



Complete Summary

GUIDELINE TITLE

VA/DoD clinical practice guideline for the management of tobacco use.

BIBLIOGRAPHIC SOURCE(S)

Veterans Administration, Department of Defense. VA/DoD clinical practice guideline for the management of tobacco use. Washington (DC): Department of Veteran Affairs; 2004 Jun. 81 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Tobacco use cessation in the primary care setting. Department of Veterans Affairs (U.S.); 1999 May. Various p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [May 2, 2007, Antidepressant drugs](#): Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

CONTRAINDICATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

SCOPE

DISEASE/CONDITION(S)

Tobacco dependence

GUIDELINE CATEGORY

Counseling
Evaluation
Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Students

GUIDELINE OBJECTIVE(S)

- To assist providers and tobacco specialists in delivering more effective treatments that reduce the prevalence of tobacco use among the beneficiaries of the Veterans Health Administration and the Department of Defense
- To assist patients to quit using tobacco and therefore, improve clinical outcomes

TARGET POPULATION

Any person (age greater than 12 years) who is eligible for care in the Veterans Health Administration or the Department of Defense health care delivery system (including adults, and students in elementary and middle schools)

INTERVENTIONS AND PRACTICES CONSIDERED

Screening/Assessment

1. Assess tobacco status and willingness to quit, availability of tobacco cessation programs, and person's willingness to attend a program (such as Quit Smart, American Lung Association Freedom from Smoking Program, Group Health of Puget Sound program).
2. Address comorbid medical and psychiatric conditions/risks to determine whether the person has other clinical conditions that need prioritized intervention before instituting a tobacco cessation program. For persons ready to quit, provide additional assessment as appropriate:
 - Fagerstrom Nicotine Tolerance Questionnaire
 - Physiological measures (carbon monoxide, urine or serum nicotine or cotinine level, or pulmonary function tests)
 - Self administered test "Why Do I Smoke?"

Management/Treatment

1. Initiate interventions (series of office visits) addressing the patient's interest in quitting, severity of tobacco dependence and withdrawal symptoms, length of previous quit attempts, reasons for relapse, appropriateness of behavioral and pharmacotherapy, the reasons why they use tobacco (stress control, habit, pleasure, etc.), and concerns about consequences of quitting such as weight gain.
2. Advise quitting.
3. Assist patients to quit by providing counseling (problem solving/skills training), a quit plan, and social support
4. Provide self-help educational material (e.g., pamphlets/books, videotapes, computer programs, etc)
5. Establish a quit date, encourage use of behavioral techniques to disrupt the habits and rituals of tobacco use schedule follow-up visits within 1 to 2 weeks of the quit date.
6. Initiate pharmacological treatment as appropriate:
 - *Nicotine replacement products (NRT)*:
 - Transdermal delivery system (patches, e.g., Nicoderm CQ)
 - Polacrilex resin (gum)
 - Polacrilex resin (lozenge)
 - Nasal spray (Nicotrol NS)
 - Oral vapor inhaler (Nicotrol Inhaler)
 - *Non-nicotine replacement products*:
 - *First line*: Bupropion SR (sustained release) and bupropion IR (immediate release)
 - *Second Line*: Clonidine and nortriptyline

Risk Assessment/Prevention

1. Initiate/reinforce relapse prevention.
2. Promote motivation to quit using a motivational technique characterized by the "five Rs:" relevance, risks, rewards, repetition, and roadblocks; use motivational interviewing.
3. Congratulate and encourage continued abstinence.
4. Assess risk for relapse for patients who have recently quit and risk for starting tobacco use in persons who never used tobacco.

5. Initiate primary prevention among adolescents and young adults.
6. Address individual conditions in special populations including:
 - Children and adolescents
 - Pregnant women
 - Military recruits and trainees
 - Hospitalized patients
 - Older patients

MAJOR OUTCOMES CONSIDERED

- Efficacy of treatment
- Patient satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Medical Subject Headings terms used for the search were: key therapies in tobacco use cessation treatment, study characteristics, and study design. In this search, study characteristics were those of analytic studies, case-control studies, retrospective studies, cohort studies, longitudinal studies, follow-up studies, prospective studies, cross-sectional studies, clinical protocols, controlled clinical trials, randomized clinical trials, intervention studies, and sampling studies. Study design included crossover studies, double-blind studies, matched pair analysis, meta-analysis, random allocation, reproducibility of results, and sample size.

Eighteen researchable questions and associated key terms were developed by the Working Group after orientation to the seed guidelines and to goals that had been identified by the Working Group. The questions specified (adapted from the Evidence-Based Medicine [EBM] toolbox, Centre for Evidence-Based Medicine, (<http://www.cebm.net>):

- Population - characteristics of the target patient population
- Intervention - exposure, diagnostic, or prognosis
- Comparison - intervention, exposure, or control used for comparison
- Outcome - outcomes of interest

These specifications served as the preliminary criteria for selecting studies.

Published, peer-reviewed, randomized controlled trials (RCTs) were considered to constitute the strongest level of *evidence* in support of guideline recommendations. This decision was based on the judgment that RCTs provide the clearest, scientifically sound basis for judging comparative efficacy.

A systematic search of the literature was conducted. It focused on the best available evidence to address each key question and ensured maximum coverage

of studies at the top of the hierarchy of study types: evidence-based guidelines, meta-analyses, and systematic reviews. When available, the search sought out critical appraisals already performed by others that described explicit criteria for deciding what evidence was selected and how it was determined to be valid. The sources that have already undergone rigorous critical appraisal include Cochrane Reviews, Best Evidence, Technology Assessment, and EPC reports.

The search continued using well-known and widely available databases that were appropriate for the clinical subject. In addition to Medline/PubMed, the following databases were searched: Database of Abstracts of Reviews of Effectiveness (DARE) and Cochrane Central Register of Controlled Trials. For Medline/PubMed, limits were set for language (English), date of publication (1998 through December 2002) and type of research (RCT and meta-analysis).

Once definitive reviews or clinical studies that provided valid relevant answers to the question were identified, the search ended. The search was extended to studies/reports of lower quality (observational studies) only if there were no high quality studies.

Exclusion criteria included reviews that omitted clinical course or treatment. Some retrieved studies were rejected on the basis of published abstracts, and a few were rejected after the researchers scanned the retrieved citation for inclusion criteria.

The results of the search were organized and reported using reference manager software. At this point, additional exclusion criteria were applied. The bibliographies of the retrieved articles were hand-searched for articles that may have been missed by the computer search. Additional experts were consulted for articles that may also have been missed.

The articles identified during the literature reviews formed the basis for updating the guideline recommendations.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The following rating schemes are from the U.S. Preventive Services Task Force (USPSTF) (2001).

Quality of Evidence (QE)

I: Evidence obtained from at least one properly randomized controlled trial

II-1: Evidence obtained from well-designed controlled trials without

randomization

II-2: Evidence obtained from well-designed cohort or case-control analytic study

II-3: Evidence obtained from multiple time series, dramatic results of uncontrolled experiment

III: Opinions of respected authorities; case reports, and reports of expert committees

Overall Quality

Good: High grade evidence (I or II-1) directly linked to health outcome

Fair: High grade evidence (I or II-1 linked to intermediate outcome or moderate grade evidence (II-2 or II-3) directly linked to health outcome

Poor: Level III evidence or no linkage of evidence to health outcome

Net Effect of Intervention

Substantial:

- More than a small relative impact on a frequent condition with a substantial burden of suffering, or
- A large impact on an infrequent condition with a significant impact on the individual patient level

Moderate:

- A small relative impact on a frequent condition with a substantial burden of suffering, or
- A moderate impact on an infrequent condition with a significant impact on the individual patient level

Small:

- A negligible relative impact on a frequent condition with a substantial burden of suffering, or
- A small impact on an infrequent condition with a significant impact on the individual patient level

Zero or Negative:

- Negative impact on patients, or
- No relative impact on either a frequent condition with a substantial burden of suffering, or
- An infrequent condition with a significant impact on the individual patient level

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Five of the researchable questions were selected by the Working Group for detailed evidence review. A group of clinician reviewers and other researchers in health care, with experience in evidence-based appraisal, independently read and coded each article that met inclusion criteria. Each article was turned into a one-page summary of the critical appraisal by the research team and added to a central electronic database. Clinicians from the Center for Evidence-Based Practice at the State University of New York (SUNY), Upstate Medical University, Department of Family Medicine contributed several of the appraisal reports. Each of the evidence reports covered:

- Summary of findings
- Methodology
- Search terms
- Resources searched
- Summary table of findings
- Critical appraisal of each study

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Offices of Quality and Performance and Patient Care Service, in collaboration with the network Clinical Managers, the Deputy Assistant Under Secretary for Health, and the Medical Center Command of the Department of Defense (DoD) identified clinical leaders to champion the guideline development process. During a preplanning conference call, the clinical leaders defined the scope of the guideline and identified a group of clinical experts from the Veterans Administration (VA) and DoD that formed the Guideline Development Working Group.

The Working Group participated in two face-to-face sessions to reach a consensus about the guideline recommendations and to prepare a draft document. The draft was revised by the experts through numerous conference calls and individual contributions to the document.

The guideline is the product of many months of diligent effort and consensus building among knowledgeable individuals from the VA, DoD, academia, and guideline facilitators from the private sector. An experienced moderator facilitated the multidisciplinary Working Group.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The following rating scheme is from the U.S. Preventive Services Task Force (USPSTF) (2001).

Grade of Recommendation

- A:** A strong recommendation that the intervention is always indicated and acceptable
B: A recommendation that the intervention may be useful/effective
C: A recommendation that the intervention may be considered
D: A recommendation that a procedure may be considered not useful/effective, or may be harmful
I: Insufficient evidence to recommend for or against; the clinician will use clinical judgment

COST ANALYSIS

Published cost analyses were reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Clinical experts in the Veterans Administration (VA) and Department of Defense (DoD) reviewed the final draft. Their feedback was integrated into the final draft.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for the management of tobacco use are organized into two major algorithms. The algorithm annotations, objectives, and recommendations that accompany them, and the evidence supporting the recommendations are presented below. The quality of evidence (I, II-1, II-2, II-3, III), overall quality (good, fair, poor), net effect of intervention (substantial, moderate, small, zero or negative), and strength of recommendation grading (A-D, I) are defined at the end of the "Major Recommendations" field. *Note: A list of abbreviations is provided at the end of the "Major Recommendations" field.*

Assessment and Treatment Algorithm

A. Person Encountering the Veterans Health Administration/Department of Defense (VHA/DoD) Health Care Delivery Systems

Definition

Any person (age greater than 12 years) who is eligible for care in the Veterans Health Administration (VHA) or the Department of Defense (DoD) health care delivery system should be screened for tobacco use as defined in this guideline.

B. Ask About Tobacco Use

Objective

Identify tobacco users.

Recommendations

1. Patients should be asked about tobacco use at most visits, as repeated screening increases rates of clinical intervention. **[A]**
 - Screening for tobacco use in primary care should occur at least three times/year. **[Expert Consensus]**
 - Screening for tobacco use by other specialties or disciplines should be done at least once per year. **[Expert Consensus]**
 - Screening adolescents should include assessment of environmental tobacco exposure (see Annotation Q-1 - Children and Adolescents)

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|---|---|-----------|------------------------|----------|
| 1 | Tobacco use screening system to identify smokers. | U.S. Department of Health and Human Services et al., 2000 | I | Good | A |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

C. Advise to Quit

Objective

Promote motivation to quit tobacco use.

Recommendations

1. Tobacco users should be advised to quit at every visit because there is a dose response relationship between number of contacts and abstinence. **[A]**
2. Physicians should strongly advise tobacco users to quit, as physician advice increases abstinence rates. **[A]**
3. Health care team members should strongly advise all tobacco users to quit. **[B]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|---|-----------|------------------------|----------|
| 1 | Physician advice to quit smoking increases abstinence rates. | U.S. Department of Health and Human Services et al., 2000; Silagy & Stead, 2001; U.S. Preventive Services Task Force (USPSTF), 1996 | I | Good | A |
| 2 | Minimal contact time increases long-term abstinence. | U.S. Department of Health and Human Services et al., 2000 | I | Good | A |
| 3 | Advice to quit by all types of non-physician | Rice & Stead, 2001 | I | Fair | B |

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|--|---|----------------------------|-----------|------------------------|----------|
| | clinicians is effective in increasing patients' long-term quit rates. | | | | |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

D. Assess Willingness to Quit

Objective

Determine the individual's level of interest to quit tobacco use.

Recommendations

1. Tobacco users should be assessed for willingness to quit at every visit. **[C]**
 - Willingness to quit should be assessed at least three times/year. **[Expert Consensus]**

E. Educate about Treatment Options; Arrive at Shared Decision for Choice of Treatment; Determine and Document Treatment Plan

Objective

Provide the tobacco user who desires to quit choices and a variety of treatment modalities.

Recommendations

1. Providers and patients should discuss the range of available treatment options and arrive at a mutually agreeable treatment plan. Discussion should address **[Expert Consensus]**:
 - Individually relevant information regarding effectiveness, availability, suitability, and contraindications of different treatment options
 - Patient's individual preferences and concerns about the treatment options/combinations
 - Tailoring treatment for patients with special needs (pregnancy, adolescents, comorbid conditions) (see Annotations Q1- 6 - Special Populations)
 - Choosing the most intensive treatment option that the patient is willing to use/attend
2. Patient education and a treatment plan should be documented in the patient's record. **[Expert Consensus]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|--|-----------------|----------------------------|-----------|------------------------|----------|
| | | | | | |

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|---|---|-----------|------------------------|----------|
| 1 | Patient selection of the treatment option based on current tobacco use, daily schedule, relapse risk factors, concern about weight gain and available support | Leischow & Stitzer, 1991 | I | Fair | B |
| 2 | Shared decision making increases patient willingness to enter treatment. | Edwards et al., 2003; O'Connor et al., 2001 | I | Fair | C |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

F. Assist Tobacco User to Quit

Objective

Initiate intervention to assist the tobacco user to quit tobacco use.

Recommendations

1. All tobacco users who are willing to quit should be offered an effective tobacco cessation intervention, including:
 - Pharmacotherapy
 - Counseling
 - Follow-up
2. All tobacco users must have reasonable access to minimal counseling and to either an intermediate or intensive cessation program. **[A]**
3. Cessation treatment may include the following components:
 - Tobacco use cessation pharmacotherapy **[A]**
 - Counseling techniques that have been shown to be effective (problem solving, skill training, intra and extra treatment support) **[A]**
 - Multiple treatment sessions **[A]**
 - Multiple formats, proactive telephone counseling, and group or individual counseling **[A]**
 - Multiple types of counselors (e.g., physicians, psychologists, nurses, pharmacists, health educators) **[B]**
4. Aversive smoking interventions (rapid smoking, rapid puffing, other aversive smoking techniques) increase abstinence rates and may be used with smokers who desire such treatment or who have been unsuccessful using other interventions. **[B]** Although aversive smoking has been demonstrated to be effective, it is rarely used due to the availability of medication.
5. There is insufficient evidence to recommend for or against the use of the following interventions:
 - Acupuncture **[C]**
 - Hypnosis **[C]**

- Physiological feedback and restricted environmental stimulation therapy [C]
- "Harm reduction" products [C]

6. There is insufficient evidence to support the following strategies: relaxation/breathing, contingency contracting, weight/diet, cigarette fading, exercise, and negative affect. Exercise may be considered to help prevent the weight gain associated with tobacco cessation. [I]

Strategies for Tobacco Use Cessation

| Strategy | Counseling | Pharmacotherapy (e.g., nicotine replacement therapy [NRT] or bupropion) | Typical Setting (individual or group) | Follow-up |
|--------------------------|---|--|---|------------------------------|
| Minimal | 1 session less than 3 min | YES + Instructions print-out | Primary care provider <i>and/or</i> Other health care team members | Next routine visit |
| Intermediate | 2 to 3 sessions 3 to 10 min | YES + Instructions print-out | Telephone Quitline* <i>and/or</i> Primary care provider | 1 to 2 weeks after quit date |
| Intensive program | Greater than or equal to 4 sessions greater than 10 min | YES + Instructions print-out | Cessation program or Telephone Quitline* <i>and/or</i> Primary care provider | 1 to 2 weeks after quit date |

*Medication may be prescribed by the primary care provider or other providers.

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|---|-----------|------------------------|----------|
| 1 | Smoking cessation counseling can assist smokers to quit. | Lancaster & Stead, 2002 | I | Good | A |
| 2 | There is a dose response relationship between number of contacts and abstinence. | U.S. Department of Health and Human Services et al., 2000 | I | Good | A |
| 3 | Pharmacotherapy increases abstinence rates. | See Annotation H (below) | I | Good | A |
| 4 | Brief counseling increases abstinence rates. | Silagy & Stead, 2001 | I | Good | A |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

G. Initiate Counseling

Objective

Facilitate abstinence through counseling and behavioral interventions.

Recommendations

Counseling in the Clinic

1. Tobacco users who are willing to quit should receive some form of counseling. There is a dose response relationship in counseling and rate of abstinence. **[A]**
 - Minimal counseling (lasting <3 minutes) increases overall tobacco abstinence rates. **[A]**
 - Intensive counseling (>10 minutes) increases abstinence rates. **[A]**
 - Multiple counseling sessions increase abstinence rates. **[A]**
2. Effective counseling can be delivered in multiple formats (e.g., group counseling, proactive telephone counseling, and individual counseling) and may be more effective when combined. **[A]**
3. Counseling should be provided by a variety of clinician types (physicians or nonphysician clinicians, such as nurses, dentists, dental hygienists, psychologists, pharmacists, and health educators) to increase quit rates. **[A]**
4. All patients who are willing to quit should have access to intensive counseling (Quitlines or intensive cessation program).

Quitlines

5. Tobacco users who are willing to quit may receive counseling via telephone Quitlines, as proactive telephone counseling has been demonstrated to be effective. Pharmacotherapy still needs to be coordinated by the primary care provider. **[A]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|---|-----------|------------------------|----------|
| 1 | Dose response relationship between extent of counseling contact and rate of abstinence | U.S. Department of Health and Human Services et al., 2000 | I | Good | A |
| 2 | Minimal tobacco use cessation counseling (<3 minutes) is effective | U.S. Department of Health and Human Services et al., 2000 Silagy & Stead, 2001 | I | Good | A |
| 3 | Proactive telephone counseling is effective. | U.S. Department of Health and Human | I | Good | A |

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|---|---|-----------|------------------------|----------|
| | | Services et al., 2000 Hopkins et al., "Reviews" 2001; Stead, Lancaster & Perera, 2001 | | | |
| 4 | Multiple formats (e.g., group, telephone, individual) are effective. | U.S. Department of Health and Human Services et al., 2000 | I | Good | A |
| 5 | Counseling by a variety of clinician types is effective. Counseling by nurses is effective. | U.S. Department of Health and Human Services et al., 2000; Rice & Stead, 2001 | I | Good | A |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

H. Initiate Pharmacotherapy to Assist Quit

Objective

Facilitate tobacco abstinence through pharmacotherapy to treat tobacco dependence.

Recommendations

1. Tobacco users attempting to quit should be prescribed one or more effective first-line pharmacotherapies for tobacco use cessation. **[A]**
 - First-line therapies include five nicotine replacement therapies (NRT) (transdermal patch, gum, nasal spray, lozenges, or vapor inhaler) and non-nicotine replacement (bupropion immediate release [IR] or sustained release [SR]). **[A]**
 - Pharmacotherapy should be combined with minimal counseling (less than 3 minutes). **[A]**
 - Patient should be strongly advised not to use tobacco while using NRT
 - Selection of an agent should be based on patient characteristics, relative contraindications, and patient preferences. **[Expert Consensus]**
 - Typical duration for NRT is 8 to 12 weeks, and for bupropion 7 to 12 weeks **[Expert Consensus]**
2. Tobacco users who do not respond to first-line therapies should:
 - Continue the same agent for a longer duration
 - Switch to a different first-line agent or
 - Consider combination of two agents.
3. Combination therapy may be effective for patients unable to quit with a single first-line agent. **[B]**

- Combining the nicotine patch with a self-administered form of NRT (gum or nasal spray) is more efficacious than a single form of NRT. **[B]**
 - There is some suggestive evidence for combining bupropion SR with NRT, but it is inconclusive. **[B]**
4. If patient has not responded after 2 courses of treatment, re-evaluate to assess the need of referral to intensive cessation program
 5. Pharmacotherapies NOT recommended for tobacco cessation: antidepressants other than bupropion SR and nortriptyline; anxiolytics/benzodiazepines/beta-blockers; silver acetate; and mecamylamine.
 6. Special consideration should be given to the potential risks versus benefits in the presence of special circumstances (e.g., adolescents, pregnant women, mental health comorbidity, and populations with special military duties). **[Expert Consensus]**
 7. Patient who responded to therapy and successfully quit the use of tobacco and then relapsed should be treated in same manner as the initial therapy. (See also Annotation K - Initiate/Reinforce Relapse Prevention)
 8. Insufficient evidence exists to recommend the use of extended pharmacotherapy for relapse prevention. **[I]**
 9. Consider referral for intensive behavioral modification counseling for tobacco users with multiple relapses. **[Expert Consensus]**

First Line-NRT

Treatment of nicotine dependence with NRT should adhere to the three guiding principles of substance use disorder pharmacotherapy:

- Dose to effect: The initial dose should be sufficient to provide the patient with a nicotine dose similar to that seen prior to cessation of tobacco. Providers should always assess the patient's nicotine dependence before prescribing cessation aids.
- Treat withdrawal symptoms: The nicotine replacement dose should be sufficient to prevent or minimize craving for tobacco products.
- Avoid adverse reactions: The nicotine replacement dose should be small enough that signs and symptoms of over medication (i.e., headache, nausea, and palpitations) do not occur.

Five types of NRT products are available in the U.S. for pharmacological treatment of tobacco dependence.

1. Transdermal delivery system (patches)
2. Polacrilex resin (gum)
3. Polacrilex resin (lozenge)
4. Nasal spray
5. Oral vapor inhaler

First Line Non-NRT

There are a number of *factors to be considered* when determining whether a person desiring help in tobacco cessation would be a candidate for bupropion SR, including:

1. Nicotine dependence
2. Motivation to quit
3. Inability or disinclination to use nicotine replacement
4. Contraindicated drugs or disease states [e.g., seizures, alcohol dependency]

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|---|-------------------|------------------------|----------|
| 1 | Pharmacotherapy (NRT, bupropion) are effective in increasing abstinence rates. | U.S. Department of Health and Human Services et al., 2000; Hughes, Stead, & Lancaster, 2002; Silagy et al., 2002 | I | Good | A |
| 2 | NRT (gum, patch, nasal spray, oral inhaler, lozenge) is an effective first-line medication for smoking cessation. | U.S. Department of Health and Human Services et al., 2000; Silagy et al., 2002 | I | Good | A |
| 3 | Bupropion SR is an effective first-line medication for smoking cessation. | U.S. Department of Health and Human Services et al., 2000; Hughes, Stead, & Lancaster, 2002 | I | Good | A |
| 4 | Pharmacotherapy is more effective when combined with counseling. | Silagy et al., 2002; Stead & Lancaster, 2002 | I | Poor | C |
| 5 | Combination of two forms of NRT (nicotine patch with self-administered form of NRT) is more efficacious than single form. | U.S. Department of Health and Human Services et al., 2000; Jorenby et al., 1999; Silagy et al., 2002 | II; I; I | Fair | B |
| 6 | Bupropion SR and nortriptyline are effective in treating tobacco dependence in patients with current/past history of depression. | U.S. Department of Health and Human Services et al., 2000; Hughes, Stead, & Lancaster, 2002; Hayford et al., 1999 | I | Good | A |
| 7 | Prescriptions for effective pharmacotherapies for smoking cessation should be considered in adolescents | Hurt et al., 2000; Smith et al., 1996; Sussman et al., 1999 | II; II; III | Fair; Fair; Poor | C |

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|---|---|-----------|------------------------|----------|
| | with higher degrees of dependence and willingness to quit. | | | | |
| 8 | Extended pharmacotherapy may reduce cravings but not prevent relapse. | Durcan et al., 2002; Hays et al., 2001; Shiffman et al., 2000 | I | Fair | C |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

I. Offer Self-Help Material

Recommendations

1. Consider offering a variety of effective self-help educational materials to motivate and aid in the quitting process (e.g., pamphlets/booklets/mailings/manuals, videotapes, audiotapes, Internet Web pages, and computer programs). **[Expert Consensus]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|---|----------------------------|-----------|------------------------|----------|
| 1 | Self-help materials are more effective than no interventions. | Lancaster & Stead, 2002 | I | Fair | B |
| 2 | Additional benefits of self-help when combined with other interventions | Lancaster & Stead, 2002 | I | Poor | C |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

J. Arrange Follow-Up

Objective

Develop a follow-up plan for patients interested in quitting tobacco use.

Recommendations

1. Tobacco users who receive a tobacco cessation intervention should be scheduled for ongoing follow-up for abstinence. **[B]**

Follow-up should be documented and should:

- Establish contact with the tobacco user 1 to 2 weeks after quitting date to assess abstinence **[B]**
- Assess effectiveness of pharmacotherapy and appropriate use **[Expert Consensus]**

- Assess for abstinence at the completion of the treatment and during subsequent clinical contact for the duration of at least 6 months **[Expert Consensus]**
 - Provide relapse prevention to tobacco users who remain abstinent (see Annotation K - Initiate/Reinforce Relapse Prevention)
2. Tobacco users who relapse should be assessed for willingness to make another quit attempt and offered repeated interventions (see Annotation D - Assess Willingness To Quit). **[B]**
 3. Tobacco users should be tracked to increase the systematic delivery of interventions for tobacco cessation and increase the likelihood of long-term abstinence. **[B]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|---|---|-----------|------------------------|----------|
| 1 | Follow-up contact 1 to 2 weeks after quit date increases the likelihood of long-term abstinence. | Kenford et al., 1994; Reid & Pipe, 1999 | I | Fair | B |
| 2 | Assessment for abstinence at the completion of treatment | U.S. Department of Health and Human Services et al., 2000 | III | Poor | I |
| 3 | Provider reminder systems increase the systematic delivery of minimal clinical interventions and may increase abstinence. | Hopkins et al., "Evidence," 2001 | I | Fair | B |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

Prevention Algorithm

K. Initiate/Reinforce Relapse Prevention

Objective

Prevent relapse to nicotine.

Recommendations

1. Relapse prevention should be addressed with every former tobacco user. **[Expert Consensus]**
2. Providers should address individual, environmental, and biopsychosocial factors associated with relapse (see Appendix A-5 in the original guideline document). **[Expert Consensus].**
3. Providers should address weight gain after quitting, as tobacco use cessation is often followed by weight gain. Consider bupropion SR or NRT, in particular, nicotine gum, which have been shown to delay weight gain after quitting.

4. Patients with multiple relapses or who are having trouble in a current quit attempt in a clinical setting should be directed to more intense counseling programs or medication should be adjusted. **[B]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|---|-----------|------------------------|----------|
| 1 | Assessment of patients who have relapsed to determine whether they are willing to make another quit attempt | Brandon et al., 1990; "Smoking cessation," 1993; Westman et al., 1997; Zhu et al., 1996 | III | Fair | C |
| 2 | Individuals who have been abstinent for less than 3 months at the time of the visit are at higher risk for relapse and are candidates for relapse prevention counseling. | Brownell et al., 1998 | III | Poor | I |
| 3 | Long-term pharmacotherapy, as indicated, for patient's expressing difficulty | U.S. Department of Health & Human Services (USDHHS), 2000 | III | Fair | B |
| 4 | More intense counseling programs for patients with multiple relapses or who having trouble in a current quit attempt in a clinical setting | USDHHS, 2000 | II | Fair | B |
| 5 | Treatment of weight gain in prevention of relapse | Dale et al., 2002; Leischow & Stitzer, 1991 | I | Fair | B |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

L. Promote Motivation to Quit

Objective

Motivate tobacco users who are presently unwilling to quit tobacco to do so in the future.

Motivational strategies include, but are not limited, to the following:

- Avoid confrontation.
- Remain neutral.
- Acknowledge the tobacco user's ambivalence about quitting.
- Elicit the tobacco user's view of the pros and cons of smoking and smoking cessation.
- Correct the tobacco user's misperceptions about health risks of smoking and the process of quitting smoking.

- Formulate an agenda; make it explicit.
- Avoid conflict of agendas (e.g., "I can't talk to anybody" = "I can't talk to you.").
- Negotiate.
- Summarize.

Recommendations

1. Tobacco users who are not willing to quit at this time should receive brief, non-judgmental motivational counseling designed to increase their motivation to quit, to include discussion about **[Expert Consensus]**:
 - **Relevance:** connection between tobacco use and current symptoms, disease and medical history
 - **Risks:** risks of continued tobacco use and tailor the message to individual risk/relevance of cardiovascular disease or exacerbation of preexisting disease
 - **Rewards:** potential benefits for quitting tobacco use to their medical, financial, and psychosocial well-being
 - **Roadblocks:** barriers to quitting and discuss options and strategies to address patient's barriers
 - **Repetition:** Reassess willingness to quit at subsequent visits; repeat intervention for unmotivated patients at every visit.
2. Use of motivational intervention should be considered. This technique has been shown to be beneficial in motivating and changing behaviors of individuals with other substance use dependencies, including some evidence in cessation of smoking. **[B]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|--|--------------------------------------|------------------------|----------|
| 1 | Use of brief motivational interventions. | Cigrang, Severson, & Peterson, 2002; Colby et al., 1998; Emmons et al., 2001; Ershoff et al., 1999; Hajek et al., 2001; McHugh et al., 2001; Smith et al., 2001; Stotts, DiClemente, & Dolan-Mullen, 2002; Tappin et al., 2000 | II-2; I; I; II-2; II; II; II; II; II | Fair | B |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

M. Congratulate and Encourage Continued Abstinence

Objective

Congratulate non-users for changing a difficult behavior and encourage continued abstinence.

Recommendations

1. All tobacco non-users should be congratulated for not using tobacco ("Good for you") and advised to avoid initiation of tobacco. ("The single best thing you can do for your health is to avoid all tobacco products.") **[B]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|----------------------------|-----------|------------------------|----------|
| 1 | Congratulate all non-tobacco users and advise all non-tobacco users to avoid initiation of tobacco products. | Fidler & Lambert, 2001 | II | Good | B |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

N. Assess Risk for Relapse

Objective

Assess the risk for relapse for patients who have recently quit.

Recommendations

1. Tobacco users who have been abstinent for less than three months should be assessed for relapse. **[B]**
2. Tobacco users attempting to quit should be screened for a history of depression or a presentation of depressive symptoms predating the quit attempt as these factors strongly predict relapse. **[B]**
3. Psychosocial and environmental risk factors for relapse should be assessed to include stress, depression, withdrawal symptoms, previous quit attempts, close presence of other tobacco users, history of substance use disorder, and/or other risky behaviors. **[C]**
4. Patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt. **[C]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|--|-----------|------------------------|----------|
| 1 | Assessment for relapse in patients abstinent for less than 3 months | Brandon et al., 1990; Hatziandreu et al., 1990; Westman et al., 1997; Zhu et al., 1996 | II | Fair | B |
| 2 | Assessment of history of depression or depressed mood predating quit attempt | Niaura et al., 2001 | II | Good | B |
| 3 | Assessment of psychosocial and | Brownell et al., 1998 | III | Poor | I |

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|---|-----------|------------------------|----------|
| | environmental risk factors for relapse | | | | |
| 4 | Assessment for willingness for another quit attempt in relapsed patients | Brandon et al., 1990; Westman et al., 1997; Zhu et al., 1996; U.S. Department of Health and Human Services et al., 2000 | III | Poor | C |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

O. Assess Risk for Starting Tobacco Use

Objective

To assess the potential for tobacco use in persons who have never used tobacco, based on existing risk factors.

Recommendation

1. Providers should ask non-users about their intention to smoke in the future, as this predicts the likelihood of initiation of tobacco use. **[B]**
2. Providers should be aware of the following risk factors for initiation of tobacco use in order to closely follow non-users with a proclivity toward initiation of tobacco use: **[C]**
 - Individual (e.g., low self-esteem, susceptibility to peer pressure, rebelliousness, depression, anxiety)
 - Family (e.g., family member who uses tobacco, especially parent, sibling, or spouse)
 - Educational level (e.g., less than 12 years of education, poor school performance, anticipated dropping out of school)
 - Societal/cultural/environmental (e.g., peers who use tobacco, exposure to tobacco advertising and products, white females with concerns of body image)
 - Military recruits (e.g., during special assignments with high stress or long periods of down time with access to tobacco)
3. Providers should be aware of the following protective factors that make tobacco use less likely: **[B]**
 - Individual (high self-esteem, assertiveness, social competence)
 - Family (positive parental support, close communication with parents)
 - Educational (school success, future goals)
 - Social/cultural/environmental (nonsmoking peer group, social competence, strong sense of right and wrong, religious observance)

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|--|----------------------|------------------------|----------|
| 1 | Intention to smoke in the future predicts tobacco use. | Adelman et al., 2001; Ary & Biglan, 1998 | I; II | Fair | B |
| 2 | Provider awareness of the risks for tobacco use initiation | American Academy of Pediatrics Committee on Substance Abuse, 1998; American Academy of Pediatrics, 2001; Lynch & Bonnie, 1994; Elders et al., 1994 | III; II-3; III | Poor; Fair; Poor | C |
| 3 | Provider recognition of protective factors against initiation of tobacco | Belcher & Shinitzky, 1998 | II-2 | Fair | B |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

P. Initiate Prevention (Primary Prevention)

Objective

Promote strategies that are most effective to prevent initiation of tobacco use among adolescents and young adults who have not started smoking (primary prevention).

Recommendations

1. Health care providers should be aware of, and support, community and school-based tobacco prevention programs, as they are effective in the short-term. **[B]**
2. Health care providers who treat children, adolescents, and young adults should reinforce community prevention messages and may consider brief prevention interventions delivered in a developmentally appropriate manner. **[C]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|--|--|--|----------|
| 1 | Community efforts are easy to implement, improve short-term outcomes, and have a broad effect. | Biglan et al., 2000; "Guidelines for school health programs," 1994; "Reducing tobacco use," 2000; Dent, 1998; U.S. Department of Health and Human Services et al., 2000; Schinke, Gilchrist, & Snow, 1985; Sowden, Arblaster, & Stead, 2003; | I; III; II-2; III; II; I; II-3 | Fair; Poor; Fair; Poor; Fair; Fair; Fair | B |

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|---|----------------|------------------------|----------|
| | | Sussman et al., 1999 | | | |
| 2 | Office-based reinforcement and primary prevention may be beneficial. | Fidler & Lambert, 2001; U.S. Department of Health and Human Services et al., 2000; Stevens et al., 2002; USDHHS, 1994 | I; III; I; III | Good; Poor; Fair; Fair | C |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

Q. Address Individual Conditions in Special Populations

Q-1. Children and Adolescents

Objective

Describe unique issues relevant to the health care provider who comes in contact with children and adolescents.

Recommendations

1. Pediatric and adolescent patients and their parents should be screened by health care providers for tobacco use and provided a strong message regarding the importance of total abstinence from tobacco use. **[Expert Consensus]**
2. Health care providers in a pediatric setting should advise parents to quit smoking to limit their children's exposure to second-hand smoke. **[A]**
3. Health care providers in a pediatric setting should offer smoking cessation advice and interventions to parents to improve the parent's chance of quitting use of tobacco. **[C]**
4. Adolescents who use tobacco and are interested in quitting should be offered counseling and behavioral interventions that were developed for adolescents. **[A]**
5. Counseling and behavioral interventions shown to be effective with adults may be considered for use with adolescents. **[Expert Consensus]**
6. When treating adolescents, providers may consider prescriptions for bupropion SR or NRT when there is evidence of nicotine dependence and desire to quit tobacco use. **[Expert Consensus]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|---|-----------|------------------------|----------|
| 1 | Smoking cessation for parents to limit exposure of children to tobacco smoke | Emmons et al., 2001; Greenberg et al., 1994; Hovell et al., 2002, 1994, 2000; Severson et | I | Good | A |

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|---|--|--------------------|------------------------|----------|
| | | al., 1997 | | | |
| 2 | Smoking cessation for parents to improve quit | Severson et al., 1997; Wall et al., 1995; Winickoff et al., 2003 | II | Good | C |
| 3 | Adolescent specific group intervention | Adelman et al., 2001; Sussman, 2001; Sussman et al., 1999 | I; II-1; III | Good | A |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

Q-2. Pregnant Women

Objective

Encourage all health care team members to advise pregnant tobacco users to quit and provide tobacco cessation treatment.

Recommendations

1. Refer to the [VA/DoD Clinical Practice Guidelines for the Management of Uncomplicated Pregnancy](#).

Q-3. Military Recruits and Trainees

Objective

Prevent relapse of basic trainees who quit using tobacco as a result of their participation in basic military training.

Recommendations

1. Relapse prevention should be addressed with every former tobacco user (see Annotation K - Initiate/Reinforce Relapse Prevention). **[Expert Consensus]**

Q-4. Hospitalized Patients

Objective

Encourage all health care team members to advise hospitalized tobacco users to quit and provide tobacco cessation treatment.

Recommendations

1. All patients admitted to hospitals should have tobacco use status identified in the medical record. **[A]**

2. Tobacco users who are hospitalized should be given advice to quit. **[B]**
3. Tobacco users who are hospitalized should be given tobacco cessation treatment including medication and counseling. **[B]**
4. Whenever possible, augmented smoking cessation treatment should be provided to tobacco users who are hospitalized. **[Expert Consensus]**
5. Tobacco users should be referred for continuing treatment and support upon discharge. **[Expert Consensus]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|---|---|-----------|------------------------|----------|
| 1 | Augmented interventions among hospitalized tobacco users are effective. | U.S. Department of Health and Human Services et al., 2000 | I | Fair | B |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

Q-5. Older Patients

Objectives

Encourage all health care team members to advise older tobacco users to quit and provide tobacco cessation treatment.

Recommendations

1. Tobacco users who are older should be given advice to quit. **[A]**
2. Tobacco users who are older should be given tobacco cessation treatment, including medication and counseling. **[A]**
3. There are insufficient data to support or refute variations on smoking cessation interventions among the elderly. Assessment and treatment of tobacco users who are older should follow the recommendations included in the guideline. **[I]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|---|-----------|------------------------|----------|
| 1 | Assessment and treatment of older tobacco users are effective. | Burton et al., 1995; Cohen & Fowlie, 1992; Hermanson et al., 1988; Morgan et al., 1996; Rogers et al., 1985 | I | Good | A |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

Q-6. Psychiatric/Mental Health Patient

Objective

Provide effective tobacco cessation services to patients with psychiatric comorbidities

Recommendations

1. Tobacco users with comorbid psychiatric and substance abuse conditions should be provided tobacco cessation treatment. **[B]**
2. Tobacco users receiving treatment for chemical dependency should be provided tobacco cessation treatments to include counseling and pharmacotherapy. **[C]**
3. Tobacco users with other comorbidities may have a low rate of successful treatment. The optimal treatment for tobacco users with current/past depression is uncertain, but they may require longer and more intensive treatment. **[B]**

| | Evidence | Sources of Evidence | QE | Overall Quality | R |
|---|--|---|-----------|------------------------|----------|
| 1 | Smoking cessation in psychiatric patients is recommended. | Brown et al., 2001; Dalack & Meador-Woodruff, 1999; Evins et al., 2001; George et al., 2002, 2000; Hayford et al., 1999; Hertzberg et al., 2001; Hughes, Stead, & Lancaster, 2002; Thorsteinsson et al., 2001 | I | Fair | B |
| 2 | Bupropion SR and nortriptyline are effective in treating tobacco dependence in patients with current/past history of depression. | U.S. Department of Health and Human Services et al., 2000; Hughes, Stead, & Lancaster, 2002; Hayford et al., 1999 | I | Good | A |
| 3 | Smoking cessation for substance abuse patients is recommended. | Bobo et al., 1998; Burling, Burling, & Latini, 2001; Ellingstad et al., 1999; Hurt et al., 1993; Patten et al., 2002, 2000, 2001; Shoptaw et al., 2002 | I | Fair | C |

QE = Quality of Evidence; R = Recommendation (see Appendix B)

Definitions:

Quality of Evidence (QE)

I: Evidence obtained from at least one properly randomized controlled trial

II-1: Evidence obtained from well-designed controlled trials without randomization

II-2: Evidence obtained from well-designed cohort or case-control analytic studies

II-3: Evidence obtained from multiple time series, dramatic results in uncontrolled experiments

III: Opinions of respected authorities; case reports, and reports of expert committees

Overall Quality

Good: High grade evidence (I or II-1) directly linked to health outcome

Fair: High grade evidence (I or II-1) linked to intermediate outcome or moderate grade evidence (II-2 or II-3) directly linked to health outcome

Poor: Level III evidence or no linkage of evidence to health outcome

Net Effect of Intervention

Substantial:

- More than a small relative impact on a frequent condition with a substantial burden of suffering, or
- A large impact on an infrequent condition with a significant impact on the individual patient level

Moderate:

- A small relative impact on a frequent condition with a substantial burden of suffering, or
- A moderate impact on an infrequent condition with a significant impact on the individual patient level

Small:

- A negligible relative impact on a frequent condition with a substantial burden of suffering, or
- A small impact on an infrequent condition with a significant impact on the individual patient level

Zero or Negative:

- Negative impact on patients, or
- No relative impact on either a frequent condition with a substantial burden of suffering, or
- An infrequent condition with a significant impact on the individual patient level

Grade of Recommendation

- A:** A strong recommendation that the intervention is always indicated and acceptable
B: A recommendation that the intervention may be useful/effective
C: A recommendation that the intervention be considered
D: A recommendation that a procedure may be considered not useful/effective, or may be harmful
I: Insufficient evidence to recommend for or against; the clinician will use clinical judgment

Abbreviations

- AAP** - American Academy of Pediatrics
CDC - Centers for Disease Control and Prevention
DHHS - Department of Health and Human Services
DoD - Department of Defense
NRT - Nicotine replacement therapy
QE - Quality of evidence
SR - Strength of recommendation
U.S. PSTF - U.S. Preventive Service Task Force
VA - Veterans Affairs
VAMC - Veterans Affairs Medical Center

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for the management of tobacco use:

- [Algorithm A: Assessment and Treatment](#)
- [Algorithm B: Prevention](#)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Early detection of tobacco use
- Decreased rates of tobacco use
- Increased rates of smoking cessation

- Prevention of tobacco use in students who have not started using tobacco
- Decreased rates of relapse in persons who have quit tobacco use.
- Flexibility to accommodate local policies or procedures, including those regarding staffing patterns and referral to or consultation with other health care providers.
- Appropriate management of tobacco use in target population
- Improved patient education regarding abstinence from tobacco

Subgroups Most Likely to Benefit

There are special target populations of smokers who need to be identified and referred for intervention because of the high likelihood of adverse outcomes that accompany continued tobacco use. These include:

- Pregnancy - Due to increased risk to the mother and potential fetal prematurity, all pregnant patients should be encouraged to stop smoking as early in pregnancy as possible.
- Chronic tobacco related disease - Smokers who have developed a progressive, chronic tobacco related disease (emphysema, coronary artery disease, peripheral vascular disease) that will continue to deteriorate should be urged to make an attempt to quit tobacco during routine primary care for those disorders.
- Complications of surgical anesthesia - Smoking cessation should be addressed with all pre-operative patients. If tobacco users will quit smoking 4 to 6 weeks prior to anesthesia, complications and postoperative recovery (infections, wound healing, cardiac procedures) can be reduced.

POTENTIAL HARMS

Adverse Effects of Medication

- **Nicotine Transdermal (patch):** sleep disturbance, local irritation, bone pain, headache, nausea.
- **Nicotine Polacrilex Resin (gum):** local mouth irritation, jaw pain, rhinitis, nausea.
- **Nicotine Polacrilex Resin (lozenge):** local mouth irritation, headache, nausea, diarrhea, flatulence, hiccup, heartburn, cough.
- **Nicotine Nasal Spray:** headache, nausea, confusion, palpitations, nasal irritation.
- **Nicotine Oral Vapor Inhaler:** local irritation, cough, rhinitis, headache, dyspepsia.
- **Bupropion Sustained Release (SR) and Bupropion Immediate Release (IR):** anxiety, disturbed concentration, dizziness, insomnia, constipation, dry mouth, nausea.
- **Clonidine and nortriptyline** are associated with more severe adverse effects (significant drug-drug interactions) than either nicotine replacement therapy (NRT) or bupropion SR. Withdrawal effects from abrupt discontinuation can also be serious. These agents should be used only under the supervision of a physician.

Subgroups Most Likely to Be Harmed

- Use of NRT must be carefully assessed and monitored in persons with hyperthyroidism, peptic ulcer disease, insulin-dependent diabetes mellitus, temporomandibular joint (TMJ) syndrome (nicotine gum), severe renal impairment, and certain peripheral vascular diseases.
- Nicotine from any NRT product may be harmful to children and pets if taken orally.

CONTRAINDICATIONS

CONTRAINDICATIONS

- **Nicotine Replacement Therapy (NRT):** Relative contraindications include hypersensitivity, pregnancy (Category D), and coronary artery disease (within 14 days post myocardial infarction)
- **Bupropion Sustained Release (SR) and Bupropion Immediate Release (IR):** Contraindications include history of seizures; predisposition to seizures; severe head trauma; recent stroke; abrupt withdrawal from heavy, daily alcohol or other sedative; monoamine oxidase (MAO) inhibitors within 14 days; bulimia or anorexia nervosa. Relative contraindications include hypersensitivity and pregnancy (Category B).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Clinical practice guidelines, which are increasingly being used in health care, are seen by many as a potential solution to inefficiency and inappropriate variations in care. Guidelines should be evidenced-based as well as based upon explicit criteria to ensure consensus regarding their internal validity. However, it must be remembered that the use of guidelines must always be in the context of a health care provider's clinical judgment in the care of a particular patient. For that reason, the guidelines may be viewed as an educational tool analogous to textbooks and journals, but in a more user-friendly tone.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Explicit indicators to measure implementation system wide are a part of the Veterans Health Administration's performance measurement system and are described in the Technical Manual available from the [Department of Veterans Affairs \(VA\) Web site](#).

IMPLEMENTATION TOOLS

Clinical Algorithm
Quality Measures
Quick Reference Guides/Physician Guides
Resources

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- [Smoking cessation: percent of patients using tobacco who have been offered a referral to smoking cessation specialty program to assist with cessation within the past year.](#)

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Veterans Administration, Department of Defense. VA/DoD clinical practice guideline for the management of tobacco use. Washington (DC): Department of Veteran Affairs; 2004 Jun. 81 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 May (revised 2004 Jun)

GUIDELINE DEVELOPER(S)

Department of Defense - Federal Government Agency [U.S.]
Department of Veterans Affairs - Federal Government Agency [U.S.]
Veterans Health Administration - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

The Management of Tobacco Use Working Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Tobacco use cessation in the primary care setting. Department of Veterans Affairs (U.S.); 1999 May. Various p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [Department of Veterans Affairs \(VA\) Web site](#).

Print copies: Available from the Department of Veterans Affairs, Veterans Health Administration (VHA), Office of Quality and Performance (10Q), 810 Vermont Ave. NW, Washington, DC 20420.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- VA/DoD clinical practice guideline for the management of tobacco use. Guideline summary. Washington (DC): Department of Veterans Affairs (U.S.); 2004 Jul. 15 p.
- VA/DoD clinical practice guideline for the management of tobacco use. Pocket guide. Washington (DC): Department of Veterans Affairs (U.S.); 2004. 2 p.
- VA/DoD clinical practice guideline for the management of tobacco use. Key points. Washington (DC): Department of Veterans Affairs (U.S.); 2004. 2 p.

Electronic copies: Available from the [Department of Veterans Affairs Web site](#).

Print copies: Available from the Department of Veterans Affairs, Veterans Health Administration (VHA), Office of Quality and Performance (10Q), 810 Vermont Ave. NW, Washington, DC 20420.

The following is also available:

- Putting clinical practice guidelines to work [online tutorial]. Available from the [Department of Veterans Affairs Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 1, 2001. The information was verified by the guideline developer as of November 1, 2001. This NGC summary was updated by ECRI on December 29, 2004. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs.

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