIENT.

ASSESSING READINESS to QUIT

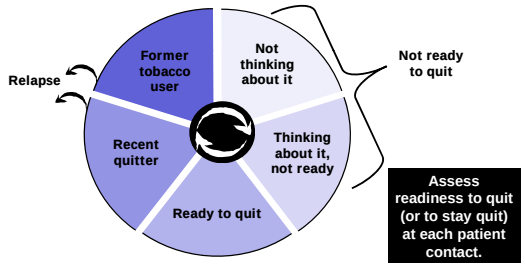
Patients differ in their readiness to quit.

- STAGE 1: Not ready to quit in the next month
- STAGE 2: Ready to quit in the next month
- STAGE 3: Recent quitter, quit within past 6 months
- STAGE 4: Former tobacco user, quit > 6 months ago

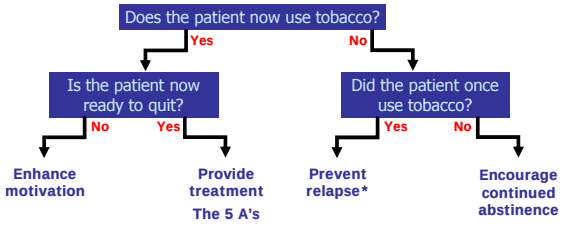
Assessing a patient's readiness to quit enables clinicians to deliver relevant, appropriate counseling messages.

ASSESSING READINESS to QUIT (cont'd)

For most patients, quitting is a cyclical process, and their readiness to quit (or stay quit) will change over time.



IS a PATIENT READY to QUIT?



*Relapse prevention interventions not necessary if patient has not used tobacco for many years and is not at risk for re-initiation.

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

ASSESSING READINESS to QUIT (cont'd)

STAGE 1: Not ready to quit

Not thinking about quitting in the next month

- Some patients are aware of the need to quit.
- Patients struggle with ambivalence about change.
- Patients are not ready to change, yet.
- Pros of continued tobacco use outweigh the cons.

GOAL: Start thinking about quitting.

STAGE 1: NOT READY to QUIT Counseling Strategies

DO

- Strongly advise to quit
- Provide information
- Ask noninvasive questions; identify reasons for tobacco use
- Raise awareness of health consequences/concerns
- Demonstrate empathy, foster communication
- Leave decision up to patient

DON'T

- Persuade
- "Cheerlead"
- Tell patient how bad tobacco is, in a judgmental manner
- Provide a treatment plan

STAGE 1: NOT READY to QUIT Counseling Strategies (cont'd)

Consider asking:

"Do you **ever** plan to quit?" → If NO: Advise patients to quit, and offer to assist (if or when they change their mind).

If YES ↓

"What might be some of the benefits of quitting now, instead of later?"

Most patients will agree: there is no "good" time to quit, and there are benefits to quitting sooner as opposed to later.

"What would have to change for you to decide to quit sooner?"

Responses will reveal some of the barriers to quitting.

STAGE 1: NOT READY to QUIT Counseling Strategies (cont'd)

The 5 R's—Methods for enhancing motivation:

- Relevance
- Risks
- Rewards
- Roadblocks
- Repetition

Tailored, motivational messages

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

STAGE 1: NOT READY to QUIT A Demonstration

CASE SCENARIO:
Ms. Lilly Vitale

You are a clinician providing care to Ms. Vitale, a young woman with early-stage emphysema.

VIDEO # V6a

ASSESSING READINESS to QUIT (cont'd)

STAGE 2: Ready to quit

Ready to quit in the next month

- Patients are aware of the need to, and the benefits of, making the behavioral change.
- Patients are getting ready to take action.

GOAL: Achieve cessation.

STAGE 2: READY to QUIT Three Key Elements of Counseling

- Assess tobacco use history
- Discuss key issues
- Facilitate quitting process
  - Practical counseling (problem solving/skills training)
  - Social support delivered as part of treatment

STAGE 2: READY to QUIT Assess Tobacco Use History

- Praise the patient's readiness
- Assess tobacco use history
  - Current use: type(s) of tobacco, amount
  - Past use: duration, recent changes
  - Past quit attempts:
    - Number, date, length
    - Methods used, compliance, duration
    - Reasons for relapse

STAGE 2: READY to QUIT
Discuss Key Issues

- Reasons/motivation to quit
- Confidence in ability to quit
- Triggers for tobacco use
  - What situations lead to temptations to use tobacco?
  - What led to relapse in the past?
- Routines/situations associated with tobacco use
  - When drinking coffee
  - While driving in the car
  - When bored or stressed
  - While watching television
  - While at a bar with friends
  - After meals or after sex
  - During breaks at work
  - While on the telephone
  - While with specific friends or family members who use tobacco

STAGE 2: READY to QUIT
Discuss Key Issues (cont'd)

Stress-Related Tobacco Use

THE MYTHS

- "Smoking gets rid of all my stress."
- "I can't relax without a cigarette."

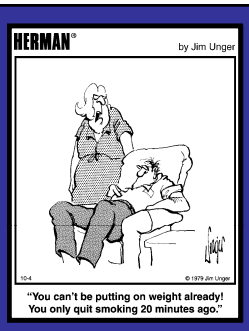
THE FACTS

- There will always be stress in one's life.
- There are many ways to relax without a cigarette.

Smokers confuse the relief of withdrawal with the feeling of relaxation.

STRESS MANAGEMENT SUGGESTIONS:

Deep breathing, shifting focus, taking a break.



Most smokers gain fewer than 10 pounds, but there is a wide range.

STAGE 2: READY to QUIT
Discuss Key Issues (cont'd)

Concerns about Weight Gain

- Discourage strict dieting while quitting
  - Encourage healthful diet and meal planning
  - Suggest increasing water intake or chewing sugarless gum
  - Recommend selection of nonfood rewards
- When fear of weight gain is a barrier to quitting
  - Consider pharmacotherapy with evidence of delaying weight gain (bupropion SR or 4-mg nicotine gum or lozenge)
  - Assist patient with weight maintenance or refer patient to specialist or program

STAGE 2: READY to QUIT
Discuss Key Issues (cont'd)

Concerns about Withdrawal Symptoms

- Most pass within 2–4 weeks after quitting
- Cravings can last longer, up to several months or years
  - Often can be ameliorated with cognitive or behavioral coping strategies
- Refer to Withdrawal Symptoms Information Sheet
  - Symptom, cause, duration, relief

Most symptoms manifest within the first 1–2 days, peak within the first week, and subside within 2–4 weeks.

HANDOUT

STAGE 2: READY to QUIT
Facilitate Quitting Process

- Discuss methods for quitting
  - Discuss pros and cons of available methods
  - Pharmacotherapy: a treatment, not a crutch!
  - Importance of behavioral counseling
- Set a quit date
- Recommend Tobacco Use Log HANDOUT
  - Helps patients to understand when and why they use tobacco
  - Identifies activities or situations that trigger tobacco use
  - Can be used to develop coping strategies to overcome the temptation to use tobacco

STAGE 2: READY to QUIT
Facilitate Quitting Process (cont'd)

Tobacco Use Log: Instructions for use

- Continue regular tobacco use for 3 or more days
- Each time any form of tobacco is used, log the following information:
  - Time of day
  - Activity or situation during use
  - "Importance" rating (scale of 1–3)
- Review log to identify situational triggers for tobacco use; develop patient-specific coping strategies

STAGE 2: READY to QUIT
Facilitate Quitting Process (cont'd)

- Discuss coping strategies
  - Cognitive coping strategies
    - Focus on retraining the way a patient thinks
  - Behavioral coping strategies
    - Involve specific actions to reduce risk for relapse

HANDOUT

STAGE 2: READY to QUIT
Facilitate Quitting Process (cont'd)

Cognitive Coping Strategies

- Review commitment to quit
- Distractive thinking
- Positive self-talk
- Relaxation through imagery
- Mental rehearsal and visualization

STAGE 2: READY to QUIT
Facilitate Quitting Process (cont'd)

Cognitive Coping Strategies: Examples

- Thinking about cigarettes doesn't mean you have to smoke one:
  - "Just because you think about something doesn't mean you have to do it!"
  - Tell yourself, "It's just a thought," or "I am in control."
  - Say the word "STOP!" out loud, or visualize a stop sign.
- When you have a craving, remind yourself:
  - "The urge for tobacco will only go away if I don't use it."
- As soon as you get up in the morning, look in the mirror and say to yourself:
  - "I am proud that I made it through another day without tobacco."

STAGE 2: READY to QUIT
Facilitate Quitting Process (cont'd)

Behavioral Coping Strategies

- Control your environment
  - Tobacco-free home and workplace
  - Remove cues to tobacco use; actively avoid trigger situations
  - Modify behaviors that you associate with tobacco: when, what, where, how, with whom
- Substitutes for smoking
  - Water, sugar-free chewing gum or hard candies (oral substitutes)
- Take a walk, diaphragmatic breathing, self-massage
- Actively work to reduce stress, obtain social support, and alleviate withdrawal symptoms

STAGE 2: READY to QUIT
Facilitate Quitting Process (cont'd)

- Provide medication counseling
  - Promote compliance
  - Discuss proper use, with demonstration
- Discuss concept of "slip" versus relapse
  - "Let a slip slide."
- Offer to assist throughout quit attempt
  - Follow-up contact #1: first week after quitting
  - Follow-up contact #2: in the first month
  - Additional follow-up contacts as needed
- Congratulate the patient!

STAGE 2: READY to QUIT
A Demonstration

CASE SCENARIO:
Ms. Staal

You are a clinician providing care to Ms. Staal, a 44-year old woman in the emergency room with pulmonary distress.

VIDEO # V17a

ASSESSING READINESS to QUIT (cont'd)

STAGE 3: Recent quitter

Actively trying to quit for good

- Patients have quit using tobacco sometime in the past 6 months and are taking steps to increase their success.
- Withdrawal symptoms occur.
- Patients are at risk for relapse.

GOAL: Remain tobacco-free for at least 6 months.

STAGE 3: RECENT QUITTERS
Evaluate the Quit Attempt

- Status of attempt
  - Ask about social support
  - Identify ongoing temptations and triggers for relapse (negative affect, smokers, eating, alcohol, cravings, stress)
  - Encourage healthy behaviors to replace tobacco use
- Slips and relapse
  - Has the patient used tobacco at all—even a puff?
- Medication adherence, plans for termination
  - Is the regimen being followed?
  - Are withdrawal symptoms being alleviated?
  - How and when should pharmacotherapy be terminated?

STAGE 3: RECENT QUITTERS
Facilitate Quitting Process

Relapse Prevention

- Congratulate success!
- Encourage continued abstinence
  - Discuss benefits of quitting, problems encountered, successes achieved, and potential barriers to continued abstinence
  - Ask about strong or prolonged withdrawal symptoms (change dose, combine or extend use of medications)
  - Promote smoke-free environments
- Social support provided as part of treatment
  - Schedule additional follow-up as needed

STAGE 3: RECENT QUITTER
A Demonstration

CASE SCENARIO:
Mr. Angelo Fleury

You are a clinician providing follow-up care to Mr. Angelo Fleury, who recently quit and is experiencing difficulty sleeping and coping with job-related stress.

VIDEO # V25b

ASSESSING READINESS to QUIT (cont'd)

STAGE 4: Former tobacco user

Tobacco-free for 6 months

- Patients remain vulnerable to relapse.
- Ongoing relapse prevention is needed.

GOAL: Remain tobacco-free for life.

STAGE 4: FORMER TOBACCO USERS

- Assess status of quit attempt
- Slips and relapse
- Medication compliance, plans for termination
  - Has pharmacotherapy been terminated?
- Continue to offer tips for relapse prevention
- Encourage healthy behaviors
- Congratulate continued success

Continue to assist throughout the quit attempt.

BRIEF COUNSELING: ASK, ADVISE, REFER (cont'd)

- Brief interventions have been shown to be effective
- In the absence of time or expertise:
  - Ask, advise, and refer to other resources, such as local group programs or the toll-free quitline **1-800-QUIT-NOW**

This brief intervention can be achieved in less than 1 minute.

WHAT ARE "TOBACCO QUITLINES"?

- Tobacco cessation counseling, provided at no cost via telephone to all Americans
- Staffed by trained specialists
- Up to 4–6 personalized sessions (varies by state)
- Some state quitlines offer pharmacotherapy at no cost (or reduced cost)
- Up to 30% success rate for patients who complete sessions

Most health-care providers, and most patients, are not familiar with tobacco quitlines.

METHODS for QUITTING

- Nonpharmacologic
  - Counseling and other non-drug approaches
- Pharmacologic
  - FDA-approved medications

Counseling and medications are both effective, but the combination of counseling and medication is more effective than either alone.

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

NONPHARMACOLOGIC METHODS

- Cold turkey: Just do it!
- Unassisted tapering (fading)
  - Reduced frequency of use
  - Lower nicotine cigarettes
  - Special filters or holders
- Assisted tapering
  - QuitKey (PICS, Inc.)
    - Computer developed taper based on patient's smoking level
    - Includes telephone counseling support

NONPHARMACOLOGIC METHODS (cont'd)

- Formal cessation programs
  - Self-help programs
  - Individual counseling
  - Group programs
  - Telephone counseling
    - 1-800-QUITNOW
    - 1-800-786-8669
  - Web-based counseling
    - www.smokefree.gov
    - www.quitnet.com
    - www.becomeanex.org
- Acupuncture therapy
- Hypnotherapy
- Massage therapy

PHARMACOLOGIC METHODS: FIRST-LINE THERAPIES

Three general classes of FDA-approved drugs for smoking cessation:

- Nicotine replacement therapy (NRT)
  - Nicotine gum, patch, lozenge, nasal spray, inhaler
- Psychotropics
  - Sustained-release bupropion
- Partial nicotinic receptor agonist
  - Varenicline

PHARMACOTHERAPY

"Clinicians should encourage all patients attempting to quit to use effective medications for tobacco dependence treatment, except where contraindicated or for specific populations* for which there is insufficient evidence of effectiveness."

** Includes pregnant women, smokeless tobacco users, light smokers, and adolescents.*

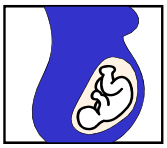
Medications significantly improve success rates.

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

PHARMACOTHERAPY: USE in PREGNANCY

- The Clinical Practice Guideline makes no recommendation regarding use of medications in pregnant smokers
  - Insufficient evidence of effectiveness
- Category C: varenicline, bupropion SR
- Category D: prescription formulations of NRT

"Because of the serious risks of smoking to the pregnant smoker and the fetus, whenever possible pregnant smokers should be offered person-to-person psychosocial interventions that exceed minimal advice to quit." (p. 165)



Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

PHARMACOTHERAPY: OTHER SPECIAL POPULATIONS

Pharmacotherapy is **not** recommended for:

- Smokeless tobacco users
  - No FDA indication for smokeless tobacco cessation
- Individuals smoking fewer than 10 cigarettes per day
- Adolescents
  - Nonprescription sales (patch, gum, lozenge) are restricted to adults ≥18 years of age
  - NRT use in minors requires a prescription

Recommended treatment is behavioral counseling.

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

NRT: RATIONALE for USE

- Reduces physical withdrawal from nicotine
- Eliminates the immediate, reinforcing effects of nicotine that is rapidly absorbed via tobacco smoke
- Allows patient to focus on behavioral and psychological aspects of tobacco cessation

NRT products approximately doubles quit rates.

NRT: PRODUCTS

Polacrilex gum
- Nicorette (OTC)
- Generic nicotine gum (OTC)

Lozenge
- Nicorette Lozenge (OTC)
- Nicorette Mini Lozenge (OTC)
- Generic nicotine lozenge (OTC)

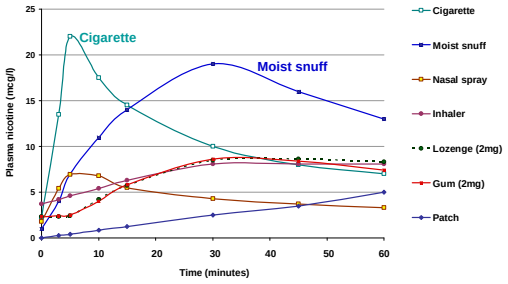
Transdermal patch
- NicoDerm CQ (OTC)
- Generic nicotine patches (OTC, Rx)

Nasal spray
- Nicotrol NS (Rx)

Inhaler
- Nicotrol (Rx)

Patients should stop using all forms of tobacco upon initiation of the NRT regimen.

PLASMA NICOTINE CONCENTRATIONS for NICOTINE-CONTAINING PRODUCTS



NRT: PRECAUTIONS

- Patients with underlying cardiovascular disease
  - Recent myocardial infarction (within past 2 weeks)
  - Serious arrhythmias
  - Serious or worsening angina

NRT products may be appropriate for these patients if they are under medical supervision.

NICOTINE GUM
Nicorette (GlaxoSmithKline); generics

- Resin complex
  - Nicotine
  - Polacrilin
- Sugar-free chewing gum base
- Contains buffering agents to enhance buccal absorption of nicotine
- Available: 2 mg, 4 mg; original, cinnamon, fruit, mint (various), and orange flavors

NICOTINE GUM: DOSING

Dosage based on current smoking patterns:

If patient smokes	Recommended strength
≥25 cigarettes/day	4 mg
<25 cigarettes/day	2 mg

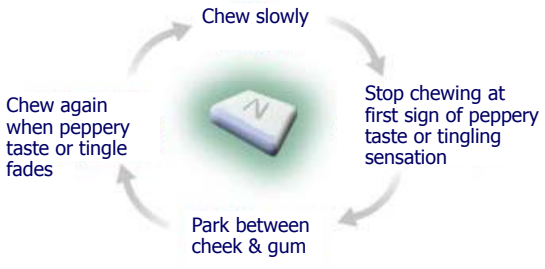
NICOTINE GUM: DOSING (cont'd)

Recommended Usage Schedule for Nicotine Gum		
Weeks 1–6	**Weeks 7–9**	**Weeks 10–12**
1 piece q 1–2 h	1 piece q 2–4 h	1 piece q 4–8 h
DO NOT USE MORE THAN 24 PIECES PER DAY.		

NICOTINE GUM: DIRECTIONS for USE

- Chew each piece very *slowly* several times
- Stop chewing at first sign of peppery taste or slight tingling in mouth (~15 chews, but varies)
- "Park" gum between cheek and gum (to allow absorption of nicotine across buccal mucosa)
- Resume slow chewing when taste or tingle fades
- When taste or tingle returns, stop and park gum in different place in mouth
- Repeat chew/park steps until most of the nicotine is gone (taste or tingle does not return; generally 30 minutes)

NICOTINE GUM: CHEWING TECHNIQUE SUMMARY



NICOTINE GUM: ADDITIONAL PATIENT EDUCATION

- To improve chances of quitting, use at least nine pieces of gum daily
- The effectiveness of nicotine gum may be reduced by some foods and beverages:
  - Coffee
  - Juices
  - Wine
  - Soft drinks

Do NOT eat or drink for 15 minutes BEFORE or while using nicotine gum.

NICOTINE GUM: ADD'L PATIENT EDUCATION (cont'd)

- Chewing gum will *not* provide same rapid satisfaction that smoking provides
- Chewing gum too rapidly can cause excessive release of nicotine, resulting in
  - Lightheadedness
  - Nausea and vomiting
  - Irritation of throat and mouth
  - Hiccups
  - Indigestion

NICOTINE GUM: ADD'L PATIENT EDUCATION (cont'd)

- Side effects of nicotine gum include
  - Mouth soreness
  - Hiccups
  - Dyspepsia
  - Jaw muscle ache
- Nicotine gum may stick to dental work
  - Discontinue use if excessive sticking or damage to dental work occurs

NICOTINE GUM: SUMMARY

ADVANTAGES

- Might satisfy oral cravings.
- Might delay weight gain (4-mg strength).
- Patients can titrate therapy to manage withdrawal symptoms.
- A variety of flavors are available.

DISADVANTAGES

- Need for frequent dosing can compromise compliance.
- Might be problematic for patients with significant dental work.
- Patients must use proper chewing technique to minimize adverse effects.
- Gum chewing might not be socially acceptable.

NICOTINE LOZENGE

Nicorette Lozenge and Nicorette Mini Lozenge (GlaxoSmithKline); generics

- Nicotine polacrilex formulation
  - Delivers ~25% more nicotine than equivalent gum dose
- Sugar-free mint, cherry flavors
- Contains buffering agents to enhance buccal absorption of nicotine
- Available: 2 mg, 4 mg

NICOTINE LOZENGE: DOSING

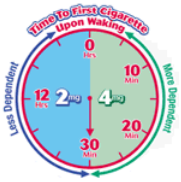
Dosage is based on the "time to first cigarette" (TTFC) as an indicator of nicotine dependence

Use the 2 mg lozenge:

If you smoke your first cigarette more than 30 minutes after waking

Use the 4 mg lozenge:

If you smoke your first cigarette of the day within 30 minutes of waking



NICOTINE LOZENGE: DOSING (cont'd)

Recommended Usage Schedule for the Nicotine Lozenge		
Weeks 1–6	**Weeks 7–9**	**Weeks 10–12**
1 lozenge q 1–2 h	**1 lozenge q 2–4 h**	**1 lozenge q 4–8 h**
DO NOT USE MORE THAN 20 LOZENGES PER DAY.		

NICOTINE LOZENGE: DIRECTIONS for USE

- Use according to recommended dosing schedule
- Place in mouth and allow to dissolve slowly (nicotine release may cause warm, tingling sensation)
- Do not chew or swallow lozenge.
- Occasionally rotate to different areas of the mouth.
- Standard lozenges will dissolve completely in about 20–30 minutes; Nicorette Mini lozenge will dissolve in 10 minutes.

NICOTINE LOZENGE: ADDITIONAL PATIENT EDUCATION

- To improve chances of quitting, use at least nine lozenges daily during the first 6 weeks
- The lozenge will *not* provide the same rapid satisfaction that smoking provides
- The effectiveness of the nicotine lozenge may be reduced by some foods and beverages:
  - Coffee
  - Juices
  - Wine
  - Soft drinks

Do NOT eat or drink for 15 minutes BEFORE or while using the nicotine lozenge.

NICOTINE LOZENGE: ADD'L PATIENT EDUCATION (cont'd)

- Side effects of the nicotine lozenge include
  - Nausea
  - Hiccups
  - Cough
  - Heartburn
  - Headache
  - Flatulence
  - Insomnia

NICOTINE LOZENGE: SUMMARY

ADVANTAGES

- Might satisfy oral cravings.
- Might delay weight gain (4-mg strength).
- Easy to use and conceal.
- Patients can titrate therapy to manage withdrawal symptoms.
- Several flavors are available.

DISADVANTAGES

- Need for frequent dosing can compromise compliance
- Gastrointestinal side effects (nausea, hiccups, and heartburn) may be bothersome.

TRANSDERMAL NICOTINE PATCH
NicoDerm CQ (GlaxoSmithKline); generic

- Nicotine is well absorbed across the skin
- Delivery to systemic circulation avoids hepatic first-pass metabolism
- Plasma nicotine levels are lower and fluctuate less than with smoking

TRANSDERMAL NICOTINE PATCH: PREPARATION COMPARISON

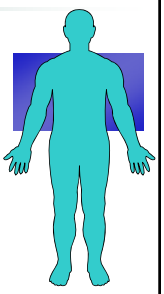
Product	NicoDerm CQ	Generic
Nicotine delivery	24 hours	24 hours
Availability	OTC	Rx/OTC
Patch strengths	7 mg 14 mg 21 mg	7 mg 14 mg 21 mg

TRANSDERMAL NICOTINE PATCH: DOSING

Product	Light Smoker	Heavy Smoker
NicoDerm CQ	**≤10 cigarettes/day** Step 2 (14 mg x 6 weeks) Step 3 (7 mg x 2 weeks)	**>10 cigarettes/day** Step 1 (21 mg x 6 weeks) Step 2 (14 mg x 2 weeks) Step 3 (7 mg x 2 weeks)
Generic (formerly Habitrol)	**≤10 cigarettes/day** Step 2 (14 mg x 6 weeks) Step 3 (7 mg x 2 weeks)	**>10 cigarettes/day** Step 1 (21 mg x 4 weeks) Step 2 (14 mg x 2 weeks) Step 3 (7 mg x 2 weeks)

TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE

- Choose an area of skin on the upper body or upper outer part of the arm
- Make sure skin is clean, dry, hairless, and not irritated
- Apply patch to different area each day
- Do not use same area again for at least 1 week

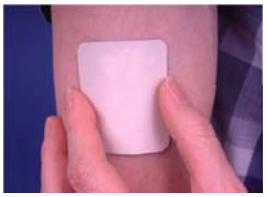


TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE (cont'd)

- Remove patch from protective pouch
- Peel off half of the backing from patch

TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE (cont'd)

- Apply adhesive side of patch to skin
- Peel off remaining protective covering
- Press firmly with palm of hand for 10 seconds
- Make sure patch sticks well to skin, especially around edges



TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE (cont'd)

- Wash hands: Nicotine on hands can get into eyes or nose and cause stinging or redness
- Do not leave patch on skin for more than 24 hours—doing so may lead to skin irritation
- Adhesive remaining on skin may be removed with rubbing alcohol or acetone
- Dispose of used patch by folding it onto itself, completely covering adhesive area

TRANSDERMAL NICOTINE PATCH: ADDITIONAL PATIENT EDUCATION

- Water will not harm the nicotine patch if it is applied correctly; patients may bathe, swim, shower, or exercise while wearing the patch
- Do *not* cut patches to adjust dose
  - Nicotine may evaporate from cut edges
  - Patch may be less effective
- Keep new and used patches out of the reach of children and pets
- Remove patch before MRI procedures

TRANSDERMAL NICOTINE PATCH: ADD'L PATIENT EDUCATION (cont'd)

- Side effects to expect in first hour:
  - Mild itching
  - Burning
  - Tingling
- Additional possible side effects:
  - Vivid dreams or sleep disturbances
  - Headache

TRANSDERMAL NICOTINE PATCH: ADD'L PATIENT EDUCATION (cont'd)

- After patch removal, skin may appear red for 24 hours
  - If skin stays red more than 4 days or if it swells or a rash appears, contact health care provider—do not apply new patch
- Local skin reactions (redness, burning, itching)
  - Usually caused by adhesive
  - Up to 50% of patients experience this reaction
  - Fewer than 5% of patients discontinue therapy
  - Avoid use in patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)

TRANSDERMAL NICOTINE PATCH: SUMMARY

ADVANTAGES

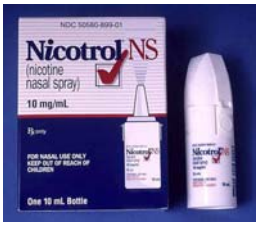
- Provides consistent nicotine levels.
- Easy to use and conceal.
- Once daily dosing associated with fewer compliance problems.

DISADVANTAGES

- Patients cannot titrate the dose to acutely manage withdrawal symptoms.
- Allergic reactions to the adhesive may occur.
- Patients with dermatologic conditions should not use the patch.

NICOTINE NASAL SPRAY
Nicotrol NS (Pfizer)

- Aqueous solution of nicotine in a 10-ml spray bottle
- Each metered dose actuation delivers
  - 50 mcL spray
  - 0.5 mg nicotine
- ~100 doses/bottle
- Rapid absorption across nasal mucosa



NICOTINE NASAL SPRAY: DOSING & ADMINISTRATION

- One dose = 1 mg nicotine (2 sprays, one 0.5 mg spray in **each** nostril)
- Start with 1–2 doses per hour
- Increase prn to *maximum* dosage of 5 doses per hour or 40 mg (80 sprays; ~½ bottle) daily
- For best results, patients should use at least 8 doses daily for the first 6–8 weeks
- Termination:
  - Gradual tapering over an additional 4–6 weeks

NICOTINE NASAL SPRAY: DIRECTIONS for USE

- Press in circles on sides of bottle and pull to remove cap

NICOTINE NASAL SPRAY: DIRECTIONS for USE (cont'd)

- Prime the pump (before first use)
  - Re-prime (1-2 sprays) if spray not used for 24 hours
- Blow nose (if not clear)
- Tilt head back slightly and insert tip of bottle into nostril as far as comfortable
- Breathe through mouth, and spray once in each nostril
- Do not sniff or inhale while spraying

NICOTINE NASAL SPRAY: DIRECTIONS for USE (cont'd)

- If nose runs, gently sniff to keep nasal spray in nose
- Wait 2–3 minutes before blowing nose
- Wait 5 minutes before driving or operating heavy machinery
  - Spray may cause tearing, coughing, and sneezing
- Avoid contact with skin, eyes, and mouth
  - If contact occurs, rinse with water immediately
  - Nicotine is absorbed through skin and mucous membranes

NICOTINE NASAL SPRAY: ADDITIONAL PATIENT EDUCATION

- What to expect (first week):
  - Hot peppery feeling in back of throat or nose
  - Sneezing
  - Coughing
  - Watery eyes
  - Runny nose
- Side effects should lessen over a few days
  - Regular use during the first week will help in development of tolerance to the irritant effects of the spray
- If side effects do not decrease after a week, contact health care provider

NICOTINE NASAL SPRAY: SUMMARY

ADVANTAGES

- Patients can easily titrate therapy to rapidly manage withdrawal symptoms.

DISADVANTAGES

- Need for frequent dosing can compromise compliance.
- Nasal/throat irritation may be bothersome.
- Higher dependence potential.
- Patients with chronic nasal disorders or severe reactive airway disease should not use the spray.

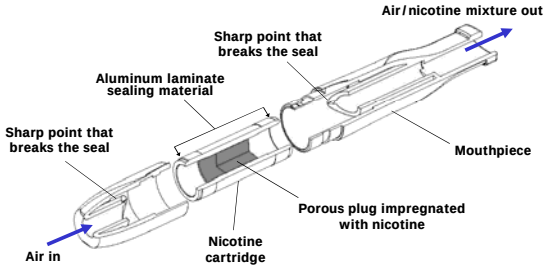
NICOTINE INHALER
Nicotrol Inhaler (Pfizer)

- Nicotine inhalation system consists of:
  - Mouthpiece
  - Cartridge with porous plug containing 10 mg nicotine and 1 mg menthol
- Delivers 4 mg nicotine vapor, absorbed across buccal mucosa

NICOTINE INHALER: DOSING

- Start with at least 6 cartridges/day during the first 3-6 weeks of treatment
  - Increase prn to *maximum* of 16 cartridges/day
  - In general, use 1 cartridge every 1-2 hours
- Recommended duration of therapy is 3 months
- Gradually reduce daily dosage over the following 6–12 weeks

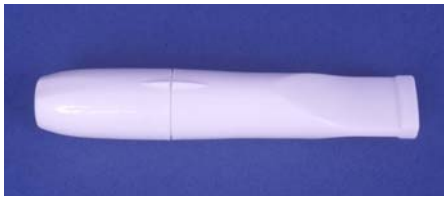
NICOTINE INHALER: SCHEMATIC DIAGRAM



Reprinted with permission from Schneider et al. (2001). *Clinical Pharmacokinetics* 40:661–684. Adis International, Inc.

NICOTINE INHALER: DIRECTIONS for USE

- Align marks on the mouthpiece



NICOTINE INHALER: DIRECTIONS for USE (cont'd)

- Pull and separate mouthpiece into two parts

NICOTINE INHALER: DIRECTIONS for USE (cont'd)

- Press nicotine cartridge firmly into bottom of mouthpiece until seal breaks

NICOTINE INHALER: DIRECTIONS for USE (cont'd)

- Put top on mouthpiece and align marks to close
- Press down firmly to break top seal of cartridge
- Twist top to misalign marks and secure unit

NICOTINE INHALER: DIRECTIONS for USE (cont'd)

- During inhalation, nicotine is vaporized and absorbed across oropharyngeal mucosa
- Inhale into back of throat or puff in short breaths
- Nicotine in cartridges is depleted after about 20 minutes of active puffing
  - Cartridge does *not* have to be used all at once
  - Open cartridge retains potency for 24 hours
- Mouthpiece is reusable; clean regularly with mild detergent

NICOTINE INHALER: ADDITIONAL PATIENT EDUCATION

- Side effects associated with the nicotine inhaler include:
  - Mild irritation of the mouth or throat
  - Cough
  - Headache
  - Rhinitis
  - Dyspepsia
- Severity generally rated as mild, and frequency of symptoms declined with continued use

NICOTINE INHALER: ADD'L PATIENT EDUCATION (cont'd)

- The inhaler may not be as effective in very cold (<59°F) temperatures—delivery of nicotine vapor may be compromised
- Use the inhaler longer and more often at first to help control cravings (best results are achieved with frequent continuous puffing over 20 minutes)
- Effectiveness of the nicotine inhaler may be reduced by some foods and beverages

Do NOT eat or drink for 15 minutes BEFORE or while using the nicotine inhaler.

NICOTINE INHALER: SUMMARY

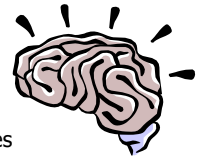
ADVANTAGES	DISADVANTAGES
▪ Patients can easily titrate therapy to manage withdrawal symptoms. ▪ The inhaler mimics the hand-to-mouth ritual of smoking.	▪ Need for frequent dosing can compromise compliance. ▪ Initial throat or mouth irritation can be bothersome. ▪ Cartridges should not be stored in very warm conditions or used in very cold conditions. ▪ Patients with underlying bronchospastic disease must use the inhaler with caution.

BUPROPION SR
Zyban (GlaxoSmithKline); generic

- Nonnicotine cessation aid
- Sustained-release antidepressant
- Oral formulation

BUPROPION: MECHANISM of ACTION

- Atypical antidepressant thought to affect levels of various brain neurotransmitters
  - Dopamine
  - Norepinephrine
- Clinical effects
  - ↓ craving for cigarettes
  - ↓ symptoms of nicotine withdrawal



BUPROPION: PHARMACOKINETICS

Absorption
- Bioavailability: 5–20%

Metabolism
- Undergoes extensive hepatic metabolism (CYP2B6)

Elimination
- Urine (87%) and feces (10%)

Half-life
- Bupropion (21 hours); metabolites (20–37 hours)

BUPROPION: CONTRAINDICATIONS

- Patients with a seizure disorder
- Patients taking
  - Wellbutrin, Wellbutrin SR, Wellbutrin XL
  - MAO inhibitors in preceding 14 days
- Patients with a current or prior diagnosis of anorexia or bulimia nervosa
- Patients undergoing abrupt discontinuation of alcohol or sedatives (including benzodiazepines)

BUPROPION: WARNINGS and PRECAUTIONS

- Neuropsychiatric symptoms and suicide risk
  - Changes in mood (depression and mania)
  - Psychosis/hallucinations/paranoia/delusions
  - Homicidal ideation/hostility
  - Agitation/anxiety/panic
  - Suicidal ideation or attempts
  - Completed suicide

Patients should stop bupropion and contact a health care provider immediately if agitation, hostility, depressed mood or changes in thinking or behavior (including suicidal ideation) are observed

BUPROPION: WARNINGS and PRECAUTIONS (cont'd)

Bupropion should be used with caution in the following populations:

- Patients with a history of seizure
- Patients with a history of cranial trauma
- Patients taking medications that lower the seizure threshold (antipsychotics, antidepressants, theophylline, systemic steroids)
- Patients with severe hepatic cirrhosis
- Patients with depressive or psychiatric disorders

BUPROPION SR: DOSING

Patients should begin therapy 1 to 2 weeks PRIOR to their quit date to ensure that therapeutic plasma levels of the drug are achieved.

Initial treatment

- 150 mg po q AM x 3 days

Then…

- 150 mg po bid
- Duration, 7–12 weeks

BUPROPION: ADVERSE EFFECTS

Common side effects include the following:

- Insomnia (avoid bedtime dosing)
- Dry mouth

Less common but reported effects:

- Tremor
- Skin rash

BUPROPION: ADDITIONAL PATIENT EDUCATION

- Dose tapering not necessary when discontinuing treatment
- If no significant progress toward abstinence by seventh week, therapy is unlikely to be effective
  - Discontinue treatment
  - Reevaluate and restart at later date

BUPROPION SR: SUMMARY

ADVANTAGES	DISADVANTAGES
▪ Easy to use oral formulation. ▪ Twice daily dosing might reduce compliance problems. ▪ Might delay weight gain ▪ Bupropion might be beneficial for patients with depression.	▪ The seizure risk is increased. ▪ Several contraindications and precautions preclude use in some patients.

VARENICLINE Chantix (Pfizer)

- Nonnicotine cessation aid
- Partial nicotinic receptor agonist
- Oral formulation

VARENICLINE: MECHANISM of ACTION

- Binds with high affinity and selectivity at $\alpha_4\beta_2$ neuronal nicotinic acetylcholine receptors
  - Stimulates low-level agonist activity
  - Competitively inhibits binding of nicotine
- Clinical effects
  - ↓ symptoms of nicotine withdrawal
  - Blocks dopaminergic stimulation responsible for reinforcement & reward associated with smoking

VARENICLINE: PHARMACOKINETICS

Absorption

- Virtually complete after oral administration; not affected by food

Metabolism

- Undergoes minimal metabolism

Elimination

- Primarily renal through glomerular filtration and active tubular secretion; 92% excreted unchanged in urine

Half-life

- 24 hours

VARENICLINE: WARNINGS and PRECAUTIONS

- Neuropsychiatric Symptoms and Suicidality
  - Changes in mood (depression and mania)
  - Psychosis/hallucinations/paranoia/delusions
  - Homicidal ideation/hostility
  - Agitation/anxiety/panic
  - Suicidal ideation or attempts
  - Completed suicide

Patients should stop varenicline and contact a health care provider immediately if agitation, hostility, depressed mood or changes in thinking or behavior (including suicidal ideation) are observed

VARENICLINE: WARNINGS and PRECAUTIONS (cont'd)

- Cardiovascular adverse events in patients with existing cardiovascular disease
- Hypersensitivity reactions
- Serious skin reactions
- Accidental injury
- Nausea

VARENICLINE: DOSING

Patients should begin therapy 1 week PRIOR to their quit date. The dose is gradually increased to minimize treatment-related nausea and insomnia.

	Treatment Day	Dose
Initial dose titration	Day 1 to day 3	0.5 mg qd
	Day 4 to day 7	0.5 mg bid
	Day 8 to end of treatment*	1 mg bid

* Up to 12 weeks

VARENICLINE: ADVERSE EFFECTS

- Common (≥5% and 2-fold higher than placebo)
  - Nausea
  - Sleep disturbances (insomnia, abnormal dreams)
  - Constipation
  - Flatulence
  - Vomiting

VARENICLINE: ADDITIONAL PATIENT EDUCATION

- Doses should be taken after eating, with a full glass of water
- Nausea and insomnia are usually temporary side effects
  - If symptoms persist, notify your health care provider
- May experience vivid, unusual or strange dreams during treatment
- Use caution driving or operating machinery until effects of quitting smoking with varenicline are known

VARENICLINE: ADDITIONAL PATIENT EDUCATION (cont'd)

- Stop taking varenicline and contact a health-care provider immediately if agitation, depressed mood, suicidal thoughts or changes in behavior are noted
- Stop taking varenicline at the first sign of rash with mucosal lesions and contact a health-care provider immediately
- Discontinue varenicline and seek immediate medical care if swelling of the face, mouth (lip, gum, tongue) and neck are noted

VARENICLINE: SUMMARY

ADVANTAGES

- Easy to use oral formulation.
- Twice daily dosing might reduce compliance problems.
- Offers a new mechanism of action for persons who have failed other agents.

DISADVANTAGES

- May induce nausea in up to one third of patients.
- Post-marketing surveillance data indicate potential for neuropsychiatric symptoms.

PHARMACOLOGIC METHODS: SECOND-LINE THERAPIES

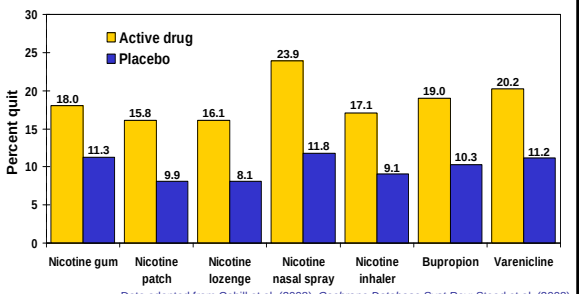
- Clonidine (Catapres transdermal or oral)
- Nortriptyline (Pamelor oral)

HERBAL DRUGS for SMOKING CESSATION

- Lobeline
  - Derived from leaves of Indian tobacco plant (*Lobelia inflata*)
  - Partial nicotinic agonist
  - No scientifically rigorous trials with long-term follow-up
  - No evidence to support use for smoking cessation

Illustration courtesy of Missouri Botanical Garden ©1995-2005. http://www.illustratedgarden.org/

LONG-TERM (≥6 month) QUIT RATES for AVAILABLE CESSATION MEDICATIONS



Data adapted from Cahill et al. (2008). *Cochrane Database Syst Rev;* Stead et al. (2008). *Cochrane Database Syst Rev;* Hughes et al. (2007). *Cochrane Database Syst Rev*

COMBINATION PHARMACOTHERAPY

Regimens with enough evidence to be 'recommended' first-line

- **Combination NRT**

  Long-acting formulation (patch)
  - Produces relatively constant levels of nicotine

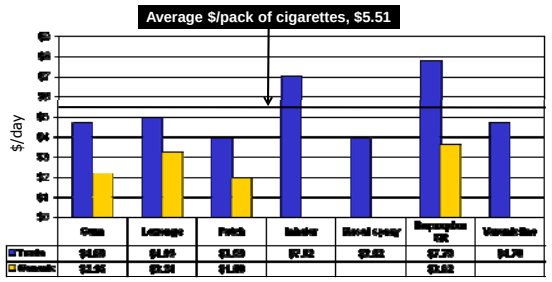
  PLUS

  Short-acting formulation (gum, inhaler, nasal spray)
  - Allows for acute dose titration as needed for nicotine withdrawal symptoms
- **Bupropion SR + Nicotine Patch**

COMPLIANCE IS KEY to QUITTING

- Promote compliance with prescribed regimens.
- Use according to dosing schedule, NOT as needed.
- Consider telling the patient:
  - "When you use a cessation product it is important to read all the directions thoroughly before using the product. The products work best in alleviating withdrawal symptoms when used correctly, and according to the recommended dosing schedule."

COMPARATIVE DAILY COSTS of PHARMACOTHERAPY



The RESPONSIBILITY of HEALTH PROFESSIONALS

It is **inconsistent**

to provide health care and

—at the same time—

remain silent (or inactive)

about a major health risk.

TOBACCO CESSATION is an important component of THERAPY.

MAKE a COMMITMENT…

Address tobacco use
with all patients.

At a minimum,
make a commitment to incorporate brief tobacco interventions as part of routine patient care.

Ask, Advise, and Refer.

DR. GRO HARLEM BRUNTLAND, FORMER DIRECTOR-GENERAL of the WHO:

"If we do not act decisively, a hundred years from now our grandchildren and their children will look back and seriously question how people claiming to be committed to public health and social justice allowed the tobacco epidemic to unfold unchecked."

USDHHS. (2001). *Women and Smoking: A Report of the Surgeon General.* Washington, DC: PHS.

TOBACCO CESSATION COUNSELING GUIDESHEET

STEP One: ASK about Tobacco Use

➲ Suggested Dialogue

✓ Do you ever smoke or use any type of tobacco?

– I take time to talk with all of my patients about tobacco use—because it's important.

✓ Condition X often is caused or worsened by exposure to tobacco smoke. Do you, or does someone in your household smoke?

✓ Medication X often is used for conditions linked with or caused by smoking. Do you, or does someone in your household smoke?

STEP Two: ADVISE to Quit

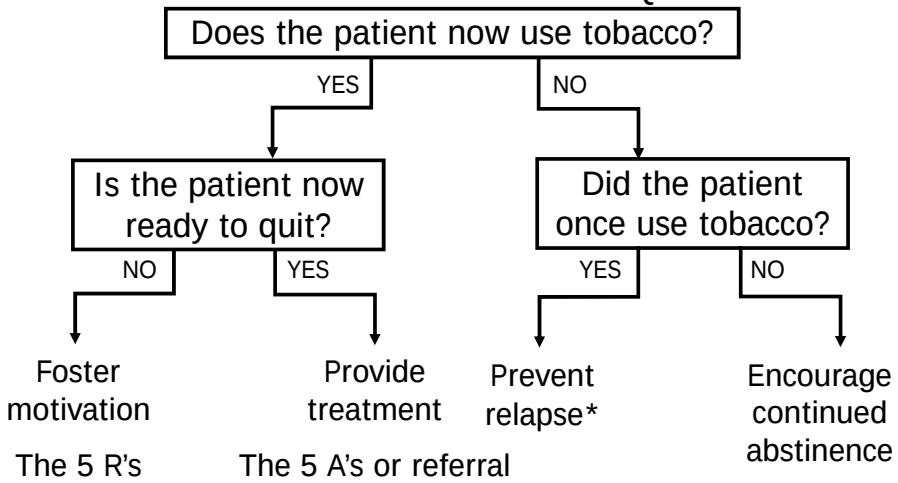
➲ Suggested Dialogue

– Quitting is the most important thing you can do to protect your health now and in the future. I have training to help my patients quit, and when you are ready I would be more than happy to work with you to design a treatment plan.

– What are your thoughts about quitting? Might you consider quitting sometime in the next month?

Prior to imparting advice, consider asking the patient for permission to do so – e.g., "May I tell you why this concerns me?" [then elaborate on patient-specific concerns]

STEP Three: ASSESS Readiness to Quit



* Relapse prevention interventions are not necessary if patient has not used tobacco for many years and is not at risk for re-initiation.

Fiore MC, Jaén CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update.* Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.

STEP Four: ASSIST with Quitting

Rx for Change

✓ **Assess Tobacco Use History**
- Current use: type(s) of tobacco used, amount
- Past use:
  - – Duration of tobacco use
  - – Changes in levels of use recently
- Past quit attempts:
  - – Number of attempts, date of most recent attempt, duration
  - – Methods used previously—What did or didn't work? Why or why not?
  - – Prior medication administration, dose, compliance, duration of treatment
  - – Reasons for relapse

✓ **Discuss Key Issues** (for the upcoming or current quit attempt)
- Reasons/motivation for wanting to quit (or avoid relapse)
- Confidence in ability to quit (or avoid relapse)
- Triggers for tobacco use
- Routines and situations associated with tobacco use
- Stress-related tobacco use
- Concerns about weight gain
- Concerns about withdrawal symptoms

✓ **Facilitate Quitting Process**
- Discuss methods for quitting: pros and cons of the different methods
- Set a quit date: ideally, less than 2 weeks away
- Recommend Tobacco Use Log
- Discuss coping strategies (cognitive, behavioral)
- Discuss withdrawal symptoms
- Discuss concept of "slip" versus relapse
- Provide medication counseling: compliance, proper use, with demonstration
- Offer to assist throughout the quit attempt

✓ **Evaluate the Quit Attempt** (at follow-up)
- Status of attempt
- "Slips" and relapse
- Medication compliance and plans for discontinuation

STEP Five: ARRANGE Follow-up Counseling

✓ Monitor patients' progress throughout the quit attempt. Follow-up contact should occur during the first week after quitting. A second follow-up contact is recommended in the first month. Additional contacts should be scheduled as needed. Counseling contacts can occur face-to-face, by telephone, or by e-mail. Keep patient progress notes.

✓ Address temptations and triggers; discuss strategies to prevent relapse.

✓ Congratulate patients for continued success.

WITHDRAWAL SYMPTOMS INFORMATION SHEET

Quitting tobacco use brings about a variety of physical and psychological withdrawal symptoms. For some people, coping with withdrawal symptoms is like riding a roller coaster—there may be sharp turns, slow climbs, and unexpected plunges. **Most symptoms manifest within the first 1 to 2 days, peak within the first week, and subside within 2 to 4 weeks.** Report new symptoms to your health-care provider, especially if severe. Consider the impact of recent medication changes and your caffeine intake.

SYMPTOM	CAUSE	DURATION	RELIEF
Chest tightness	Tightness is likely due to tension created by the body's need for nicotine or may be caused by sore muscles from coughing.	A few days	▪ Use relaxation techniques ▪ Try deep breathing ▪ Use of NRT may help
Constipation, stomach pain, gas	Intestinal movement decreases for a brief period.	1–2 weeks	▪ Drink plenty of fluids ▪ Add fruits, vegetables, and whole-grain cereals to diet
Cough, dry throat, nasal drip	The body is getting rid of mucus, which has blocked airways and restricted breathing.	A few days	▪ Drink plenty of fluids ▪ Avoid additional stress during first few weeks
Craving for a cigarette	Nicotine is a strongly addictive drug, and withdrawal causes cravings.	Frequent for 2–3 days; can happen for months or years	▪ Wait out the urge, which lasts only a few minutes ▪ Distract yourself ▪ Exercise (take walks) ▪ Use of a nicotine medication may help
Depressed mood	It is normal to feel sad for a period of time after you first quit smoking. Many people have a strong urge to smoke when they feel depressed.	1–2 weeks	▪ Increase pleasurable activities ▪ Talk with your clinician about changes in your mood when quitting ▪ Get extra support from friends and family
Difficulty concentrating	The body needs time to adjust to not having constant stimulation from nicotine.	A few weeks	▪ Plan workload accordingly ▪ Avoid additional stress during first few weeks
Dizziness	The body is getting extra oxygen.	1–2 days	▪ Use extra caution ▪ Change positions slowly
Fatigue	Nicotine is a stimulant.	2–4 weeks	▪ Take naps ▪ Do not push yourself ▪ Use of a nicotine medication may help
Hunger	Cravings for a cigarette can be confused with hunger pangs; sensation may result from oral cravings or the desire for something in the mouth.	Up to several weeks	▪ Drink water or low-calorie liquids ▪ Be prepared with low-calorie snacks
Insomnia	Nicotine affects brain wave function and influences sleep patterns; coughing and dreams about smoking are common.	1 week	▪ Limit caffeine intake (and none after 12 noon), because its effects will increase with quitting smoking ▪ Use relaxation techniques
Irritability	The body's craving for nicotine can produce irritability.	2–4 weeks	▪ Take walks ▪ Try hot baths ▪ Use relaxation techniques

Adapted from materials from the National Cancer Institute.

DRUG INTERACTIONS WITH TOBACCO SMOKE

Many interactions between tobacco smoke and medications have been identified. Note that in most cases it is the tobacco smoke—not the nicotine—that causes these drug interactions. Tobacco smoke interacts with medications through pharmacokinetic (PK) and pharmacodynamic (PD) mechanisms. PK interactions affect the absorption, distribution, metabolism, or elimination of other drugs, potentially causing an altered pharmacologic response. The majority of PK interactions with smoking are the result of induction of hepatic cytochrome P450 enzymes (primarily CYP1A2). PD interactions alter the expected response or actions of other drugs. The amount of tobacco smoking needed to have an effect has not been established, and the assumption is that any smoker is susceptible to the same degree of interaction. The most clinically significant interactions are depicted in the shaded rows.

DRUG/CLASS	MECHANISM OF INTERACTION AND EFFECTS
Pharmacokinetic Interactions	
Alprazolam (Xanax)	▪ Conflicting data on significance, but possible ↓ plasma concentrations (up to 50%); ↓ half-life (35%).
Bendamustine (Treanda)	▪ Metabolized by CYP1A2. Manufacturer recommends using with caution in smokers due to likely ↓ bendamustine concentrations, with ↑ concentrations of its two active metabolites.
Caffeine	▪ ↑ Metabolism (induction of CYP1A2); ↑ clearance (56%). Caffeine levels likely ↑ after cessation.
Chlorpromazine (Thorazine)	▪ ↓ Area under the curve (AUC) (36%) and serum concentrations (24%). ▪ ↓ Sedation and hypotension possible in smokers; smokers may require ↑ dosages.
Clopidogrel (Plavix)	▪ ↑ Metabolism (induction of CYP1A2) of clopidogrel to its active metabolite. ▪ Clopidogrel's effects are enhanced in smokers (≥10 cigarettes/day): significant ↑ platelet inhibition, ↓ platelet aggregation; while improved clinical outcomes have been shown, may also ↑ risk of bleeding.
Clozapine (Clozaril)	▪ ↑ Metabolism (induction of CYP1A2); ↓ plasma concentrations (18%). ▪ ↑ Levels upon cessation may occur; closely monitor drug levels and reduce dose as required to avoid toxicity.
Erlotinib (Tarceva)	▪ ↑ Clearance (24%); ↓ trough serum concentrations (2-fold).
Flecainide (Tambocor)	▪ ↑ Clearance (61%); ↓ trough serum concentrations (25%). Smokers may need ↑ dosages.
Fluvoxamine (Luvox)	▪ ↑ Metabolism (induction of CYP1A2); ↑ clearance (24%); ↓ AUC (31%); ↓ plasma concentrations (32%). ▪ Dosage modifications not routinely recommended but smokers may need ↑ dosages.
Haloperidol (Haldol)	▪ ↑ Clearance (44%); ↓ serum concentrations (70%).
Heparin	▪ Mechanism unknown but ↑ clearance and ↓ half-life are observed. Smoking has prothrombotic effects. ▪ Smokers may need ↑ dosages due to PK and PD interactions.
Insulin, subcutaneous	▪ Possible ↓ insulin absorption secondary to peripheral vasoconstriction; smoking may cause release of endogenous substances that cause insulin resistance. ▪ PK & PD interactions likely not clinically significant; smokers may need ↑ dosages.
Irinotecan (Camptosar)	▪ ↑ Clearance (18%); ↓ serum concentrations of active metabolite, SN-38 (~40%; via induction of glucuronidation); ↓ systemic exposure resulting in lower hematologic toxicity and may reduce efficacy. ▪ Smokers may need ↑ dosages.
Mexiletine (Mexitil)	▪ ↑ Clearance (25%; via oxidation and glucuronidation); ↓ half-life (36%).
Olanzapine (Zyprexa)	▪ ↑ Metabolism (induction of CYP1A2); ↑ clearance (98%); ↓ serum concentrations (12%). ▪ Dosage modifications not routinely recommended but smokers may need ↑ dosages.
Propranolol (Inderal)	▪ ↑ Clearance (77%; via side-chain oxidation and glucuronidation).
Ropinirole (Requip)	▪ ↓ Cmax (30%) and AUC (38%) in study with patients with restless legs syndrome. ▪ Smokers may need ↑ dosages.
Tacrine (Cognex)	▪ ↑ Metabolism (induction of CYP1A2); ↓ half-life (50%); serum concentrations 3-fold lower. ▪ Smokers may need ↑ dosages.
Theophylline (Theo Dur, etc.)	▪ ↑ Metabolism (induction of CYP1A2); ↑ clearance (58–100%); ↓ half-life (63%). ▪ Levels should be monitored if smoking is initiated, discontinued, or changed. Maintenance doses are considerably higher in smokers. ▪ ↑ Clearance with second-hand smoke exposure.
Tricyclic antidepressants (e.g., imipramine, nortriptyline)	▪ Possible interaction with tricyclic antidepressants in the direction of ↓ blood levels, but the clinical significance is not established.
Tizanidine (Zanaflex)	▪ ↓ AUC (30-40%) and ↓ half-life (10%) observed in male smokers.
Warfarin	▪ ↑ Metabolism (induction of CYP1A2) of R-enantiomer; however, S-enantiomer is more potent and effect on INR is inconclusive. Consider monitoring INR upon smoking cessation.
Pharmacodynamic Interactions	
Benzodiazepines (diazepam, chlordiazepoxide)	▪ ↓ Sedation and drowsiness, possibly caused by nicotine stimulation of central nervous system.
Beta-blockers	▪ Less effective antihypertensive and heart rate control effects; possibly caused by nicotine-mediated sympathetic activation. ▪ Smokers may need ↑ dosages.
Corticosteroids, inhaled	▪ Smokers with asthma may have less of a response to inhaled corticosteroids.
Hormonal contraceptives	▪ ↑ Risk of cardiovascular adverse effects (e.g., stroke, myocardial infarction, thromboembolism) in women who smoke and use oral contraceptives. Ortho Evra patch users shown to have 2-fold ↑risk of venous thromboembolism compared to oral contraceptive users, likely due to ↑ estrogen exposure (60% higher levels). ▪ ↑ Risk with age and with heavy smoking (≥15 cigarettes per day) and is quite marked in women ≥35 years old.
Opioids (propoxyphene, pentazocine)	▪ ↓ Analgesic effect; smoking may ↑ the metabolism of propoxyphene (15–20%) and pentazocine (40%). Mechanism unknown. ▪ Smokers may need ↑ opioid dosages for pain relief.

Adapted and updated, from Zevin S, Benowitz NL. Drug interactions with tobacco smoking. *Clin Pharmacokinet* 1999;36:425–438.

TOBACCO USE LOG

The Tobacco Use Log can help patients to identify activities or situations that trigger the desire to smoke or use other forms of tobacco. It is important for patients to understand these environmental cues so that they can develop coping strategies to overcome the temptation to use tobacco. Clinicians can use this information to suggest alternative behaviors to increase the likelihood of a successful quit attempt. The log is most appropriate for patients who are preparing for a quit attempt, but it can be used with any patient who wants to learn more about his or her smoking behavior.

Instructions for use:
The Tobacco Use Log is a piece of paper that is kept with the patient's tobacco. It can be folded and wrapped around the cigarette pack or can of snuff with a rubber band. Alternatively, patients may keep the log in their wallet or day planner. It is important that the log be readily available at the times when the patient uses the tobacco. Through careful documentation of tobacco use over a period of several days, patient-specific tobacco usage patterns become evident.

1. Instruct the patient to continue his or her regular tobacco use for a period of *at least three days* (including one non–work day). It is preferable to complete the *Tobacco Use Log* for *seven consecutive days*, because usage patterns might fluctuate as a function of the day of the week (e.g. weekends vs. work days). The patient should not attempt to reduce his or her tobacco use during this time. The intent is to document current tobacco use habits and patterns, so that the patient can understand the triggers and situations associated with his or her tobacco use.

2. The following information should be noted in the Tobacco Use Log **each time** tobacco is used:
   - **Time** of day (indicate AM or PM)
   - Description of the **activity**/situation **at the time of** tobacco use (e.g., were others present?)
   - **Need rating** of the patient's perceived importance of using tobacco, at that time, using the following scale:

Not very important (would *not* have missed it) **1**	**Moderately important** **2**	**Very important** (would have missed it a great deal) **3**

3. The patient should use a separate log sheet each day. *Note: Heavy tobacco users will require more than one log sheet per day.*

4. Just prior to the quit date, review the Tobacco Use Log with the patient to identify specific situations that trigger tobacco use. Additionally, develop specific cognitive and behavioral strategies to prevent relapse.

Adapted from The Wrap Sheet and The Daily Cigarette Count (Wrap Sheet). In: The Washington State Pharmacists Association, *Smoking Cessation Training: Pharmacists Becoming Smoking Cessation Counselors,* 1997, pp. 3, 25.

Tobacco Use Log for (date): ___/___/___

	Time	Describe the situation/activity at the time of this tobacco use.	Need Rating Circle one number*		
1.			1	2	3
2.			1	2	3
3.			1	2	3
4.			1	2	3
5.			1	2	3
6.			1	2	3
7.			1	2	3
8.			1	2	3
9.			1	2	3
10.			1	2	3
11.			1	2	3
12.			1	2	3
13.			1	2	3
14.			1	2	3
15.			1	2	3
16.			1	2	3
17.			1	2	3
18.			1	2	3
19.			1	2	3
20.			1	2	3

***Need RATING:** Rate the importance of your *need* to use tobacco *for each instance* of use—based on the following scale:

Not very important (would *not* have missed it) **1**	**Moderately important** **2**	**Very important** (would have missed it a great deal) **3**

COPING WITH QUITTING: COGNITIVE AND BEHAVIORAL STRATEGIES

COGNITIVE STRATEGIES focus on *retraining the way a patient thinks*. Often, patients mentally deliberate on the fact that they are thinking about a cigarette, and this leads to relapse. Patients must recognize that thinking about a cigarette doesn't mean they need to have one.	
REVIEW COMMITMENT TO QUIT	Each morning, say, "I am proud that I made it through another day without tobacco!" Remind oneself that cravings and temptations are temporary and will pass. Announce, either silently or aloud, "I am a nonsmoker, and the temptation will pass."
DISTRACTIVE THINKING	Use deliberate, immediate refocusing of thinking toward other thoughts when cued by thoughts about tobacco use.
POSITIVE SELF-TALKS, PEP TALKS	Say, "I can do this," and remind oneself of previous difficult situations in which tobacco use was avoided.
RELAXATION THROUGH IMAGERY	Center mind toward positive, relaxing thoughts.
MENTAL REHEARSAL, VISUALIZATION	Prepare for situations that might arise by envisioning how best to handle them. For example, envision what would happen if offered a cigarette by a friend—mentally craft and rehearse a response, and perhaps even practice it by saying it aloud.
BEHAVIORAL STRATEGIES involve *specific actions to reduce risk for relapse*. These strategies should be considered prior to quitting, after determining patient-specific triggers and routines or situations associated with tobacco use. Below are strategies for several of the more common cues or causes for relapse.	
STRESS	Anticipate upcoming challenges at work, at school, or in personal life. Develop a substitute plan for tobacco use during times of stress (e.g., use deep breathing, take a break or leave the situation, call a supportive friend or family member, perform self-massage, use nicotine replacement therapy).
ALCOHOL	*Drinking alcohol can lead to relapse.* Consider limiting or abstaining from alcohol during the early stages of quitting.
OTHER TOBACCO USERS	*Quitting is more difficult if the patient is around other tobacco users. This is especially difficult if another tobacco user is in the household.* During the early stages of quitting, limit prolonged contact with individuals who are using tobacco. Ask co-workers, friends, and housemates not to smoke or use tobacco in your presence.
ORAL GRATIFICATION NEEDS	Have nontobacco oral substitutes (e.g., gum, sugarless candy, straws, toothpicks, lip balm, toothbrush, nicotine replacement therapy, bottled water) readily available.
AUTOMATIC SMOKING ROUTINES	Anticipate routines associated with tobacco use and develop an alternative plan. Examples: MORNING COFFEE: change morning routine, drink tea instead of coffee, take shower before drinking coffee, take a brisk walk shortly after awakening. WHILE DRIVING: remove all tobacco from car, have car interior detailed, listen to a book on tape or talk radio, use oral substitute. WHILE ON THE PHONE: stand while talking, limit call duration, change phone location, keep hands occupied by doodling or sketching. AFTER MEALS: get up and immediately do dishes or take a brisk walk after eating, call supportive friend.
POSTCESSATION WEIGHT GAIN	Do not attempt to modify multiple behaviors at one time. If weight gain is a barrier to quitting, engage in regular physical activity and adhere to a healthful diet (as opposed to strict dieting). Carefully plan and prepare meals, increase fruit and water intake to create a feeling of fullness, and chew sugarless gum or eat sugarless candies. Consider use of pharmacotherapy shown to delay weight gain (e.g., nicotine gum, nicotine lozenge, bupropion).
CRAVINGS FOR TOBACCO	Cravings for tobacco are temporary and usually pass within 5–10 minutes. Handle cravings through distractive thinking, take a break, do something else, take deep breaths, perform self-massage.

PLANNING FOR CHANGE: THINKING ABOUT QUITTING

Understanding the reasons why you smoke, in addition to considering your smoking patterns and routines, are important to the design of a successful quitting plan.
Consider the following before you quit:

WHY DO I STILL SMOKE?

My top 3 reasons for continuing to smoke are:

(1)

(2)

(3)

WHY IS QUITTING IMPORTANT?

My top 3 reasons for wanting to quit smoking are:

(1)

(2)

(3)

WHAT WERE YOUR MAIN DIFFICULTIES WITH QUITTING IN THE PAST?

My top 3 difficulties with quitting in the past were:

(1)

(2)

(3)

WHAT ARE YOUR BARRIERS TO QUITTING NOW?

My top 3 barriers to quitting now are:

(1)

(2)

(3)

WHAT IS THE WORST THING THAT COULD HAPPEN TO YOU IF YOU QUIT SMOKING FOR GOOD?

ARE YOU READY TO QUIT NOW? (WITHIN THE NEXT MONTH)

If YES, what will be your official quit date? _____ / _____ / _____ **(ENTER DATE)**

If NO, how will it benefit you to quit later?

PLANNING FOR CHANGE: GETTING READY TO QUIT

Smokers don't plan to fail. Most *fail* to plan. To plan for quitting you should: (1) identify triggers for smoking and how to cope with them, (2) identify persons to help you throughout your quit attempt, and (3) choose the best methods—for you—for quitting.

WHAT ARE YOUR THREE MAIN TRIGGERS OR SITUATIONS FOR SMOKING?

To deal with situations when you feel the urge to smoke, you should (1) identify the trigger situation, (2) change what you do or how you do it, and (3) change the thoughts that trigger the desire to smoke.

Trigger #1:	▪ I will change *what I do* in this situation by: ▪ I will change *how I think* in this situation by:
Trigger #2:	▪ I will change *what I do* in this situation by: ▪ I will change *how I think* in this situation by:
Trigger #3:	▪ I will change *what I do* in this situation by: ▪ I will change *how I think* in this situation by:

WHO WILL HELP YOU WITH QUITTING?

My top 3 persons who will have a positive influence on my ability to quit for good:

(1)

(2)

(3)

WHAT FORM OF COUNSELING ASSISTANCE WILL YOU RECEIVE WHILE QUITTING?

WHAT MEDICATION(S) WILL YOU USE FOR QUITTING, AND HOW WILL YOU USE THEM?

Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation

	Nicotine Replacement Therapy (NRT) Formulations					Bupropion SR	Varenicline
	Gum	Lozenge	Transdermal Patch	Nasal Spray	Oral Inhaler		
Product	Nicorette[1], Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint, orange	Nicorette Lozenge,[1] Nicorette Mini Lozenge,[1] Generic OTC 2 mg, 4 mg cherry, mint	NicoDerm CQ[1], Generic OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	Nicotrol NS[2] Rx Metered spray 0.5 mg nicotine in 50 mcL aqueous nicotine solution	Nicotrol Inhaler[2] Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	Zyban[1], Generic Rx 150 mg sustained-release tablet	Chantix[2] Rx 0.5 mg, 1 mg tablet
Precautions	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] (Rx formulations, category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) ▪ Severe reactive airway disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Concomitant therapy with medications or medical conditions known to lower the seizure threshold ▪ Severe hepatic cirrhosis ▪ Pregnancy[3] (category C) and breastfeeding ▪ Adolescents (<18 years) Warning: ▪ Black-boxed warning for neuropsychiatric symptoms[4] Contraindications: ▪ Seizure disorder ▪ Concomitant bupropion (e.g., Wellbutrin) therapy ▪ Current or prior diagnosis of bulimia or anorexia nervosa ▪ Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines ▪ MAO inhibitor therapy in previous 14 days	▪ Severe renal impairment (dosage adjustment is necessary) ▪ Pregnancy[3] (category C) and breastfeeding ▪ Adolescents (<18 years) Warnings: ▪ Black-boxed warning for neuropsychiatric symptoms[4] ▪ Cardiovascular adverse events in patients with existing cardiovascular disease
Dosing	*≥25 cigarettes/day:* 4 mg *<25 cigarettes/day:* 2 mg Weeks 1–6: 1 piece q 1–2 hours Weeks 7–9: 1 piece q 2–4 hours Weeks 10–12: 1 piece q 4–8 hours ▪ Maximum, 24 pieces/day ▪ Chew each piece slowly ▪ Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) ▪ Resume chewing when tingle fades ▪ Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) ▪ Park in different areas of mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 lozenge q 1–2 hours Weeks 7–9: 1 lozenge q 2–4 hours Weeks 10–12: 1 lozenge q 4–8 hours ▪ Maximum, 20 lozenges/day ▪ Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) ▪ Nicotine release may cause a warm, tingling sensation ▪ Do not chew or swallow ▪ Occasionally rotate to different areas of the mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*>10 cigarettes/day:* 21 mg/day x 4 weeks (generic) 6 weeks (NicoDerm CQ) 14 mg/day x 2 weeks 7 mg/day x 2 weeks *≤10 cigarettes/day:* 14 mg/day x 6 weeks 7 mg/day x 2 weeks ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8–10 weeks	1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa ▪ Maximum – 5 doses/hour or – 40 doses/day ▪ For best results, initially use at least 8 doses/day ▪ Do not sniff, swallow, or inhale through the nose as the spray is being administered ▪ Duration: 3–6 months	6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours ▪ Best effects with continuous puffing for 20 minutes ▪ Initially use at least 6 cartridges/day ▪ Nicotine in cartridge is depleted after 20 minutes of active puffing ▪ Inhale into back of throat or puff in short breaths ▪ Do NOT inhale into the lungs (like a cigarette) but "puff" as if lighting a pipe ▪ Open cartridge retains potency for 24 hours ▪ No food or beverages 15 minutes before or during use ▪ Duration: 3–6 months	150 mg po q AM x 3 days, then 150 mg po bid ▪ Do not exceed 300 mg/day ▪ Begin therapy 1–2 weeks prior to quit date ▪ Allow at least 8 hours between doses ▪ Avoid bedtime dosing to minimize insomnia ▪ Dose tapering is not necessary ▪ Can be used safely with NRT ▪ Duration: 7–12 weeks, with maintenance up to 6 months in selected patients	Days 1–3: 0.5 mg po q AM Days 4–7: 0.5 mg po bid Weeks 2–12: 1 mg po bid ▪ Begin therapy 1 week prior to quit date ▪ Take dose after eating and with a full glass of water ▪ Dose tapering is not necessary ▪ Duration: 12 weeks; an additional 12-week course may be used in selected patients

	Nicotine Replacement Therapy (NRT) Formulations					Bupropion SR	Varenicline
	Gum	Lozenge	Transdermal Patch	Nasal Spray	Oral Inhaler		
Adverse Effects	▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: – Lightheadedness – Nausea/vomiting – Throat and mouth irritation	▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia	▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption	▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache	▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups	▪ Insomnia ▪ Dry mouth ▪ Nervousness/difficulty concentrating ▪ Rash ▪ Constipation ▪ Seizures (risk is 0.1%) ▪ Neuropsychiatric symptoms (rare; see Precautions)	▪ Nausea ▪ Sleep disturbances (insomnia, abnormal/vivid dreams) ▪ Constipation ▪ Flatulence ▪ Vomiting ▪ Neuropsychiatric symptoms (rare; see Precautions)
Advantages	▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available	▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Easy to use and conceal ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available	▪ Provides consistent nicotine levels over 24 hours ▪ Easy to use and conceal ▪ Once daily dosing associated with fewer compliance problems	▪ Patients can titrate therapy to rapidly manage withdrawal symptoms	▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking (could also be perceived as a disadvantage)	▪ Easy to use; oral formulation might be associated with fewer compliance problems ▪ Might delay weight gain ▪ Can be used with NRT ▪ Might be beneficial in patients with depression	▪ Easy to use; oral formulation might be associated with fewer compliance problems ▪ Offers a new mechanism of action for patients who have failed other agents
Disadvantages	▪ Need for frequent dosing can compromise compliance ▪ Might be problematic for patients with significant dental work ▪ Patients must use proper chewing technique to minimize adverse effects ▪ Gum chewing may not be socially acceptable	▪ Need for frequent dosing can compromise compliance ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	▪ Patients cannot titrate the dose to acutely manage withdrawal symptoms ▪ Allergic reactions to adhesive might occur ▪ Patients with dermatologic conditions should not use the patch	▪ Need for frequent dosing can compromise compliance ▪ Nasal/throat irritation may be bothersome ▪ Patients must wait 5 minutes before driving or operating heavy machinery ▪ Patients with chronic nasal disorders or severe reactive airway disease should not use the spray	▪ Need for frequent dosing can compromise compliance ▪ Initial throat or mouth irritation can be bothersome ▪ Cartridges should not be stored in very warm conditions or used in very cold conditions ▪ Patients with underlying bronchospastic disease must use with caution	▪ Seizure risk is increased ▪ Several contraindications and precautions preclude use in some patients (see Precautions) ▪ Patients should be monitored for potential neuropsychiatric symptoms[4] (see Precautions)	▪ May induce nausea in up to one third of patients ▪ Patients should be monitored for potential neuropsychiatric symptoms[4] (see Precautions)
Cost/day[5]	2 mg or 4 mg: $2.25–$4.41 (9 pieces)	2 mg or 4 mg: $2.61–$4.95 (9 pieces)	$1.87–$3.52 (1 patch)	$4.43 (8 doses)	$7.68 (6 cartridges)	$3.62–$7.46 (2 tablets)	$5.38–$6.20 (2 tablets)

[1] Marketed by GlaxoSmithKline.
[2] Marketed by Pfizer.
[3] The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.
[4] In July 2009, the FDA mandated that the prescribing information for all bupropion- and varenicline-containing products include a black-boxed warning highlighting the risk of serious neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. Clinicians should advise patients to stop taking varenicline or bupropion SR and contact a healthcare provider immediately if they experience agitation, depressed mood, and any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. If treatment is stopped due to neuropsychiatric symptoms, patients should be monitored until the symptoms resolve.
[5] Average wholesale price from Medi-Span Electronic Drug File. Indianapolis, IN: Wolters Kluwer Health, July 2011.

Abbreviations: MAO, monoamine oxidase; NRT, nicotine replacement therapy; OTC, over-the-counter (non-prescription product); Rx, prescription product.

For complete prescribing information, please refer to the manufacturers' package inserts.

RELAPSED SMOKERS WHO ARE READY TO TRY AGAIN: WHAT TO DO?

A 3-STEP PROTOCOL FOR CLINICIANS (PAGE 1 OF 2)

Many smokers who relapse do so because they fail to plan. Often, patients think that they can simply "make" themselves quit and do not avail themselves of the many proven behavior change programs provided by various sources. Furthermore, most smokers do not use a cessation medication or, if they do, they use it incorrectly. Generally speaking, patients significantly under-dose or stop pharmacologic therapy too soon.

You can help relapsed smokers regain abstinence by encouraging them to learn from their prior experiences rather than use those experiences as proof that they cannot quit. To underscore this perspective, inform patients that the best way to quit smoking is to combine a behavior change program with a cessation medication. The following **3-step protocol** will help you provide this information in an efficient, effective manner for patients who are ready to try again:

STEP 1: **ASK**

- "TELL ME ABOUT YOUR LAST QUIT ATTEMPT(S)."
- "DID YOU USE A SMOKING CESSATION MEDICATION?"
  - If yes: "EXPLAIN HOW YOU USED YOUR MEDICATION."
    - Reinforce proper usage/ rectify incorrect usage or dosage
  - If no: "WHAT WAS YOUR REASONING FOR NOT USING A MEDICATION?"
- "DID YOU RECEIVE ANY PROFESSIONAL ADVICE OR ENROLL IN A BEHAVIOR CHANGE PROGRAM?"
  - If yes: "TELL ME WHAT YOU LIKED, OR DIDN'T LIKE ABOUT THE ASSISTANCE YOU RECEIVED."
  - If no: "WHAT WAS YOUR REASONING FOR NOT SEEKING ADVICE OR ENROLLING IN A PROGRAM?"

STEP 2: **ADVISE**

- "ACCORDING TO THE MOST CURRENT RESEARCH AND THE SURGEON GENERAL, THE BEST WAY TO QUIT IS TO COMBINE A SMOKING CESSATION MEDICATION WITH A BEHAVIORAL PROGRAM."

  NOTE: Examples of behavior change programs are listed on the reverse side, under the "Refer" section of the protocol.
- "LET'S DISCUSS WHICH MEDICATION(S) WOULD BE BEST FOR YOU."
- Review current level of tobacco use, past usage of medications, personal preference, precautions/ contraindications, etc. to determine best product for current quit attempt.

  NOTE: Refer to the Rx for Change ***Pharmacologic Product Guide*** for dosing instructions, etc. for FDA-approved smoking cessation medications.
- Consider the following options:
  - If prior medication was used correctly, was well tolerated, and appeared to have been effective, consider repeating the same medication regimen in conjunction with an enhanced behavioral program.
  - If prior medication was used incorrectly, carefully review usage instructions.
  - If prior medication was used correctly but did not control urges/withdrawal, or if patient prefers something new, review other medication options, including both single and combination therapy:

CONTINUED ON BACK

RELAPSED SMOKERS WHO ARE READY TO TRY AGAIN: WHAT TO DO?

A 3-STEP PROTOCOL FOR CLINICIANS (PAGE 2 OF 2)

Combination therapy currently is off-label for all cessation medications, but is supported by multiple clinical trials and the *Clinical Practice Guideline for Treating Tobacco Use and Dependence* (p. 118):

- *Safe:* Most smokers are highly tolerant to nicotine from years of smoking. Side effects are rare and easily mitigated by reducing or stopping use.
- *Effective:* Especially in those who failed with one medication. Also useful in patients who are heavily dependent (2 or more packs/day).

Suggested combinations:

- Nicotine patch + *ad libitum* gum, lozenge, inhaler, or nasal spray as needed for breakthrough urges.
- Sustained-release bupropion (Zyban) + nicotine patch

Currently, varenicline (Chantix) is not recommended for combination therapy

STEP 3: **REFER**

The amount of counseling that patients receive is linearly related to their success in quitting. More counseling contacts yield higher quit rates. If you do not have the time or expertise to assist patients with quitting and to provide follow-up counseling, refer patients to other resources:

- To a behavior change program:

  "HERE ARE SOME SUGGESTIONS. WHICH DO YOU THINK WOULD WORK BEST FOR YOU?"

  - 1 800 QUIT NOW, the national toll-free telephone quit line
  - All products are accompanied by a free behavior change program: Refer to usage instructions for enrollment procedures
  - Hospital-based or other local resources (e.g., a group program)
  - www.quitnet.com, an on-line tobacco cessation support program
  - smokefree.gov, an on-line guide for quitting
  - American Lung Association, American Cancer Society, or American Heart Association web-sites or cessation programs (e.g., American Lung Association's *Freedom From Smoking* group cessation program)
  - Local pharmacist, physician, or other health-care provider specializing in cessation

- To a community pharmacist:

  - "WHEN YOU PURCHASE YOUR SMOKING CESSATION MEDICATION, PLEASE TAKE A FEW MINUTES TO DISCUSS PROPER USAGE WITH THE PHARMACIST, EVEN IF IT IS A PRODUCT YOU HAVE USED IN THE PAST. PROPER USAGE WILL GIVE YOU THE BEST CHANCE OF SUCCESS."

- To other staff:

  - If you have dedicated cessation staff within your clinic or health-care organization, refer patient to these resources for follow-up counseling.

For more information, see Fiore MC, Jaén CR, Baker TB, et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. Available at: www.surgeongeneral.gov/tobacco.

For complete prescribing information, please refer to the manufacturers' package inserts.

ESTIMATED EFFICACY OF METHODS FOR TREATING TOBACCO USE AND DEPENDENCE

TREATMENT METHOD	Estimated Odds Ratio[a] (95% CI)	Estimated Abstinence Rate[b] (95% CI)
Behavioral interventions		
Advice to quit		
No advice to quit	1.0	7.9
Physician advice to quit	1.3 (1.1–1.6)	10.2 (8.5–12.0)
Clinician intervention		
No counseling by a clinician	1.0	10.2
Counseling by a non–physician	1.7 (1.3–2.1)	15.8 (12.8–18.8)
Counseling by a physician	2.2 (1.5–3.2)	19.9 (13.7–26.2)
Format of smoking cessation counseling		
No format	1.0	10.8
Self-help	1.2 (1.0–1.3)	12.3 (10.9–13.6)
Proactive telephone counseling[c]	1.2 (1.1–1.4)	13.1 (11.4–14.8)
Group counseling	1.3 (1.1–1.6)	13.9 (11.6–16.1)
Individual counseling	1.7 (1.4–2.0)	16.8 (14.7–19.1)
Pharmacotherapy		
Placebo	1.0	13.8
First-line agents		
Bupropion SR	2.0 (1.8–2.2)	24.2 (22.2–26.4)
Nicotine gum (6–14 weeks)	1.5 (1.2–1.7)	19.0 (16.5–21.9)
Nicotine inhaler	2.1 (1.5–2.9)	24.8 (19.1–31.6)
Nicotine lozenge (2 mg)	2.0 (1.4–2.8)	24.2[d]
Nicotine patch (6–14 weeks)	1.9 (1.7–2.2)	23.4 (21.3–25.8)
Nicotine nasal spray	2.3 (1.7–3.0)	26.7 (21.5–32.7)
Varenicline (2 mg/day)	3.1 (2.5–3.8)	33.2 (28.9–37.8)
Second-line agents[e]		
Clonidine	2.1 (1.2–3.7)	25.0 (15.7–37.3)
Nortriptyline	1.8 (1.3–2.6)	22.5 (16.8–29.4)
Combination therapy		
Patch (>14 weeks) + *ad lib* nicotine (gum or nasal spray)	3.6 (2.5–5.2)	36.5 (28.6–45.3)
Nicotine patch + bupropion SR	2.5 (1.9–3.4)	28.9 (23.5–35.1)
Nicotine patch + nortriptyline	2.3 (1.3–4.2)	27.3 (17.2–40.4)
Nicotine patch + nicotine inhaler	2.2 (1.2–3.6)	25.8 (17.4–36.5)

[a] Estimated relative to referent group
[b] Abstinence percentages for specified treatment method
[c] A quitline that responds to incoming calls and makes outbound followup calls. Following an initial request by the smoker or via a fax-to-quit program, the clinician initiates telephone contact to counsel the patient.
[d] One qualifying randomized trial; 95% CI not reported in 2008 Clinical Practice Guideline
[e] Not approved by the U.S. Food and Drug Administration as a smoking cessation aid; recommended by the USPHS Guideline as a second-line agent for treating tobacco use and dependence.

Data from: Fiore MC, Jaén CR, Baker TB, et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: U.S. Department of Health and Human Services. Public Health Service.

CLINICAL PRACTICE GUIDELINE FOR TREATING TOBACCO USE AND DEPENDENCE: 2008 UPDATE

TEN KEY GUIDELINE RECOMMENDATIONS

Recommendation	
1	Tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit. Effective treatments exist, however, that can significantly increase rates of long-term abstinence.
2	It is essential that clinicians and health care delivery systems consistently identify and document tobacco use status and treat every tobacco user seen in a health care setting.
3	Tobacco dependence treatments are effective across a broad range of populations. Clinicians should encourage every patient willing to make a quit attempt to use the counseling treatments and medications recommended in this Guideline.
4	Brief tobacco dependence treatment is effective. Clinicians should offer every patient who uses tobacco at least the brief treatments shown to be effective in this Guideline.
5	Individual, group, and telephone counseling are effective, and their effectiveness increases with treatment intensity. Two components of counseling are especially effective, and clinicians should use these when counseling patients making a quit attempt: (a) practical counseling (problem solving/skills training) and (b) social support delivered as part of treatment.
6	Numerous effective medications are available for tobacco dependence, and clinicians should encourage their use by all patients attempting to quit smoking—except where medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). Seven first-line medications (5 nicotine and 2 non-nicotine) reliably increase long-term smoking abstinence rates: bupropion SR, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, nicotine patch, and varenicline. Clinicians also should consider the use of certain combinations of medications identified as effective in this Guideline.
7	Counseling and medication are effective when used by themselves for treating tobacco dependence. The combination of counseling and medication, however, is more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.
8	Telephone quitline counseling is effective with diverse populations and has broad reach. Therefore, both clinicians and health care delivery systems should ensure patient access to quitlines and promote quitline use.
9	If a tobacco user currently is unwilling to make a quit attempt, clinicians should use the motivational treatments shown in this Guideline to be effective in increasing future quit attempts.
10	Tobacco dependence treatments are both clinically effective and highly cost-effective relative to interventions for other clinical disorders. Providing coverage for these treatments increases quit rates. Insurers and purchasers should ensure that all insurance plans include the counseling and medication identified as effective in this Guideline as covered benefits.

For more information, see Fiore MC, Jaén CR, Baker TB, et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: U.S. Department of Health and Human Services. Public Health Service.

Available at: www.surgeongeneral.gov/tobacco.