

VHA/DOD CLINICAL PRACTICE GUIDELINE TO PROMOTE

**TOBACCO USE CESSATION**  
IN THE PRIMARY CARE SETTING

Veterans Health Administration

Department of Defense

*Prepared by:*

The Tobacco Use Cessation Workgroup

*with support from:*

The Office of Performance and Quality, VHA Headquarters, Washington,  
DC  
&  
Quality Management Directorate, United States Army MEDCOM  
&  
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INTRODUCTION

## PROMOTE TOBACCO USE CESSATION IN THE PRIMARY CARE SETTING

### Introduction

This clinical practice guideline (CPG) on the management of tobacco use cessation in the primary care setting is intended to promote evidence-based management of tobacco use and thereby improve their clinical outcomes. It can assist primary care providers or specialists in the prevention, early detection of use, assessment of the clinical situation, determination of appropriate treatment, and delivery of individualized interventions. Although it was developed for a broad range of clinical settings, it should be applied with enough flexibility to accommodate local practice and individual situations.

This clinical practice guideline (CPG) has been developed by members of the Veterans Health Administration (VHA) and the Department of Defense (DoD) pursuant to directives from the Undersecretary for Health, VHA and the Assistant Secretary of Defense, Health Affairs and by consultants from the Contractor (West Virginia Institute, Inc.) and Subcontractor (Birch & Davis Associates, Inc.) to increase the quality of medical care bestowed upon its beneficiaries by reducing undesirable variation in medical outcomes and, for the DoD in particular, help to improve the combat readiness of its forces.

The VHA and the DOD define clinical practice guidelines as:

"Recommendations for the performance or exclusion of specific procedures or services derived through a rigorous methodological approach that includes the following:

1. Determination of appropriate criteria, such as effectiveness, efficacy, population benefit, or patient satisfaction; and
2. Literature review to determine the strength of the evidence (based in part on study design) in relation to these criteria."

Based on these principles, this guideline has been developed to help assess and treat tobacco use cessation in the primary care setting. Although the guideline addresses critical decision points in managing tobacco use cessation, it is also flexible enough to accommodate local policies or procedures, including those regarding staffing patterns and referral to or consultation with other health care providers. In particular, this guideline can assist primary medical care providers and specialists in the early detection of symptoms, assessment of treatment readiness, determination of the appropriate setting and intensity of treatment, and delivery of individualized interventions. (VHA Directive 96-053; VA HSR&D MDRC, 1998)

This CPG for Tobacco Use Cessation in the Primary Care Setting is displayed in algorithmic format. An algorithm is a set of rules for solving a problem in a finite number of steps. These clinical algorithms diagram the guideline in a step-by-step decision tree presenting a linear approach to the recognition and management of tobacco use cessation; however, clinical practice often requires nonlinear and concurrent processes, e.g., a tobacco user may present initially complaining of a sore throat, back pain, yearly physical or for an acute chest pain requiring immediate attention. Similarly, given the high rates of co-occurring psychiatric and other medical conditions among enrollees served by VHA/DoD, treatment for other conditions may need to precede the tobacco use cessation screening and treatment. (Kazis 1998; Walker RD et al. 1994)

This Guideline consists of one module addressing distinct aspects of the intervention:

1. Triage
2. Assessment
3. Behavioral treatment options
4. Pharmacotherapy
5. Further evaluation and treatment. (Sackett et al. 1996)

The annotations elaborate, in an organized and systematic way, the recommendations expressed in each box of the algorithm. These annotations include bibliography, when required, and referenced evidence grading for each of these recommendations—the level of evidence (LE) and strength of recommendation (SR). The bibliography includes all the sources used directly or indirectly in the substantiation of this Guideline.

A letter in brackets within the box of an algorithm refers the reader to the corresponding annotation. The best current literature support for each algorithm is referenced throughout the annotations. The references listed have undergone a thorough review and rating by the expert panel based on the scientific rigor of the article, clinical relevance of the material presented, and applicability of the data. Where existing literature is ambiguous or conflicting, and where scientific data are lacking on an issue, recommendations are based on the expert panel’s consensual opinion based on clinical experience. The strength of the recommendation and level of evidence are provided at the end of the annotation and include indications of whether each recommendation is based on methodologically rigorous scientific data or expert opinion. In addition, some statements that do not involve recommendations are referenced to provide the user with relevant background information about tobacco use cessation.

The Medical Subject Headings (MeSH) 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.

The literature search was followed by critical analysis of the literature, primarily by the clinical experts. To promote the evidence-based approach, the quality of evidence was rated using a hierarchical rating scheme. The value of a hierarchical rating scheme is that it provides a systematic means for evaluating the scientific basis for health care services. (Sackett et al. 1996) The rating scheme used for this guideline is based on a system used by the Agency for Health Care Policy and Research. Decision points in the algorithm are annotated, and the primary source documents for the annotation are graded.

Strength of recommendation grading and level of evidence grading are based on Agency for Health Care Policy Research (AHCPR) guideline development efforts and the American College of Cardiology/American Heart Association (ACC/AHA) Task Force Report. (Modified by Birch & Davis Associates, Inc., and the Expert Panel from: AHCPR Clinical Practice Guideline No. 18. Smoking Cessation. April 1996;18:13) For a description of each, refer to the following tables:

**STRENGTH OF RECOMMENDATION GRADING**

<i>Grade</i>	<i>Strength of Recommendation</i>
I	Usually indicated, always acceptable, and considered useful and effective.
IIa	Acceptable, of uncertain efficacy, and may be controversial. Weight of evidence is in favor of usefulness/efficacy.
IIb	Acceptable, of uncertain efficacy and may be controversial. May be helpful, not likely to be harmful.
III	Not acceptable, of uncertain efficacy and may be harmful. Does not appear in the guidelines.

**LEVEL OF EVIDENCE GRADING**

<b>Type of Evidence</b>	<b>Level of Evidence Grading = A</b>	<b>Level of Evidence Grading = B</b>	<b>Level of Evidence Grading = C</b>
<i>Primary evidence</i>	Randomized controlled trials	Well-designed clinical and epidemiological studies	Panel consensus

This Guideline is the product of many months of consensus building among knowledgeable individuals. Many of the experts involved in developing this Guideline have previously participated in the development of the VHA Clinical Practice Guidelines for Diabetes Mellitus, Chronic Obstructive Pulmonary Disease, Treatment of Persons with Major Depressive Disorder and Treatment of Persons with Psychoses. Additionally VHA and DoD have jointly worked on Hypertension, Low Back Pain, Chronic Obstructive Pulmonary Disease update, and many more. The Panel included contributions from internists, family practitioners, primary care physicians, nurses, pharmacologists, social workers, program specialists in geriatrics, external peer review physicians, and expert consultants in the field of guideline and algorithm development.

The ultimate goal of this guideline is to assist practitioners in the use of evidence-based medicine for management of persons who use tobacco products. The ultimate goal is for the person “to quit” smoking, thereby, improving clinical outcomes. Evidence based practice involves integrating clinical expertise with the best available clinical evidence derived from systematic research. The reader is reminded that this document is intended as a guideline and accordingly, should not supersede the clinical judgment of the health care provider.

This initial version of the CPG to Promote Tobacco Use Cessation in the Primary Care Setting, will be updated as further research results become available and end-user feedback is obtained from field trials in both VHA and DoD health care systems.

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PARTICIPANTS

## PROMOTE TOBACCO USE CESSATION IN THE PRIMARY CARE SETTING

### Working Group

- Peter Almenoff, MD  
National Program Director  
Pulmonary/Critical Care (111)  
VA Headquarters  
4801 Linwood Blvd.  
Kansas City, MO 64128  
816-861-4700, ext. 6716  
816-922-3323 (fax)  
[peter.almenoff@med.va.gov](mailto:peter.almenoff@med.va.gov)
- Karen Berkeley, Capt, USAF, MSC  
Inpatient Pharmacist  
1050 W. Perimeter Rd.  
Andrews AFB, MD 20762  
301-981-8336  
301-981-6671 (fax)  
[berkek@mgmc.af.mil](mailto:berkek@mgmc.af.mil)
- Nancy Chapman, LTC, MS, USA  
Psychologist  
Chief Behavioral Health Service  
USA Center for Health Promotion and  
Preventive Medicine  
MCHB-TS-HBH  
5158 Blackhawk Road, Bldg. E1570  
Aberdeen Proving Ground, MD 21010  
[ltcnancychapman@chppm-ccmail.apgea.army.mil](mailto:ltcnancychapman@chppm-ccmail.apgea.army.mil)
- Linda Ferry, MD, MPH  
Chief, Preventive Medicine Section  
J. L. Pettis VAMC (605/12PM)  
11201 Benton Street  
Loma Linda, CA 92357  
909-777-3290  
909-777-3281 (fax)  
[ferryL2@LL.VISN22.med.va.gov](mailto:ferryL2@LL.VISN22.med.va.gov)
- Michael Geboy, PhD  
VA Learning University  
500 N. Highway 89  
Prescott, AZ 86313  
520-776-6124  
520-776-6137 (fax)  
[geboymiclrn.va.gov](mailto:geboymiclrn.va.gov)
- Dallas C. Hack, LTC, MC, USA  
Preventive Medicine  
Deputy Commander for Clinical Services,  
Fort Knox, KY Transitioning to:  
Commander, USA Health Clinic Supreme  
Headquarters Allied Powers Europe
- Mylene Huynh, Major, USAF, MC  
Family Practice Physician  
89<sup>th</sup> M.D.OS/SOEF  
1075 W. Perimeter Road  
Andrews AFB, MD 20762  
301-981-3956  
301-981-3011 (fax)  
[mylene@erols.com](mailto:mylene@erols.com)
- W. Robert Kiser, CAPT, MC, USN  
Navy Specialty Leader for Family Practice  
Naval Hospital  
2080 Child Street  
Jacksonville, FL 32214  
904-777-7972  
904-542-9186 (fax)  
[wrkiser@med.navy.mil](mailto:wrkiser@med.navy.mil)
- Dennis Klatt, CAPT, NC, USA  
Community Health Nurse  
Preventive Medicine Division  
USA MMEDDAC  
310 Freedom Drive  
Fort Leonard Wood, MO 65473  
573-596-0518  
573-596-0535 (fax)  
[dklatt@midmonet.net](mailto:dklatt@midmonet.net)  
[dennis\\_klatt@leonardwood.smtplink.amedd.army.mil](mailto:dennis_klatt@leonardwood.smtplink.amedd.army.mil)
- Deborah McKay, CDR, NC, USN  
Deputy Director, Health Promotion, NEHC  
2510 Walmer Avenue  
Norfolk, VA 23513  
757-462-5588  
[mckayd@nehc.med.navy.mil](mailto:mckayd@nehc.med.navy.mil)

John Mitchell, Lt Col, USAF, MC  
Chief Consultant to AF/SG  
60 MDOS/SGOMP  
101 Bodin Circle, Suite 1C508  
Travis AFB, CA 94535  
707-423-5008  
707-423-7496 (fax)  
john.mitchell@60mdg.travis.af.mil

Eugene Moore, MD, MS, MPH,  
COL, MC, USA (Retired)  
Internal Medicine  
DoD PharmacoEconomic Center  
1750 Greeley Road  
Bldg. 4011, Room 217  
Ft. Sam Houston, TX 78234  
210-295-9645  
eugene\_moore@smtplink.medcom.amedd.  
army.mil

Oliver Parr  
Health Systems Specialist  
Department of Veterans Affairs  
810 Vermont Avenue, NW (134)  
Washington, DC 20420  
202-273-8454  
202-273-9078 (fax)

Richard Suchinsky, MD  
Department of Veterans Affairs  
810 Vermont Avenue, NW  
Washington, DC 20420  
202-273-8437  
202-273-4309 (fax)  
richard.suchinsky@hq.med.va.gov

Robert Sullivan, MD  
Formally the Director, National VA Center for  
Health Promotion  
Durham VA Medical Center (NCHP)  
508 Fulton Street  
Durham, NC 27705  
919-416-5880, ext. 222  
919-416-5879 (fax)  
robert.sullivan@duke.edu

Oded Susskind, MPH  
P.O.Box 112  
Brookline, MA 02146  
617-232-3558  
617-713-4431 (fax)  
[oded@tiac.net](mailto:oded@tiac.net)

Nancy A. Swanson, CDR, NC, USN  
Dept. Head, Branch Medical Clinic Arlington  
FOB#2, Room 1319  
Washington, DC 20370  
757-498-4750  
nancy\_aswanson@bethva.med.navy.mil

Gerald W. Talcott, PhD, ABPP  
Chief, Substance Abuse Prevention  
AFMOE/SGOP  
110 Luke Avenue  
Bolling AFB, DC 20332  
202-767-4285  
wayne.talcott@usafsg.bolling.af.mil

Eric C. Westman, MD, MHS  
Director, Smoking Research Lab. (11C)  
VA Medical Center  
508 Fulton Street  
Durham, NC 27705  
919-286-6822  
919-286-6758 (fax)  
ewestman@duke.edu

Aaron Werbel, LT, MSC, USN  
Clinical Psychologist  
National Naval Medical Center  
8901 Wisconsin Avenue  
Bethesda, MD 20814  
301-295-1480  
adwerbel@bth12.navy.mil

## PROMOTE TOBACCO CESSATION IN THE PRIMARY CARE SETTING

### Other Participants

Jose Aguera-Arcas, MD  
Senior Medical Consultant  
Birch & Davis Associates, Inc.  
104 South Rolling Road  
Catonsville, MD 21228  
410-747-3144  
410-719-9152 (fax)  
[aguera@home.com](mailto:aguera@home.com)

Sid Atkinson, COL, MC, USA  
Chief, Quality Management Division  
Commander MCHO-CL-Q  
2050 Worth Rd. Suite 10  
Ft. Sam Houston, TX 78234  
210-221-6195  
210-221-6160 (fax)  
[col\\_sid\\_atkinson@smtplink.medcom.amedd.army.mil](mailto:col_sid_atkinson@smtplink.medcom.amedd.army.mil)

Margaret Baumann, MD  
Associate Chief of Staff  
Geriatrics & Extended Care  
Hines VA Hospital  
5<sup>th</sup> & Roosevelt  
Hines, IL 60141  
708-216-2592  
708-216-2163 (fax)  
[margaret.baumann@med.va.gov](mailto:margaret.baumann@med.va.gov)

Marsha Beaugrand, CDR, MSC, USN  
Health Care Operations (MED-32)  
Clinical Plans  
Bureau of Medicine & Surgery  
2300 E Street NW  
Washington, DC 20372  
202-762-3110  
202-762-3133 (fax)  
[mjbeaugrand@us.med.nave.mil](mailto:mjbeaugrand@us.med.nave.mil)

Gerard Cox, CDR, MC, USN  
Health Care Operations (MED-32)  
Director, Clinical Management & Plans  
Bureau of Medicine & Surgery  
2300 E Street, NW  
Washington, DC 20372  
202-76703138  
202-762-2133 (fax)  
[ercox@us.med.navy.mil](mailto:ercox@us.med.navy.mil)

Shan Cretin PhD  
RAND  
1700 Main Street  
Santa Monica, CA 90407  
310-393-0411, ext. 7322

Kathryn J. Dolter RN, PhD, LTC, NC, USA  
Chief, Outcomes Management, Quality Mgt  
US Army Medical Command  
2050 Worth Road, Suite 10  
Ft. Sam Houston, TX 78234  
210-221-6195  
210-221-7118 (fax)  
[ltc\\_kathryn\\_dolter@smtplink.medcom.amedd.army.mil](mailto:ltc_kathryn_dolter@smtplink.medcom.amedd.army.mil)

Donna O. Farley, PhD  
Health Policy Analyst  
1700 Main Street  
Santa Monica, CA 90407  
310-393-0411  
310-451-6957 (fax)  
[donna\\_farley@rand.org](mailto:donna_farley@rand.org)

Rosalie Fishman, RN, MSN  
Clinical Coordinator  
Birch & Davis Associates, Inc.  
890 Fairview Road  
Silver Spring, MD 20910  
301-650-0218  
301-650-0398 (fax)  
[rfishman@Birchdavis.Com](mailto:rfishman@Birchdavis.Com)

Ronald Gebhart, MD  
Chief Consultant, Primary Care  
Department of Veterans Affairs  
810 Vermont Avenue, NW (112)  
Washington, DC 20420  
202-273-8558  
202-273-9148 (fax)  
[gebhart.ron@mail.va.gov](mailto:gebhart.ron@mail.va.gov)

Sarah Ingersoll, RN  
Network Coordinator  
Birch & Davis Associates, Inc.  
1263 S. El Molino Avenue  
Pasadena, CA 91106  
626-796-4745  
626-564-0245 (fax)  
[singerso@hsu.usc.edu](mailto:singerso@hsu.usc.edu)

Gerald Jendrusch  
Health Care Specialist-Analyst  
US Army Medical Command  
2050 Worth Road, Suite 10  
Ft. Sam Houston, TX 78234  
210-221-6195  
210-221-7118 (fax)  
[gerald-jendrusch@smtplink.amedd.army.mil](mailto:gerald-jendrusch@smtplink.amedd.army.mil)

Barbara Jones, RRA  
Program Development Coordinator  
Birch & Davis Associates, Inc.  
8905 Fairview Road  
Silver Spring, MD 20910  
301-650-0269  
301-650-0398 (fax)  
[bjones@birchdavis.com](mailto:bjones@birchdavis.com)

Wendell Jones, MD  
Ambulatory Care  
VAMC  
7400 Merton-Minton Blvd  
San Antonio, TX 78284  
210.949.3297 (Fax)

Arthur Kaufman, MD  
Medical Director  
Birch & Davis Associates, Inc.  
8905 Fairview Road  
Silver Spring, MD 20910  
301-650-0268  
301-650-0398 (fax)  
[akaufman@birchdavis.com](mailto:akaufman@birchdavis.com)

Genny Krackau  
Health System Specialist  
US Army Medical Command  
2050 Worth Road, Suite 10  
Ft. Sam Houston, TX 78234  
210-221-6195  
210-221-7118 (fax)  
[genny\\_krackau@smtplink.medcom.amedd.army.mil](mailto:genny_krackau@smtplink.medcom.amedd.army.mil)

Charles Miller, COL, MC, USA  
USAMEDCOM, MCHO-CL-C  
2050 Worth Rd, Suite 10  
Ft. Sam Houston, TX 78234  
210-221-6616  
210-221-6896 (fax)  
[col\\_charles\\_miller@smtplink.medcom.amedd.army.mil](mailto:col_charles_miller@smtplink.medcom.amedd.army.mil)

Louise H. Nelson, RN  
Education and CQI Coordinator  
West Virginia Medical Institute, Inc.  
3001 Chesterfield Place  
Charleston, WV 25304  
304-346-9864  
304-342-3352 (fax)  
[lnelson@wvmi.org](mailto:lnelson@wvmi.org)

George Pickett, MD, MPH  
Clinical Project Director  
West Virginia Medical Institute, Inc.  
3001 Chesterfield Pl.  
Charleston, WV 25304  
304-346-4590, ext. 270  
304-346-9863 (fax)  
[gpickett@charleston.wvmi.org](mailto:gpickett@charleston.wvmi.org)

Arnyce Pock, Lt Col, USAF, MC  
AF/SG Consultant for Internal Medicine  
Office of the Air Force Surgeon General  
110 Luke Avenue, Rm. 405  
Bolling AFB, DC 20332  
202-767-4073  
202-404-4043 (fax)  
[arnyce.pock@usafsg.bolling.af.mil](mailto:arnyce.pock@usafsg.bolling.af.mil)

Donna Schoonover, RN, MSN  
Program Manager  
Dept. of Veterans Affairs Ed. System  
1 Jefferson Barracks Drive (14B/JB)  
St. Louis, MO 63125  
314-894-5735  
314-894-6506 (fax)  
[schoonoverdon@lrn.va.gov](mailto:schoonoverdon@lrn.va.gov)

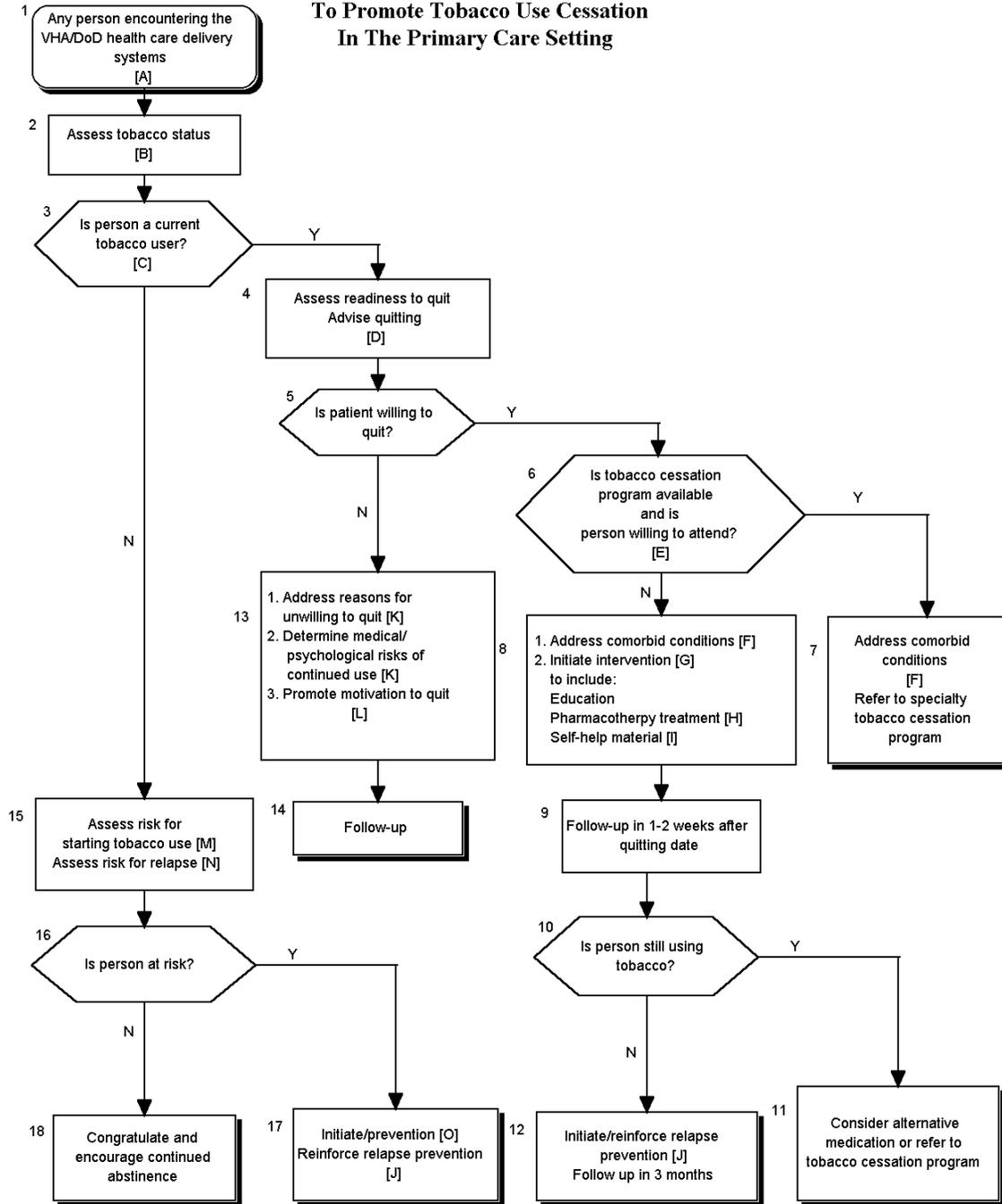
Janet Spinks, RN, MS  
Senior Consultant  
Birch & Davis Associates, Inc.  
8905 Fairview Road  
Silver Spring, MD 20910  
301-650-0285  
301-650-0398 (fax)  
[jspinks@birchdavis.com](mailto:jspinks@birchdavis.com)

Debby Walder, RN, MSN  
Performance Mgmt. Facilitator  
Department of Veterans Affairs  
810 Vermont Avenue, NW  
Washington, DC 20420  
202-273-8336  
202-273-9030 (fax)  
[debby.walder@mail.va.gov](mailto:debby.walder@mail.va.gov)

CLINICAL PRACTICE GUIDELINE TO PROMOTE  
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ALGORITHM AND SUMMARY ANNOTATIONS

### VHA/DoD Clinical Practice Guidelines To Promote Tobacco Use Cessation In The Primary Care Setting



## PROMOTE TOBACCO USE CESSATION IN THE PRIMARY CARE SETTING

### Summary Annotations

#### A. Any Person Encountering the VHA/DoD Health Care Delivery Systems

##### DEFINITION

Any person 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. Assess Tobacco Status

##### OBJECTIVE

To determine the person's current use of tobacco.

##### ANNOTATION

All persons should be asked about their use of tobacco upon visiting any provider. This is easily accomplished when the person's vital signs are taken. The tobacco use status should be noted in the person's record. Repeated assessment is not necessary in the case of the adult who has never used tobacco or has not used tobacco for many years and for whom this information is clearly documented in the medical record. The clinician can proceed further based on clinical relevance and appropriateness.

#### C. Is Person a Current Tobacco User?

##### OBJECTIVE

To identify persons who are "tobacco users" as specified in this guideline.

##### ANNOTATION

A "tobacco user" is a person who answers "yes" when asked whether he or she uses tobacco products.

#### D. Assess Readiness to Quit. Advise Quitting

##### OBJECTIVE

To ascertain the person's willingness to quit using tobacco.

##### ANNOTATION

The medical record of tobacco users who regularly visit a clinic should document at least three assessments for willingness to quit per year. Those visiting a clinic on fewer than three occasions should be assessed at every visit. Although tobacco status is to be assessed periodically throughout the year, there is no requirement that counseling about tobacco cessation should be offered at every visit. Helpful approaches in determining the person's position on the use of tobacco and/or readiness to change include:

1. State that the person's health would improve if he or she were to quit smoking.
2. Deal with the subject of addiction to tobacco in a nonjudgmental way.
3. Link health concerns to tobacco use by giving advice linking the person's chief complaint to smoking, e.g., "If you would quit smoking you wouldn't be so short of breath."

#### E. Is Tobacco Cessation Program Available and Is Person Willing to Attend?

##### OBJECTIVE

To refer the tobacco user to a tobacco cessation program, if available.

##### ANNOTATION

To be most effective, the treatment of tobacco dependence should include either individual or group counseling. There is a strong relationship between the intensity of counseling and successful recovery from tobacco dependence. Intensive interventions are most effective and should be used when resources permit.

#### F. Address Comorbid Conditions

##### OBJECTIVE

To determine whether the person has other clinical conditions that need prioritized intervention before instituting a tobacco cessation program.

## ANNOTATION

Persons must be assessed for any medical and/or psychiatric problems that may adversely affect the intervention. In the person's plan of treatment the following conditions need to be identified and treated before referral to a tobacco use cessation program.

### 1. Medical conditions:

Chronic pain disorder (chronic pain will increase after stopping nicotine from tobacco or NRT).

### 2. Psychiatric conditions/risks:

- a. Substance use disorder.
- b. Depression.
- c. Psychosis.
- d. Post-traumatic stress disorder (PTSD).
- e. Eating disorders.
- f. Anxiety.

## G. Initiate Intervention

### OBJECTIVE

To provide an office-based approach for the tobacco user who is not referred to an intensive intervention program.

### ANNOTATION

Every tobacco user should be offered at least brief or minimal support by the primary care manager (PCM)/primary care provider (PCP). The success correlates directly with the length of time spent (3 to 10 minutes minimum) with the smoker over multiple visits for a variety of related and non-tobacco related conditions.

The essential elements of the brief visits will include eliciting the patient's interest in quitting, severity of tobacco dependence and withdrawal symptoms, length of previous quit attempts and reasons for relapse, appropriateness of behavioral and pharmacotherapy, the reasons why they use tobacco (stress control, habit, pleasure, etc.), and patients concerns about consequences about quitting such as weight gain. The PCM/PCP can provide self-help reading material (see Appendix 4), prescribe the medications that are appropriate (see Appendix 2), establish a quit date, encourage use of

behavioral techniques to disrupt the habits and rituals of tobacco use and schedule follow-up visits within 1 to 2 weeks of the quit date.

## H. Pharmacological Treatment

### OBJECTIVE

To facilitate abstinence through provision of Pharmacological therapy to treat tobacco dependence.

### ANNOTATION

Pharmacological therapy can be divided into nicotine replacement products and non-nicotine products. Every person who answers "no" should be offered pharmacotherapy except when medically contraindicated. Selection should be based on a review of the risks and benefits for each drug and the person's preference. Appendix 2, Pharmacology, includes a comprehensive review of these drugs. Appendix 3, Treatment/Cost, rates the relative cost of dosing.

### I. Self-Help Material

#### OBJECTIVE

To assist the person in learning about the benefits of quitting.

#### ANNOTATION

Provide the person with self-help material. Provide Primary Care Managers (PCM)s and Primary Care Providers (PCP)s "How to" literature and a list of established "stop smoking" programs available. (See Appendix 4, Self-Help Material).

## J. Initiate/reinforce Relapse Prevention

### OBJECTIVE

To reinforce and motivate abstinence from tobacco and prevent future relapses (tertiary prevention).

### ANNOTATION

Most tobacco relapses occur within the first three months after cessation, but some relapses occur years after quitting. Telephone calls, clinic visits, or any time the clinician encounters a former tobacco user can be appropriate times to accomplish intervention for relapse prevention. Minimal relapse prevention should be part of every primary care encounter with persons who have recently quit. Minimal reinforcement approaches can be expressed as:

1. Offer congratulations on quitting.
2. Encourage the person to continue tobacco free.
3. Encourage active discussion of the benefits of quitting by asking the person open-ended questions designed to include the person's problem solving on:
  - a. Anticipated health benefits derived from cessation.
  - b. Success the person has had in quitting.
  - c. The most notable tobacco withdrawal symptoms experienced.
  - d. Problems or threats anticipated or encountered while maintaining abstinence (e.g., weight gain; negative mood, depression, or anxiety; prolonged withdrawal symptoms; and lack of social support for cessation).

**K. Address Reasons for Unwillingness to Quit. Determine Medical/Psychological Risks of Continued Use**

**OBJECTIVE**

To determine the existence of any medical or psychological conditions that may have predictable adverse outcomes if the person does not stop using tobacco products.

**ANNOTATION**

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:

1. 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. (See the discussion about use of medications during pregnancy in Annotation H).

2. 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.
3. 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 post – operative recovery (infections, wound healing, cardiac procedures) can be reduced.

**L. Promote Motivation to Quit**

**OBJECTIVE**

To provide guidance and encouragement to heighten the motivation to quit tobacco use.

**ANNOTATION**

The PCM/PCP should use a motivational technique characterized by the "four Rs:" relevance, risks, rewards, and repetition.

1. **Relevance**—Motivational information given to a person has the greatest impact if it is relevant to a person's disease status, family life or social situation.
2. **Risks**—Ask the person to identify the potential negative consequences of smoking; then discuss the most relevant risks for the person in detail.
3. **Rewards**—Ask the person to identify the potential benefits of quitting smoking. Highlight and elaborate on the benefits that are most relevant to the person.
4. **Repetition**—The motivational intervention should be repeated when an unmotivated

person visits the PCM/PCP in a primary care setting.

There are many reasons to address prevention in the early and middle school age groups. This group of children and young adults are very susceptible to adult role models and peer pressure. Tobacco use prevention pamphlets can be very informative and address age appropriate issues.

**M. 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.

ANNOTATION

The PCM/PCP can help identify the following information derived in the history and physical

1. The role of the family.
2. Societal/cultural expectations.
3. Tobacco industry's promotion.
4. Military recruits.
5. Low educational attainment.

**N. Assess Risk for Relapse**

OBJECTIVE

To assess former tobacco user's risk of relapse and determine if relapse prevention counseling is advisable at this stage.

ANNOTATION

Tobacco use has been characterized as a chronic relapsing disorder due to the high frequency of relapse after a single quitting attempt. Indeed, relapse rates of up to 89 percent are expected among previous tobacco users who have achieved cessation after a single quitting attempt, cold turkey. However, cumulative success rates over multiple quitting attempts may improve the success rate.

**O. Initiate Prevention**

OBJECTIVE

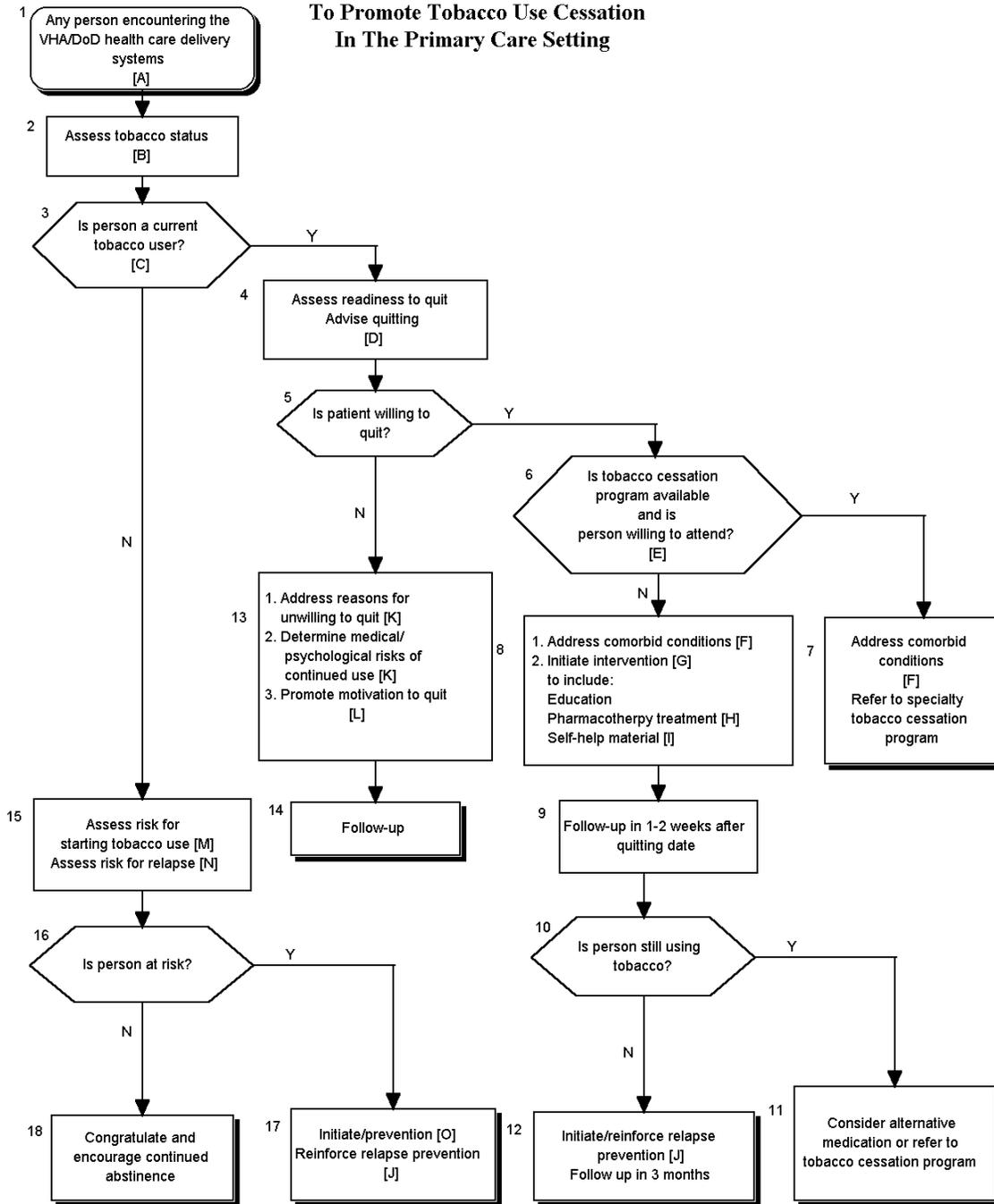
To educate potential tobacco users and prevent them from ever starting (primary prevention).

ANNOTATION

CLINICAL PRACTICE GUIDELINE TO PROMOTE  
**TOBACCO USE CESSATION**  
IN THE PRIMARY CARE SETTING

ALGORITHM AND EXPANDED ANNOTATIONS

### VHA/DoD Clinical Practice Guidelines To Promote Tobacco Use Cessation In The Primary Care Setting



## PROMOTE TOBACCO USE CESSATION IN THE PRIMARY CARE SETTING

### Expanded Annotations

#### A. Any Person Encountering the VHA/DoD Health Care Delivery Systems

##### DEFINITION

Any person 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. Assess Tobacco Status

##### OBJECTIVE

To determine the person's current use of tobacco.

##### ANNOTATION

All persons should be asked about their use of tobacco upon visiting any provider. This is easily accomplished when the person's vital signs are taken. The tobacco use status should be noted in the person's record. Repeated assessment is not necessary in the case of the adult who has never used tobacco or has not used tobacco for many years and for whom this information is clearly documented in the medical record. The clinician can proceed further based on clinical relevance and appropriateness.

#### C. Is Person a Current Tobacco User?

##### OBJECTIVE

To identify persons who are "tobacco users" as specified in this guideline.

##### ANNOTATION

A "tobacco user" is a person who answers "yes" when asked whether he or she uses tobacco products.

##### DISCUSSION

As defined by the Centers for Disease Control and Prevention (CDC), current tobacco users are persons who report having used tobacco over 100 cigarettes during their lifetime and who used tobacco every day or some days when interviewed. Former tobacco users are those who have used tobacco over 100 cigarettes during their lifetime but who do not use tobacco currently. (MMWR 1997)

#### D. Assess Readiness to Quit. Advise Quitting

##### OBJECTIVE

To ascertain the person's willingness to quit using tobacco.

## ANNOTATION

The medical record of tobacco users who regularly visit a clinic should document at least three assessments for willingness to quit per year. Those visiting a clinic on fewer than three occasions should be assessed at every visit. Although tobacco status is to be assessed periodically throughout the year, there is no requirement that counseling about tobacco cessation should be offered at every visit. Helpful approaches in determining the person's position on the use of tobacco and/or readiness to change include:

1. State that the person's health would improve if he or she were to quit smoking.
2. Deal with the subject of addiction to tobacco in a nonjudgmental way.
3. Link health concerns to tobacco use by giving advice linking the person's chief complaint to smoking, e.g., "If you would quit smoking you wouldn't be so short of breath."

## DISCUSSION

By knowing the person's stage of readiness to quit using tobacco, the primary care manager can decide whether to provide motivational material to quit using tobacco or specific instructions to help the person quit. (Fiore et al. 1996)

Michael C. Fiore, M.D., M.P.H., chaired the AHCPR Smoking Cessation Guideline Panel, which reviewed 3,000 articles and selected 300 as a database for meta-analysis to provide a valid synthesis of smoking cessation treatment outcome data. The Panel made numerous recommendations based upon these data, each of which carries a strength of evidence rating indicating the quality and quantity of empirical support. Throughout this VHA/DoD Guideline, references to Fiore reflect ratings assigned by the AHCPR panel for the specific meta-analysis cited. The meta-analysis was graded by this Tobacco Use Cessation Working Group as Level of evidence (LE) = A and Strength of Recommendation (SR) = I. This grade is applied to all evidence attributed to Fiore in this guideline. When the LE or SR diverged on a particular aspect of diagnosis or treatment, pertinent articles were reviewed and graded in this guideline.

## EVIDENCE

*Providing motivational resources to quit using tobacco products increases the success of the person quitting.*  
LE = A, SR = I Fiore et al. 1996

**E. Is Tobacco Cessation Program Available and Is Person Willing to Attend?**

## OBJECTIVE

To refer the tobacco user to a tobacco cessation program, if available.

## ANNOTATION

To be most effective, the treatment of tobacco dependence should include either individual or group counseling. There is a strong relationship between the intensity of counseling and successful recovery from tobacco dependence. Intensive interventions are most effective and should be used when resources permit.

## EVIDENCE

*The intensity and frequency of counseling directly correlate to the success of quitting tobacco use.*  
LE= A, SR = I Fiore et al. 1996

**F. Address Comorbid Conditions**

## OBJECTIVE

To determine whether the person has other clinical conditions that need prioritized intervention before instituting a tobacco cessation program.

## ANNOTATION

Persons must be assessed for any medical and/or psychiatric problems that may adversely affect the intervention. In the person's plan of treatment the following conditions need to be identified and treated before referral to a tobacco use cessation program.

1. Medical conditions:
  - a. Chronic pain disorder (chronic pain will increase after stopping nicotine from tobacco or NRT).
2. Psychiatric conditions/risks:
  - a. Substance use disorder.
  - b. Depression.
  - c. Psychosis.
  - d. Post-traumatic stress disorder (PTSD).
  - e. Eating disorders.
  - f. Anxiety.

## DISCUSSION

When these person's comorbid conditions are clinically stable, tobacco cessation treatment may begin. (Fiore et al. 1996 Page 43; Cromwell et al. 1997)

*Tobacco cessation treatment should not be initiated until the person is clinically stable.*

LE = A, SR = I Cromwell et al.; LE = C, SR = I Fiore 1996

**G. Initiate Intervention**

## OBJECTIVE

To provide an office-based approach for the tobacco user who is not referred to an intensive intervention program.

## ANNOTATION

Every tobacco user should be offered at least brief or minimal support by the primary care manager (PCM)/primary care provider (PCP). The success correlates directly with the length of time spent (3 to 10 minutes minimum) with the smoker over multiple visits for a variety of related and non-tobacco related conditions.

The essential elements of the brief visits will include eliciting the patient's interest in quitting, severity of tobacco dependence and withdrawal symptoms, length of previous quit attempts and reasons for relapse, appropriateness of behavioral and pharmacotherapy, the reasons why they use tobacco (stress control, habit, pleasure, etc.), and patients concerns about consequences about quitting such as weight gain.

The PCM/PCP can provide self-help reading material (see Appendix 4), prescribe the medications that are appropriate (see Appendix 2), establish a quit date, encourage use of behavioral techniques to disrupt the habits and rituals of tobacco use and schedule follow-up visits within 1 to 2 weeks of the quit date.

## DISCUSSION

Every tobacco user should be offered at least a minimal or brief intervention, whether or not the individual is referred to an intensive intervention. A variety of visit formats have been shown to improve quit rates, including "minimal self-help" (odds ratio [OR] for successful cessation = 1.2), individual counseling by a clinician (OR = 2.2), and group counseling (OR = 2.2). Tobacco cessation success correlates directly with increasing length of visit from 3 to 10 minutes. (Fiore et al. 1996 p 46) The clinician should capitalize on this fact by addressing as many of the following areas as time and resources permit. Continue to cover appropriate topics at subsequent visits. If time is exceedingly limited, the clinician can skip directly to items #10-12.

1. Every individual entering a health care setting should receive an assessment to determine his or her tobacco use status and interest in quitting. The assessment represents the first step in treatment. The following should include:
  - a. Tobacco use history.
  - b. Information about previous efforts to quit tobacco use:
    - i. Number of days, weeks, months, or years of successful abstinence in the past.
    - ii. Previous methods that helped or that proved of little value.
    - iii. Medications that were helpful or that failed to help.
    - iv. Problems contributing to relapse such as withdrawal symptoms, stressful events, or mood disorders.
    - v. Problems that occur after cessation, such as weight gain.
  - c. Setting a quit date and emphasize the importance of total abstinence.
  - d. Review benefits that are personally relevant to that individual.
  - e. Addressing specific problems of concern including those listed in 1.b.v.
2. Tobacco users who express an interest in quitting require assessment for physical or medical conditions that will affect the choice of pharmacotherapy agent to control withdrawal symptoms.
3. Tobacco users who express an interest in quitting may benefit from assessment using a formal questionnaire, or physiological measures such as carbon monoxide, urine or serum nicotine or cotinine level or pulmonary function tests. For example, the Fagerstrom Nicotine Tolerance Questionnaire can measure nicotine dependence and predict withdrawal symptoms (Fagerstrom 1989), (see Appendix 1, Fagerstrom Nicotine Tolerance Questionnaire). A score of:
  - a. 0 to 3 is associated with no or minimal nicotine withdrawal symptoms.
  - b. 4 to 6 is associated with moderate symptoms.
  - c. 7 to 10 is associated with strong or severe symptoms.

Pharmacologic support and counseling measures flow from this information.

4. Use of a self-administered test such as "Why Do I Smoke?" can inform the tobacco user which of the common reasons for tobacco dependence best fits their situation. The test lists healthy alternatives to meet the needs discovered in the quiz without reliance on tobacco products.
5. Tobacco users considering cessation need to know that withdrawal symptoms will worsen for 2 to 5 days, plateau, and then diminish over the next 14 days. *The Psychiatric Diagnostic and Statistical Manual* (DSM-IVR, classification number 292.0) provides a list of symptoms commonly encountered. Most individuals exhibit several (often five or more) symptoms within 1 or 2 days after stopping or significantly reducing tobacco use.

6. Treatment of tobacco dependence is less successful when one or more of the following elements are present. Documenting these issues helps the clinician and person prepare for the challenge. Unfortunately, little research evidence is available to guide treatment based on the results of these assessments:

High nicotine dependence	The tobacco user reports severe withdrawal symptoms.
Psychiatric comorbidity	Depression, schizophrenia, chemical dependency, and/or anxiety is present.
Low motivation	The tobacco user says that quitting is not a high priority.
Low readiness to change	The tobacco user says that although quitting is important, now is not the time.
Low self-efficacy	The tobacco user says that quitting is not possible.
Environmental risks	The tobacco user says other tobacco users in the home or workplace make abstinence difficult.
High stress level	Life's events or major life change makes stopping difficult at this time.

7. Help tobacco users recognize and solve problems encountered in quitting. Use previous quitting experience to understand which issues to address. Provide personal instruction and self-help reading or viewing material as follows:

- a. Methods to cope with nicotine withdrawal symptoms.
- b. Relaxation training and stress management.
- c. Establishment of a support system. Examples include developing a relationship with an ex-tobacco user, locating a telephone counselor to call when the urge for tobacco is strong, or attending a Nicotine Anonymous meeting.
- d. Learning about personal "triggers" that contribute to tobacco craving. Examples include association with tobacco users in bars, recreation events, workplace or home. There is a strong association between the consumption of alcohol and relapse.

8. Use behavioral techniques to disrupt the routines of tobacco use before the quit date. The following have been found helpful:

- a. Try using a "2-minute time out." Every time the tobacco user feels a craving, he or she should wait two minutes until the desire stops before using tobacco products. This creates confidence and allows the user to control behavior. Craving episodes will become less overwhelming and less frequent.
- b. Create a setting to avoid "automatic tobacco use." Remove all tobacco products and ignition devices from immediate reach in home, car, and workplace. Place tobacco and lighter in different locations. Since the user must go to another location to retrieve tobacco for use, it becomes easier to observe the "2-minute time out."
- c. Alter patterns of living to avoid tobacco use. Examples include avoiding locations where tobacco use is comfortable and convenient. Always get up from the table immediately following a meal.

9. Tobacco addiction has three elements:

- a. Habit.
- b. Psychological dependence.
- c. Neuro-chemical addiction.

These three tobacco addiction habits are referred to as the addiction triangle. Knowing that habits must be disrupted before the quit date will help achieve successful cessation. Psychological dependence requires changing attitudes towards tobacco use before the quit date. Neuro-chemical dependence requires treatment by implementing nicotine substitution or modifying the brain's reward system. Help the tobacco user address the elements of the addiction triangle that will most improve their success.

10. Have the person set a firm quit date and master the behavior change tasks before the quit date.

11. Establish an appropriate pharmacotherapy regimen to use during the quit attempt. (See Annotation H)
12. Schedule follow-up visits shortly after the planned quit date:
  - a. Most relapses occur in the first two weeks. An early visit allows verification of the quit plan's success and medication compliance. Modify the plan based on progress and current issues.
  - b. A minimum of four visits and a maximum of seven over a 2 to 6-week period are recommended.

Success is measured by the outcome. Elements to measure success or failure of the intervention are: (Haziandreu et al. 1990)

1. Attendance at sessions/appointments.
2. Abstinence success by self-report or other report or carbon monoxide testing.
3. Reduced tobacco or nicotine use (harm reduction model).

#### EVIDENCE

*Success of tobacco use cessation is directly related to the intensiveness and follow-up intervention.*  
LE = B, SR = I Fiore et al. 1996

### H. Pharmacological Treatment

#### OBJECTIVE

To facilitate abstinence through provision of pharmacological therapy to treat tobacco dependence.

#### ANNOTATION

Pharmacological therapy can be divided into nicotine replacement products (NRT) and non-nicotine replacement products. Every person should be offered pharmacotherapy except when medically contraindicated. (See G in the algorithm.) Selection should be based on a review of the risks and benefits for each drug and the person's preference. Appendix 2, Pharmacology, includes a comprehensive review of these drugs. Appendix 3, Treatment/Cost, rates the relative cost of dosing.

#### DISCUSSION

Understanding the role of NRT and non-NRT prescribing is critical for the PCP/PCM.

#### *NICOTINE REPLACEMENT THERAPY*

Tobacco use is maintained by dependence on nicotine. Users often perceive that smoking or chewing tobacco helps them cope with stress and improves their mental alertness. (Davis 1998) When tobacco use is stopped, symptoms of nicotine withdrawal become noticeable. The positive reinforcement from tobacco use and the negative effects of nicotine withdrawal become powerful factors impeding cessation from tobacco use. Nicotine replacement therapy may therefore be of benefit in selected persons as an aid to tobacco use cessation. (Thompson 1998)

Four types of nicotine replacement therapy (NRT) products are available in the United States for pharmacological treatment of tobacco dependence. NRT is available as:

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

In one large trial, NRT was used safely in combination with bupropion for selected healthy, non-depressed smokers. (Jorenby 1999) Continued dependence on nicotine is possible with all four types of NRT.

Selection of the NRT should be based on the person's: level of addiction to tobacco, motivation to quit, and concomitant medical conditions.

### 1. Nicotine Addiction

The higher the person's level of addiction to nicotine, the more likely he or she is to benefit from NRT as an aid to tobacco cessation. A high level of addiction is indicated in persons who:

- a. Use tobacco products every day.
- b. Smoke his or her first cigarette within 30 minutes of arising.
- c. Usually inhale more frequently and deeply.
- d. Prefer brands of cigarettes with a nicotine level > 0.9 mg.
- e. Find it difficult to refrain from smoking in forbidden areas.
- f. Use tobacco even when so ill they are confined to bed most of the day.
- g. Develop withdrawal symptoms in first week(s) of a prior quit attempt.

### 2. Motivation to Quit

The higher the motivation to quit, the more likely the benefit from nicotine replacement therapy. Providers should determine the person's motivation to quit before prescribing NRT. (Davis 1998; Thompson 1998)

### 3. Concomitant Medical Condition

Although there are no absolute contraindications to the use of nicotine replacement therapy, caution should be used with any of following medical conditions.

- a. Cardiovascular disease — There are concerns that NRT could cause platelet activation and catecholamine release, adversely affecting persons with myocardial infarction and unstable angina. (Davis 1998)
- b. Unstable coronary artery disease — NRT is relatively contraindicated in persons with unstable coronary artery disease.
- c. Stable coronary artery disease — NRT can be initiated at intermediate doses with careful monitoring.

- d. Pregnancy — the NRT products are category D, except nicotine polacrilex, which is category X, over the counter (OTC), according to the Food and Drug Administration (FDA) pregnancy category rating. The manufacturer does, however, recommend the same cautions and warnings as the other NRT products. The risk of fetal harm due to nicotine must be weighed against the benefit of abstinence from tobacco.
- e. Miscellaneous conditions — Use of NRT must be carefully assessed and monitored in persons with hyperthyroidism, peptic ulcer disease, insulin-dependent diabetes mellitus, temporomandibular joint syndrome and certain peripheral vascular diseases.

Nicotine from any NRT product may be harmful to children or pets if taken orally

## EVIDENCE

- a. *Proper use of nicotine replacements has shown its effectiveness in helping tobacco users quit.*  
LE = A, SR = IIa Jorenby 1999
- b. *Appropriate treatment is based on person's motivation to quit.* LE = B, SR = I (Davis 1998; Thompson 1998)

### *Proper Use of Nicotine Replacement Therapy*

Each of the NRT products currently available has inherent advantages and disadvantages as described below.

1. Nicotine Transdermal (patch) (Henningfield 1995; Hurt 1997; Setter 1998; Dale et al. 1995; Greenland 1998)

Nicotine patches are available from several manufacturers in a variety of strengths. Strengths are expressed in the amount of nicotine delivered over the duration that the patch is in place (16 to 24 hours). Generally, patches are categorized as high dose (22 mg, 21 mg), intermediate dose (15 mg, 14 mg, 11 mg, 10 mg), and low dose (7 mg, 5 mg). To use, a new patch should be placed on a hairless area between the neck and waist or inner arm at the start of each day. Patches should not be occluded. Dosing is scheduled as follows:

Heavy dependence: (>24 cigarettes/day) — High-dose patch once daily for 6 weeks, intermediate patch once daily for 2 weeks, low-dose patch once daily for 2 weeks.  
Mild dependence: (≤ 24 cigarettes/day) — Intermediate-dose patch once daily for 6 weeks, low-dose patch once daily for 2 weeks.

Higher dosages have been reported (see Appendix 2, Pharmacology).

#### a. Advantages:

- 1) The controlled delivery of nicotine produces a constant and predictable blood level, once a steady state is reached. This helps avoid stimulatory effects caused by rapid nicotine delivery and the anticipatory effects caused by self-administration of nicotine gum, nasal spray, or vapor inhaler.
- 2) Overdosing is rare.

#### b. Disadvantages:

- 1) Steady-state concentration is not reached until 2 to 3 days after placement of first patch.
- 2) Tobacco users equaling fewer than 10 cigarettes a day may lose their tolerance to nicotine and experience light-headedness and nausea.
- 3) Up to 50 percent of persons may experience dermatological side effects from the patches, usually mild itching and erythema.

2. Nicotine Polacrilex Resin (gum) (Lam 1987; Murray et al. 1996)

Nicotine polacrilex gum is available in 2-mg and 4-mg strengths. The 4-mg strength is used in persons who used tobacco equaling more than 24 cigarettes per day; the 2-mg strength is recommended for persons who used tobacco equal to or less than 24 cigarettes per day.

Dosing is as follows: One piece of gum every 1 to 2 hours for 6 weeks, taper over 6 weeks. Persons should be instructed to chew the gum slowly until a tingling sensation is felt in the gums. The gum should then be "parked" in the buccal mucosa until the tingling subsides. Alternate slow and intermittent chewing and parking the gum for about 30 minutes. Acidic beverages (e.g. coffee, juice) inhibit the absorption of nicotine and should be avoided.

a. Advantages:

- 1) Allows tobacco users to take an active coping response to nicotine withdrawal symptoms.
- 2) Provides plasma nicotine concentrations approximately 30 to 64 percent of pre-cessation levels.
- 3) Not associated with as much weight gain as placebo during treatment.

b. Disadvantages:

- 1) Effect reduced by acidic beverages.
- 2) Some persons may have difficulty following instruction to "park" the gum and may treat it like regular chewing gum resulting in nausea or gastrointestinal upset.
- 3) Sticks to dentures, may dislodge fillings and inlays because of its density.
- 4) Temporomandibular joint syndrome is a relative contraindication.

3. Nicotine Nasal Spray (Hjalmarson et al. 1994; Hurt et al. 1998)

Nicotine nasal spray is available as a water-based, metered-dose, mist spray that delivers 0.5 mg of nicotine with each spray. A single dose consists of 1 spray in each nostril. The usual adult dose is 1 to 2 sprays/hour, to a maximum of 5 sprays an hour or 40 sprays a day. Persons should be cautioned not to exceed recommended doses, and to be aware of the potential for dependence that may result from use of this product.

a. Advantages:

- 1) Peak concentrations occur more rapidly than other NRT products (within 15 minutes) resembling the kinetics of nicotine seen with cigarette use.
- 2) May be better tolerated by those who have had dermatological effects from the patch or dental side effects from the gum.

b. Disadvantages:

- 1) Higher risk of nicotine dependence because of its rapid onset and user control of nicotine delivery.
- 2) Local irritant adverse effects, including nasal and throat irritation, runny nose, sneezing, watery eyes, and cough.

4. Nicotine Oral Vapor Inhaler (Tonnesen et al. 1993)

Nicotine is available as an oral vapor inhaler delivering 4 mg of nicotine from a porous plug containing 10 mg of nicotine. The cartridge is inserted in a mouthpiece resembling a cigarette before use, and inhaled orally. This action mimics the hand-mouth activities associated with smoking, thereby is a tobacco substitute for tobacco use during abstinence. The usual dose for initial treatment is 6 to 16 cartridges per day for up to 12 weeks, followed by a gradual reduction (if needed) for 6 to 12 weeks. Persons should be

told to stop smoking completely before using this product, and not to exceed the recommended maximum dosage (16 mg/day).

a. Advantages:

- 1) Peak plasma concentrations occur in 15 minutes, as seen with nicotine nasal spray.
- 2) Need for Hand-mouth action can be substituted with this product.

b. Disadvantages:

- 1) High incidence (about 66 percent) of mouth and throat irritation.
- 2) High residual level of nicotine in discarded cartridge (danger to children and pets).

## EVIDENCE

- a) *Nicotine Transdermal Patch* LE = A, SR = I (Henningfield 1995; Hurt et al. 1997; Greenland et al. 1998; Setter et al. 1998; Dale et al. 1995)
- b) *Nicotine Polacrilex Resin (gum)* LE = A, SR = I (Lam 1987; Murray 1996)
- c) *Nicotine Nasal Spray* LE = A, SR = I (Hjalmarson et al. 1994; Hurt et al. 1998)
- d) *Nicotine Oral Vapor Inhaler* LE = A, SR = I (Tonneson et al. 1993)

## NON-NICOTINE THERAPY

The only non-nicotine product currently FDA approved is bupropion SR. (Hurt et al. 1997) Bupropion is a non-nicotine aid to tobacco use cessation, initially marketed as an antidepressant. It is chemically unrelated to tricyclic, tetracyclic, selective serotonin reuptake inhibitor, or other known antidepressant agents. Bupropion is a relatively weak inhibitor of the neuronal uptake of norepinephrine and dopamine. The mechanism by which bupropion enhances the ability of persons to abstain from smoking is unknown. However, it is presumed that this action is mediated by noradrenergic and/or dopaminergic mechanisms.

There are a number of factors to be considered when considering whether a person desiring help in tobacco cessation would be a candidate for bupropion SR. Among them are:

1. Nicotine dependence.
2. Motivation to quit.
3. Inability or disinclination to use nicotine replacement.
4. Contraindicated drugs or disease states.

### *Motivation To Quit*

The higher the motivation to quit, the more likely the benefit from therapy with bupropion SR. (Setter 1998) Providers should determine the person's motivation to quit before prescribing bupropion SR.

### *Inability or Disinclination to Use Nicotine Replacement*

Persons who desire to stop using tobacco and are unable to use nicotine due to clinical conditions may be candidates for bupropion SR. Because of its category X rating in pregnancy, it may be preferable to nicotine replacement for pregnant women desiring to abstain from smoking. (Hughes et al. 1998)

### *Relative Contraindications, Drugs, or Diseases*

Bupropion is contraindicated under the following circumstances: (Dale et al. 1995)

1. In persons with a seizure disorder, bupropion can potentially lower the seizure threshold in these persons.
2. Persons who are predisposed to seizures due to a current or prior diagnosis of bulimia or anorexia nervosa.
3. Persons taking monoamine oxidase inhibitor (MAOI). At least 14 days should elapse from the last dose of the MAOI to initiation of treatment with bupropion SR.

Bupropion should be used with caution (careful evaluation, monitoring) under the following circumstances: (Jorenby 1999)

1. Persons who are taking a noradrenergic antidepressant agent.
2. Persons with medical conditions that may predispose them to seizures:
  - a. Severe head trauma.
  - b. Central nervous system tumor.
  - c. History of seizures.
  - d. Abrupt withdrawal from heavy, daily alcohol or other sedatives.
  - e. Addiction to opiates, cocaine, or stimulants.
  - f. Diabetes treated with oral hypoglycemics or insulin.
3. Persons with hepatic dysfunction or end stage cirrhosis.

#### EVIDENCE

LE = A, SR = I Hurt et al. 1997, Jorenby 1999, Hughes et al. 1998

Proper Use of Bupropion SR (Fiore et al. 1994; Hurt et al. 1997; Jorenby et al. 1999; Hughes et al. 1998; Ferry et al. 1994)

Bupropion should be given for 7 to 12 weeks. The usual dose is 150 mg daily for the first 3 days, then 150 mg twice daily for 7 to 12 weeks. Persons should start one week before quitting smoking and set a definite "quit date" sometime after the start of the second week. Persons should be told to swallow the tablets whole, not crushed or chewed. At the end of seven weeks, the prescriber should assess the person's abstinence and consider whether to continue therapy for a longer period than 7 to 12 weeks.

1. Advantages:
  - a. The only orally administered non-nicotine agent currently approved for smoking cessation.
  - b. Can be started while the person is still smoking without adverse effects.
  - c. Bupropion is nonaddicting and nicotine-free, therefore, no withdrawal symptoms occur after discontinuation.
2. Disadvantages:
  - a. Potential to lower the seizure threshold in some individuals.

#### EVIDENCE

LE = A, SR = I Hurt 1997; Setter 1998; Dale 1995

## FOLLOW-UP

A follow-up visit should be scheduled either in person or via telephone within one to two weeks after the person's quitting date. (Dale et al. 1995) Follow-up contact should be timed to occur soon after the quitting date, preferably during the first week. A second follow-up contact is recommended within the first month. Schedule further follow-up contacts as indicated. (Fiore et al. 1997)

A personalized approach to supporting the person through the tobacco cessation process includes the following steps:

1. Reinforce the decision to quit.
2. Provide self-help materials and medication prescriptions/recommendations as indicated.
3. Establish a periodic follow up plan to see the person through to successful cessation. (Hurt 1997; Law et al. 1995)

### I. Self-Help Material

#### OBJECTIVE

To assist the person in learning about the benefits of quitting.

#### ANNOTATION

Provide the person with self-help material. Provide Primary Care Managers (PCM)s and Primary Care Providers (PCP)s "How to" literature and a list of established "stop smoking" programs available. (See Appendix 4, Self-Help Material).

#### DISCUSSION

Following completion of the treatment, relapse prevention becomes the most important factor in determining success in the cessation of tobacco use. (Fiore 1996; Kenford et al. 1994)

#### EVIDENCE

LE = C, SR = I Hurt 1997; Fiore 1996

### J. Initiate/reinforce Relapse Prevention

#### OBJECTIVE

To reinforce and motivate abstinence from tobacco and prevent future relapses (tertiary prevention).

#### ANNOTATION

Most tobacco relapses occur within the first three months after cessation, but some relapses occur years after quitting. Telephone calls, clinic visits, or any time the clinician encounters a former tobacco user can be appropriate times to accomplish intervention for relapse prevention. Minimal relapse prevention should be part of every primary care encounter with persons who have recently quit. Minimal reinforcement approaches can be expressed as:

4. Offer congratulations on quitting.
5. Encourage the person to continue tobacco free.

6. Encourage active discussion of the benefits of quitting by asking the person open-ended questions designed to include the person's problem solving on:
  - a. Anticipated health benefits derived from cessation.
  - b. Success the person has had in quitting.
  - c. The most notable tobacco withdrawal symptoms experienced.
  - d. Problems or threats anticipated or encountered while maintaining abstinence (e.g., weight gain; negative mood, depression, or anxiety; prolonged withdrawal symptoms; and lack of social support for cessation).

## DISCUSSION

The purpose of relapse prevention may need to be individualized especially during the first three months of abstinence. (U.S. DHHS 1994; Hatzianreou 1990) Some relapses occur years after quitting. (Kenford et al. 1994) Intervention may need to be individualized based on problems experienced by the person while maintaining abstinence. The more intensive interventions may be delivered through the PCM/PCP, specialized clinic, or program. The components of intervention may include addressing:

1. Weight gain —The clinician can give dietary, exercise, or lifestyle recommendations; or refer the person to a specialist or program. The person should be reassured that some weight gain after quitting is common and that imposing significant dietary restrictions soon after quitting may be counterproductive.
2. Negative mood, depression or anxiety — If significant, the clinician might prescribe appropriate medications or refer the person to a mental health specialist.
3. Prolonged withdrawal symptoms — If the person reports prolonged craving or other withdrawal symptoms, the clinician might consider prescribing pharmacological therapy as appropriate.
4. Lack of social support for cessation — The clinician can help identify sources of support within the person's environment or refer the person to an appropriate organization offering cessation counseling or support (e.g., Nicotine Anonymous). (Brandon et al. 1986)

## EVIDENCE

LE = C, SR = I Kenford et al. 1994; U.S. DHHS 1994; Hatzianreou 1990.

## **K. Address Reasons for Unwillingness to Quit. Determine Medical/Psychological Risks of Continued Use**

### OBJECTIVE

To determine the existence of any medical or psychological conditions that may have predictable adverse outcomes if the person does not stop using tobacco products.

### ANNOTATION

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:

1. 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. (See the discussion about use of medications during pregnancy in Annotation H).

2. 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.
3. 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 post-operative recovery (infections, wound healing, cardiac procedures) can be reduced.

## L. Promote Motivation to Quit

### OBJECTIVE

To provide guidance and encouragement to heighten the motivation to quit tobacco use.

### ANNOTATION

The PCM/PCP should use a motivational technique characterized by the "four Rs:" relevance, risks, rewards, and repetition.

1. **Relevance**—Motivational information given to a person has the greatest impact if it is relevant to a person's disease status, family life or social situation.
2. **Risks**—Ask the person to identify the potential negative consequences of smoking; then discuss the most relevant risks for the person in detail.
3. **Rewards**—Ask the person to identify the potential benefits of quitting smoking. Highlight and elaborate on the benefits that are most relevant to the person.
4. **Repetition**—The motivational intervention should be repeated when an unmotivated person visits the PCM/PCP in a primary care setting.

### DISCUSSION

The PCM/PCP should highlight the risks most relevant to the person. It should be emphasized that switching to smoking low-tar/low-nicotine cigarettes or use of other forms of tobacco (smokeless tobacco, cigars, pipes, etc.) will not eliminate these risks. Examples of specific risks to discuss with the person include:

1. Acute health risks:
  - a. Shortness of breath.
  - b. Exacerbation of asthma.
  - c. Chronic cough or acute bronchitis.
  - d. Reproductive risks: infertility, low birth weight, infant death.
  - e. Increased serum carbon monoxide level.
  - f. Loss of smell and taste.
2. Long-term health risks:
  - a. Heart attack, stroke and vascular disease.
  - b. Lung and other cancers—larynx, oral cavity, pharynx, esophagus, pancreas, bladder, cervix, leukemia.
  - c. Chronic obstructive pulmonary diseases (chronic bronchitis and emphysema).
  - d. Impotence.

3. Environmental risks:
  - a. Increased risk of lung cancer in spouse and children.
  - b. Higher rates of tobacco use by children of tobacco users.
  - c. Increased risk for sudden infant death syndrome, asthma, middle ear disease, and respiratory infections in children of tobacco users.
  - d. Fires.

The PCM/PCP may also highlight the benefits that seem most relevant to the person. Examples of these benefits include: (Brandon et al. 1986; Fiore 1996)

1. Breathe more easily.
2. Improved overall health for the person and family.
3. Having healthier babies and children.
4. Feeling better about themselves, their clothes, car, home.
5. Won't need to worry about exposing others to tobacco use (and often receiving criticism as a result).
6. Food tastes better.
7. Breath smells better.
8. Improved sense of smell.
9. Feeling better physically.
10. Knowing one's self is free from the slavery of addiction.
11. Being able to stop worrying about quitting.
12. Setting a good example for kids.
13. Improved performance at work and in sports.
14. Significant money savings.

#### EVIDENCE

LE = C, SR = I Fiore 1996

#### **M. 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

##### ANNOTATION

The PCM/PCP can help identify the following information derived in the history and physical

1. The role of the family.

2. Societal/cultural expectations.
3. Tobacco industry's promotion.
4. Military recruits.
5. Low educational attainment.

## DISCUSSION

Speakers at the Addicted to Nicotine: A National Research Forum stated that potential tobacco users can be partially identified by the following information derived in the history and physical: (Addicted to Nicotine: a National Research Forum, Program Book 1998)

1. The role of the family.

Among white adolescents, parents and family play a role in predicting onset of tobacco use. Qualitative data suggest that parental messages about smoking do matter.

2. Societal/cultural expectations.

White females may be at risk for smoking because of expectations created by sociocultural beliefs, e.g., smoking helps to control weight, control mood, and enhance one's image of being independent and sophisticated.

3. Tobacco industry's promotion.

There is considerable evidence that the tobacco industry's promotion of its products has a major influence on initiating tobacco use by the young.

4. Military recruits.

Some situations (e.g., special military assignments) are likely to lead to tobacco use. White male and female Navy Recruits are more likely to have used tobacco than civilians. The Addicted to Nicotine Study found that at one year after boot camp:

- a. Eight percent of those who had "never used tobacco" before enlistment are now using tobacco.
- b. Twenty-six percent of those who had been "experimental tobacco users" were using tobacco.
- c. Forty-three percent of those who had been "ex-tobacco users" were using tobacco.

5. Low educational attainment.

The prevalence of smoking is highest in those with less than 12 years education.

## EVIDENCE

LE =C, SR =I Addicted to Nicotine, A National Research Forum Program Book. Bethesda, Maryland: July 27 and 28, 1998

**N. Assess Risk for Relapse**

## OBJECTIVE

To assess former tobacco user's risk of relapse and determine if relapse prevention counseling is advisable at this stage.

## ANNOTATION

Tobacco use has been characterized as a chronic relapsing disorder due to the high frequency of relapse after a single quitting attempt. Indeed, relapse rates of up to 89 percent are expected among previous tobacco users who have achieved cessation after a single quitting attempt, cold turkey. However, cumulative success rates over multiple quitting attempts may improve the success rate.

## DISCUSSION

The majority of relapses occur relatively early in the quitting process. The length of time a person has been abstinent at the time of the health care visit is an important factor in assessing a person's risk of relapse. Although relapse has been seen even after one or more years of abstinence, *the relapse rate falls significantly after three months.* (U.S. DHHS 1994) Individuals who have been abstinent for under three months at the time of the visit should be considered at risk for relapsing and viewed as candidates for relapse prevention counseling. This is especially true if they have had slips (sporadic episodes of tobacco use) early in the quitting process, since one or more slips after cessation predicts relapse. Nevertheless, three months should not necessarily be considered a safe point since relapse can and does occur after this point. Persons fitting any of the parameters below should be considered candidates in need of relapse prevention counseling: (Brownell et al. 1998)

1. Various individual factors relate to an increased likelihood for relapse:
  - a. Negative emotional states, e.g., stress, depression, anxiety, etc.
  - b. Concern about post-cessation weight gain.
  - c. The presence of significant craving and/or withdrawal symptoms.
  - d. Present or past history of substance use disorder.
  - e. Previous quit attempts.
  - f. Unaware or unconcerned about issues related to relapse.
  - g. Does not attempt to modify his or her environment.
  - h. Engages in "risky behavior" such as consumption of alcohol or other mind-altering substances.
  - i. Attends establishments where smoking is tolerated, even encouraged, e.g., bars.
  
2. Social and environmental factors also appear to be related to relapse:
  - a. Use of tobacco is socially accepted and legal.
  - b. Presence of other tobacco users.
  - c. Lack of social support for quitting.
  - d. Visual cues related to the advertising of tobacco products.
  - e. Easy access to tobacco products.

**O. Initiate Prevention**

## OBJECTIVE

To educate potential tobacco users and prevent them from starting (primary prevention).

## ANNOTATION

There are many reasons to address prevention in the early and middle school age groups. This group of children and young adults are very susceptible to adult role models and peer pressure. Tobacco use prevention pamphlets can be very informative and address age appropriate issues.

## DISCUSSION

Suggested focused interventions for PCM/PCPs to prevent initiation of tobacco use:

1. Early elementary school.
  - a. Ask the child whether he or she has experimented with tobacco.
  - b. Discuss tobacco use and its addicting effects—especially the short-term negative effects.
  - c. Identify the advantages of not smoking, including those most appropriate for the child's age and developmental stage.
  - d. Explain that he or she eventually may encounter peers who use tobacco and discuss ways in which he or she might resist peer pressure to try tobacco products.
  
2. Middle school/Junior high school.
  - a. Reassure him or her that most kids don't use tobacco including smokeless tobacco.
  - b. All forms of tobacco (snuff, cigarettes, dip, etc.) are extremely addictive, and most teens who use tobacco are addicted to nicotine.
  - c. Addiction to tobacco takes away one's independence.
  - d. Smokeless tobacco is not a safe alternative to tobacco use, because it is addicting, causes oral cancer, and damages teeth and gums.
  - e. Tobacco use makes a person's:
    - 1) Mouth, hair, and clothes smell bad.
    - 2) Teeth and skin become stained.
    - 3) Clothes are ruined, burned holes.
    - 4) Causes shortness of breath.
    - 5) Decreases athletic performance.
    - 6) Is a major cause of fires and deaths.
  - f. Tobacco use causes health problems in many young people, including chronic cough and sore throat.
  - g. Tobacco use won't make a person rugged, sexy, "cool," or successful.
  - h. Tobacco use is a gateway to other drug use, and addiction to nicotine may make a person more susceptible to trying other dangerous drugs.
  - i. Tobacco use is an increasingly expensive habit taking money needed for other things (e.g., books, clothes, makeup, music, movies, and sports).
  - j. There are other ways of being different without taking up a habit that is addicting and has such severe, long-term consequences. (Fiore et al. 1996; U.S. DHHS 1994)

## EVIDENCE

LE = C, SR = I U.S. DHHS 1994; Fiore et al. 1996

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APPENDIX 1

**PROMOTE TOBACCO USE CESSATION IN THE PRIMARY CARE SETTING****Appendix 1. Fagerstrom Nicotine Tolerance Questionnaire**

How Addicted To Nicotine Are You?

Question	A=0 Points	B=1 Point	C=2 Points	Score
1. How soon after you wake up do you smoke your first cigarette?	After 30 minutes	Within 30 minutes	-----	
2. Do you find it difficult to refrain from smoking in places where it is forbidden, such as at the library, theater, or doctor's office?	No	Yes		
3. Which of the cigarettes you smoke in a day is the most satisfying?	Any other than the first one in the morning	The first one in the morning	-----	
4. How many cigarettes a day do you smoke?	1-15	16-25	More than 25	
5. Do you smoke more during the morning than during the rest of the day?	No	Yes	-----	
6. Do you smoke when you are so ill that you are in bed most of the day?	No	Yes	-----	
7. Does the brand you smoke have a low, medium, or high nicotine content?	Low 0.4 mg	Medium 0.5 to 0.9 mg	High 1.0 mg or more	
8. How often do you inhale the smoke from your cigarette?	Never	Sometimes	Always	

If you scored 4 points or more, you may be addicted to nicotine.

**Total** \_\_\_\_

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APPENDIX 2

## PROMOTE TOBACCO USE CESSATION IN THE PRIMARY CARE SETTING

### Appendix 2. Pharmacology

Nicotine replacement products <sup>1,2,3</sup>		
<i>Transdermal nicotine</i> <sup>4,5,6,7,8</sup>		
Dosage	Heavy dependence	> 24 cigarettes/day—High dose (21 mg) for 6 weeks, then intermediate dose (14 mg) for 2 weeks, then low dose (7 mg) for 2 weeks
	Mild dependence	≤ 24 cigarettes/day— Intermediate dose (14 mg) for 6 weeks, then low dose (7 mg ) for 2 Taper over 2 weeks
Contraindications	Allergy, pregnancy (Risk Category D)	
Adverse reactions	Sleep disturbances, skin irritations	
Drug Interactions	No direct interactions; smoking cessation may alter the pharmacokinetics of some drugs	
Efficacy	One year abstinence vs placebo – Odds Ratio (O.R.) =2.1	
<i>Polacrilex nicotine</i> <sup>9,10,11,12,13</sup>		
Dosage	> 25 cigarettes/day; 4mg strength ≤ 25 cigarettes/day; 2 mg strength One piece of gum q 1 to 2 hr for 6 weeks Taper over 6 weeks	
Contraindications	Allergy; pregnancy (Risk Category X)	
Adverse Reactions	Nausea, dyspepsia, jaw fatigue, dependency	
Drug Interactions	No direct interactions; smoking cessation may alter the pharmacokinetics of some drugs	
Efficacy	One year abstinence vs placebo - O.R. = 1.4 to 1.6	
<i>Nasal spray nicotine</i> <sup>14,15</sup>		
Dosage	8 to 40 mg/day (average 15 mg) for 8 weeks Taper over 6 weeks	
Contraindications	Allergy, pregnancy (Risk Category D)	
Adverse reactions	Nasal and /or throat irritation, dependence	
Drug interactions	No direct interactions; smoking cessation may alter the pharmacokinetics of some drugs	
Efficacy	One year abstinence vs placebo - O.R. = 1.8	

<i>Oral vapor nicotine-inhaler</i> <sup>16</sup>	
Dosage	6 to 16 cartridges/day for 12 weeks (each cartridge is 4 mg) Taper over 6 to 2 weeks
Contraindications	Allergy; pregnancy (Pregnancy Category D)
Adverse reactions	Mouth and throat irritation; dependence
Drug interactions	No direct interactions; smoking cessation may alter the pharmacokinetics of some drugs
Efficacy	One year abstinence vs placebo — O.R. = 1.3
<b>Non-nicotine tobacco cessation product</b> <sup>17, 18, 19</sup>	
<i>Bupropion SR</i> <sup>20, 21</sup>	
Dosage	150 mg qd for 3 days, then 150 mg bid for 7 to 12 weeks
Contraindications	Seizure disorders, predisposition to seizures, MAOIs, allergy (Pregnancy Category B)
Adverse reactions	Sleep disturbances, dry mouth
Drug interactions	Selected antidepressants (MAOIs, norepinephrine re-uptake inhibitors), drugs metabolized by CYP2B6 and CYP2D6
Efficacy	One year abstinence vs placebo - O.R. = 1.4 to 2.35

## Pregnancy Categories Rate:

- A - Adequate studies in pregnant women have failed to show a risk to the fetus.
- B - Animal studies have not shown a risk to the fetus, but controlled studies have not been conducted in pregnant women; or animal studies have shown an adverse effect on the fetus, but adequate studies in pregnant women have not shown a risk to the fetus.
- C - Animal studies have shown an adverse effect on the fetus, but adequate studies have not been conducted in humans. The benefits from use in pregnant women may be acceptable despite potential risks.
- D - The drug may cause risk to the human fetus, but the potential benefits of use in pregnant women may be acceptable despite the risks.
- X - Studies in animals or humans show fetal abnormalities, or adverse reaction reports indicate evidence of fetal risk. The risks involved clearly outweigh potential benefits.
- NR - Not rated.

## EVIDENCE AND REFERENCES

- <sup>1</sup> PDR 1999
- <sup>2</sup> Fiore 1996
- <sup>3</sup> Drug Facts and Comparisons 1998
- <sup>4</sup> Henningfield 1995 LE=A, SR=I
- <sup>5</sup> Setter 1998
- <sup>6</sup> Dale 1995
- <sup>7</sup> Greenland 1998 LE=A, SR=I
- <sup>8</sup> Fiore 1994 LE=A, SR=I
- <sup>9</sup> Lam 1987
- <sup>10</sup> Henningfield 1995 LE=A, SR=I
- <sup>11</sup> Thompson 1998
- <sup>12</sup> Murray 1996
- <sup>13</sup> Hughes 1998
- <sup>14</sup> Hjalmarson 1994 LE=A, SR=I
- <sup>15</sup> Hurt 1998 LE=A, SR=I
- <sup>16</sup> Tonneson 1993 LE=A, SR=I
- <sup>17</sup> PDR 1999
- <sup>18</sup> Fiore, 1996
- <sup>19</sup> Drug Facts and Comparisons 1998
- <sup>20</sup> Hurt 1997 LE=A, SR=I
- <sup>21</sup> Jorenby 1999

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APPENDIX 3

**PROMOTE TOBACCO USE CESSATION IN THE PRIMARY CARE SETTING**

**Appendix 3. Treatment/Cost**

<b>Drug and dose</b>	<b>Cost/unit<sup>1</sup></b>	<b>Cost/month</b>	<b>Rank/ Cost<sup>2</sup></b>
Nicotine patch	\$2.24-\$2.96 per patch Dose 1 patch/day(varied mg)	Average price for initial therapy-30 days = \$67.34-90.00/month	\$\$\$
Nicotine gum	2mg = \$0.33 each 4mg = \$0.37 each	12/day x 30 days = \$118.80 first month 12/day x 30 days = \$133.00 first month	\$\$
Nicotine spray	\$0.22 per mg Dose 15 mg/day	\$100.53-400.00/first month	\$\$\$\$\$
Nicotine inhaler	\$0.60-0.66 each cartridge Dose 8-16 pieces/day	\$144.00-300.00/month	\$\$\$\$
Bupropion 150 mg (Zyban)	\$0.69-.95 each tablet Dose 2 tablets/day	BID = \$41.40-57.78/month	\$

<sup>1</sup> These are acquisition costs of drug alone, not intended to represent a "full blown" cost-effectiveness hierarchy combine DoD and VHA (12/98).

<sup>2</sup> Drugs are estimated for cost per range of dosing over the therapeutic time unless specified per specific time period.

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APPENDIX 4

**PROMOTE TOBACCO USE CESSATION IN THE PRIMARY CARE SETTING**

**Appendix 4. Self-Help Material**

Self-help brochures:

National Institutes of Health, National Cancer Institute Publications Ordering Service  
PO Box 24128  
Baltimore, MD 21227  
800-422-6237

1. National Cancer Institute. Clearing the Air: How to Quit Smoking ... and Quit for Keeps. NIH Publication No. 95-1647 (Order # P133)
2. Why Do You Smoke? (brochure). NIH Publication No. 94-1822, Revised July 1993 (Order # P145)

American Cancer Society. When Smokers Quit. DHHS Publication No. (CDC) 90-8416 1990 (Call 1-800-ACS-2345)

1. Smart Move! (Order #2515)
2. Quitting Spitting (Order #2090)
3. When Smokers Quit (Order #5602)
4. Helping Smokers Quit (Order #2099)

American Heart Association 1-800-AHA-USA-1 or 242-8721

1. Quitting Smoking for Good (Order #50-1097)

Agency for Health Care Policy and Research (AHCPR) Ordering Phone # is 1-800-358-9295

For the primary care provider:

How to Help Your Patients Stop Smoking: Manual for Physicians, NIH Publication. No. 95-3064 July 1998 (Order # P138)

How to Help Your Patients Stop Using Tobacco: Manual for Oral Health Team NIH Publication No. 93-3191 August 1993 (Order # T137)

Agency for Health Care Policy and Research (AHCPR) Clinical Practice Guideline: Helping Smokers Quit AHCPR Publication. No. 96-0694 April 1996 [www.ahcpr.crov/clinic/quitsmok/htm](http://www.ahcpr.crov/clinic/quitsmok/htm)

Agency for Health Care Policy and Research (AHCPR) You Can Quit Smoking. Publication No. 96- 0695 April 1996 [www.ahcpr.crov/clinic/quitsmok/htm](http://www.ahcpr.crov/clinic/quitsmok/htm)

National Technical Information Service  
5285 Port Royal Road  
Springfield, VA 22161

Established stop smoking programs commercially available:

1. Quit Smart—self contained behavior modification program 1-888-737-6278; [www.quitsmart.com](http://www.quitsmart.com)
2. American Lung Association (ALA). Freedom from Smoking—self contained behavior modification program (call local ALA)
3. Group Health of Puget Sound. Free and Clear—behavior modification and telephone support counselors for pharmacotherapy 1-800-292-2336

Carbon Monoxide Testing Machines:

Medford Scientific  
30 Jackson Road  
Jackson Commons, Suite B-3  
Medford, NJ 08055  
800-457-5804  
Price: about \$1,300

Vitalograph, Inc.  
8347 Quivira Drive  
Lanexa, KS 66215  
(913) 888-4221  
Cost of monitor: \$1,050

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GLOSSARY

## PROMOTE TOBACCO USE CESSATION IN THE PRIMARY CARE SETTING

### Glossary

ACC/AHA	American College of Cardiology/American Heart Association
AHCPR	Agency for Health Care Policy and Research
CDC	Centers for Disease Control and Prevention
CNS	Central nervous system
DoD	Department of Defense
DSM-IVR	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition. Revised
FDA	U. S. Food and Drug Administration
LE=	Level of evidence
MAOI	Monoamine oxidase inhibitor
NIH	National Institutes of Health
NRT	Nicotine replacement therapy
O.R.	Odds ratio
OTC	Over-the-counter
PCM	Primary care managers
PCP	Primary care providers
PTSD	Post-traumatic stress disorder
SIDS	Sudden infant death syndrome
SR=	Strength of recommendation
TMJ	Temporomandibular joint syndrome
US DHHS	U.S. Department of Health and Human Services
VHA	Veterans Health Administration

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