VA/DoD CLINICAL PRACTICE GUIDELINE FOR THE

MANAGEMENT OF TOBACCO USE

Department of Veterans Affairs
Department of Defense

Update Version 2.0a

Prepared by:

MANAGEMENT OF TOBACCO USE
Working Group

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Quality Management Directorate, United States Army MEDCOM
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MANAGEMENT OF TOBACCO USE

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VA/DoD CLINICAL PRACTICE GUIDELINE FOR THE **MANAGEMENT OF TOBACCO USE**

INTRODUCTION

The 2003 **VA/DoD Clinical Practice Guideline for the Management of Tobacco Use** is a modification of the 1999 VHA/DoD Clinical Practice Guideline for the Management of Tobacco Use Cessation in the Primary Care Setting and reflects tobacco research published since the completion of the previous version.

In the development of this guideline, the Working Group heavily relied on the following evidence-based guidelines: [1]

- 1999 VHA/DoD Clinical Practice Guideline to Promote Tobacco Use Cessation in the Primary Care Setting (v1.0)
- Clinical Practice Guideline for Treating Tobacco Use and Dependence. U.S. Department of Health and Human Services - Public Health Service (PHS); June 2000
- Recommendations Regarding Interventions to Reduce Tobacco Use and Exposure to Environmental Tobacco Smoke. Task Force on Community Preventive Services; 2001

The PHS guideline, published in 2000, includes an extensive review of the literature and 26 new meta-analyses that were used to formulate new recommendations. A comparison of the research findings in the PHS guideline and in additional research published after 2000 with the previous 1999 VHA/DoD guideline reveals that considerable progress has been made in tobacco research over the brief period separating these two works. The research in recent years shows:

- Strong evidence of the association between counseling intensity and successful treatment outcomes. It also reveals evidence of additional effective counseling strategies, to include telephone counseling and counseling that helps smokers enlist support outside the treatment context.
- Many more effective pharmacologic treatment strategies available to the provider than were identified in the previous guideline. There are now seven different effective smoking cessation medications, allowing the provider and patient many more treatment options. Further information is available on the efficacy of combinations of nicotine replacement therapies (NRTs) and pharmacotherapies that are obtained over-the-counter.
- Strong evidence that smoking cessation treatments shown to be effective in this guideline (both pharmacotherapy and counseling) are cost-effective relative to other routinely reimbursed medical interventions (e.g., treatment of hyperlipidemia and mammography screening).

A conclusion of these findings suggests that smoking cessation treatments should not be withheld from patients when other less cost-effective medical interventions are routinely delivered. Furthermore, *access to tobacco treatment should be as easy as purchasing tobacco products.*

The changes to the 2003 guideline provide a more comprehensive approach to the problem of tobacco use among veterans, military personnel, and their families. The Working Group hopes that this updated guideline assists 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.

[1] [1] The U.S. Preventive Services Task Force (USPSTF). Counseling to prevent tobacco use and tobacco caused disease: recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2003 Nov. 13 p. [22 references] –has been included in the final editing of this update

Population health:
The emphasis on population health represents a major change to this guideline. The prior version focused on ensuring that tobacco users were encouraged to attend a cessation program, generally regarded as the most effective treatment available. Despite major improvements in care for tobacco users, the prevalence of tobacco use remains high. Cessation programs are broadly available but are currently used by only a small proportion of tobacco users. Why then are we shifting the emphasis from cessation programs to primary care-based treatment, with a much lower rate of success? The answer is that *it should lead to more people becoming abstinent from tobacco.* To see this, it is necessary to assess the impact of a program on the entire population of tobacco users attending a health care facility. From a population perspective, the impact can be thought of as a product of the reach (percentage of population using a service) and the effectiveness of the service. Consider two examples. First, an institution that was able to get 5 percent of tobacco users to attend a cessation program with a 20 percent long-term success rate would achieve abstinence in 1 percent of the population. Alternatively, if treatment within primary care has a 7.5 percent long-term success rate and 40 percent of tobacco users are treated, the number of tobacco users who become abstinent is three times that of the first example. Therefore, population health means focusing on interventions that have broad reach and will help support all tobacco users' efforts to quit.

Access to counseling and pharmacotherapy:
Tobacco use is the targeted behavior and *tobacco users* are the clinical population of interest. Ensuring that all tobacco users have convenient access to counseling and pharmacotherapy is a necessary concomitant of the population health approach. It would be pointless to aim for high rates of treatment within primary care for treatments that are not easily available. This shift in emphasis mirrors one occurring in managed care nationwide, as newer quality measures emphasize ensuring that all tobacco users are offered treatment. In addition, it encourages intervening in a variety of medical settings, including primary care, pediatrics, and dental clinics. Recommendations also include the use of telephone Quitlines and other community resources to attempt to reach the entire population of tobacco users. This is especially relevant to a military population that tends to be young and healthy and therefore, may utilize medical clinics less frequently. The definition of the target population has been expanded in this version to include children, teenagers, and young adults (age >12 years.)

Prevention:
Because the goal of this guideline is to reduce the overall prevalence of tobacco use in the beneficiary population, prevention is included as a major emphasis area. A separate pathway for prevention has been added to the guideline to address not only those who have recently quit using tobacco, but also to reinforce those who don't use tobacco, to stay tobacco-free.

Prevention is especially important for the DoD population of new recruits, who have the highest overall prevalence of tobacco use in the DoD. Over 80 percent of smokers begin before age 18, and those who start tobacco use at an early age are most likely to continue to smoke into adult life. Every year, over 200,000 new recruits to the military are required to be tobacco-free for a minimum of six weeks while they go through their initial training (CDC, 1998). Every graduating recruit is tobacco-free when they complete recruit training. Prevention efforts are critical to help reinforce the decision to stay quit. Interventions for the primary prevention of tobacco use are included only if they are directly relevant to clinical practice. Community-level interventions (e.g., mass media campaigns) that are not usually implemented in primary care practice settings are not addressed.

Change in format:
Great effort was taken in this update to provide clear objectives and direct recommendations in a behavioral format. Establishing a set of desired treatment behaviors will hopefully make implementation much easier. Elaboration of the recommendations and a review of the evidence are included in the Discussion section of each annotation. The guideline update also emphasizes the importance of a collaborative approach between the provider and patient. Tobacco dependence is a chronic disease that often requires repeated interventions. The treatment of tobacco use carries with it the vulnerability to lapse and relapse, and the actual process of establishing long-term abstinence takes many months. Because of the chronic nature of tobacco use, the patient must be a partner and willing participant in all aspects of treatment. This underlies the shift in emphasis within the guideline, from recommending the best treatment in the prior version to arriving at a mutually agreeable

treatment plan in the current version. In addition to a focus on interventions for the motivated patient, we have also included intervention strategies aimed at increasing readiness to quit for those tobacco users not yet willing to stop.

To facilitate the provision of brief advice by providers, the guideline includes several examples and scripts for successful strategies experienced in other institutions or adopted from the PHS (see Appendix A). Several Annotations in the update of the VA/DoD guideline have been adapted from the Clinical Practice Guideline for Treating Tobacco Use and Dependence, Clinical Practice Guideline. Rockville, MD: US Department of Health and Human Services, Public Health Service (PHS); 2000. Meta-analysis tables included in the PHS guideline and the respective list of studies included in the meta-analyses is cited in these annotations using the format: "PHS Table # _".

Guideline Development

The development process of this update follows a systematic approach described in "Guideline-for-Guideline," an internal working document of VHA's National Clinical Practice Guideline Counsel. Appendix B clearly describes the guideline development process.

Although most of the tobacco research involves 'smoking', the Working Group believes that the findings are relevant to all forms of tobacco use. Providers should identify smokeless/spit tobacco users and users of cigars, pipes and other noncigarette combustible forms of tobacco, strongly urge them to quit and treat them with the same cessation interventions recommended for cigarette smokers. The term 'tobacco user' refers to anyone who uses cigarettes, non-cigarette tobacco products (cigars, pipes), and smokeless/spit tobacco products (chewing tobacco and snuff).

Evidence from randomized controlled trials (RCTs) has demonstrated that repeated advice, from different types of providers, over time has a significant effect on increasing the numbers of tobacco users who will try to quit, and has shown an increase in abstinence rates. This guideline is designed for three main audiences: primary care providers/managers (including dental providers); tobacco dependence treatment specialists; and health care team members and administrators across the health care systems of the VA and DoD. When referring to any of these providers of care the term "provider" is used throughout the guideline.

Implementation

The guideline and algorithms are designed to be adapted to the individual facility's needs and resources. They will be updated periodically or when relevant research results become available. They should be used as an impetus for administrators in the Department of Veterans Affairs or at each Veterans Integrated Services Network (VISN) facility or Department of Defense (DoD), medical center or medical treatment facility (MTF), and other care access sites to develop innovative plans to remove barriers that prevent primary care providers, sub specialists, and allied health professionals from working together, and barriers that prevent tobacco users from having convenient access to counseling and pharmacotherapy to help them quit.

There is increasing evidence that the success of any ***tobacco dependence treatment strategy cannot be divorced from the health care system*** in which it is embedded. Data strongly indicate that the consistent and effective delivery of tobacco interventions requires ***coordinated interventions***. Just as a provider must intervene with his or her patient, so must the health care administrator, insurer, and purchaser foster and support tobacco dependence treatment as an integral element of health care delivery.

The implementation of strategies for cessation and prevention of tobacco use is dependent on a systematic and consistent approach of the health care system itself. **Leadership support** in the local facility, as well as at the national level, is essential to achieve the challenge of tobacco use reduction. The utmost goal of the individual providers and the health care system is to eliminate the barriers to implementation of those treatments, which have proven to be effective in reducing tobacco use. Hence, the Working Group decided to include a list of evidence-based recommendations aimed at the system level (see Appendix E). Success should be celebrated at the individual level as well as at the system level at large.

Key Elements

1. **Every** tobacco user should be advised to quit.
2. Tobacco use is a **chronic relapsing condition** that requires repeated interventions.
3. Several **effective treatments are available** in assisting users to quit.
4. It is essential to **provide access** to effective **evidence-based** tobacco use **counseling treatments and pharmacotherapy**.
5. **Collaborative tailored treatment strategies** result in better outcomes.
6. Quitting tobacco leads **to improved health and quality of life**.
7. **Prevention strategies** aim at reducing initiation, decreasing relapse, and eliminating exposure to environmental tobacco smoke.

Performance Measurement
The inability of consumers and health care purchasers to determine if medical care is appropriate and effective has given rise to the concept that the health care system should be held accountable for what is done and the outcomes achieved. This principle of accountability has resulted in the development of so-called "performance and outcome measures" which are administered through "report card" systems. Measures must be seen as fair and reasonable and must be achievable in various practice settings, when carried out either by providers or tobacco dependence treatment specialists.

Performance measures are indicators or tools to assess the level of care provided within systems of care to populations of patients who use tobacco products. The measures are constructed to best utilize the available evidence for assessing care or outcomes of care in systems where test reliability, patient characteristics, (co-morbidity), and compliance cannot be easily determined and taken fully into consideration (i.e., the measures are not case-mix adjusted). The current state of the art measurement system does not allow full adjustment for factors outside the control of the health care system.

The Working Group suggests that the following indicators be considered in establishing the performance measurement system:

- Decrease number of **tobacco users**.
- Increase number of patients **screened** for tobacco use.
- Increase number of patients **advised to quit**.
- Increase **documentation** of patient smoking status and treatment outcomes.
- Increase **number of tobacco** users enrolled in treatment (e.g., prescribed pharmacotherapy)
- Increase level of **trained providers**.

GUIDELINE UPDATE WORKING GROUP

VA	DoD
Scott Sherman, M.D., M.P.H. (co-chairman)	**Gerald Talcott, Col, Ph.D, USAF** (co-chairman)
Linda H. Ferry, M.D., M.P.H.	**William P. Adelman, MAJ, M.D., USA**
Mark C. Geraci, Pharm.D., BCOP	**Geralyn K. Cherry, MAJ, M.S.N., R.N., USA**
Kim W. Hamlett-Berry, Ph.D.	**Steve Heaston, R.N., C.S., M.P.H.**
Richard T. Harvey, Ph.D.	**Mark A. Long, Ed.D.**
Steven Yevich, M.D.	**Eugene Moore, Pharm.D.**
	Sharon E. Reese, LTC, B.S.N., M.P.H., USA
CDC	**Pamila Richter, R.D.H.**
Abby C. Rosenthal, M.P.H.	**Lisa Schmidt, MAJ, B.S.N., M.S.A., USAF**
	Larry N. Williams, CAPT, D.D.S., USN

FACILITATOR
Oded Susskind, M.P.H.

COORDINATOR
Joanne Marko, M.S., CCC-SLP

RESEARCH TEAM–EVIDENCE APPRAISAL REPORTS

Center for Evidence-Based Practice
State University of New York, Upstate Medical University,
Department of Family Medicine

Lorne Becker, M.D. – Director
R. Eugene Bailey, M.D.
John Epling, M.D.
William Grant, Ed.D.
Jennifer Schultz, M.S.Ed.
Sandra M. Sulik, M.D., M.S.

ACS Federal Healthcare, Inc. Alexandria, VA.

Diane Boyd, Ph.D.
Paul Grimaldi, Ph.D.
Sarah Ingersoll, R.N., M.B.A.
Russell Smith, M.L.S.

TECHNICAL CONSULTANTS

Lara Bainbridge
Oneil Brown
Sara Thomas

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Task Force on Community Preventive Services. Recommendations Regarding Interventions to Reduce Tobacco Use and Exposure to Environmental Tobacco Smoke. Am J Prev Med 2001;20(2S):10-15.

VA/DoD Clinical Practice Guideline for the Management of Tobacco Use Cessation in the Primary Care Setting 1999. http://www.oqp.med.va.gov/cpg/cpg.htm or http://www.qmo.amedd.army.mil

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Assessment and Treatment

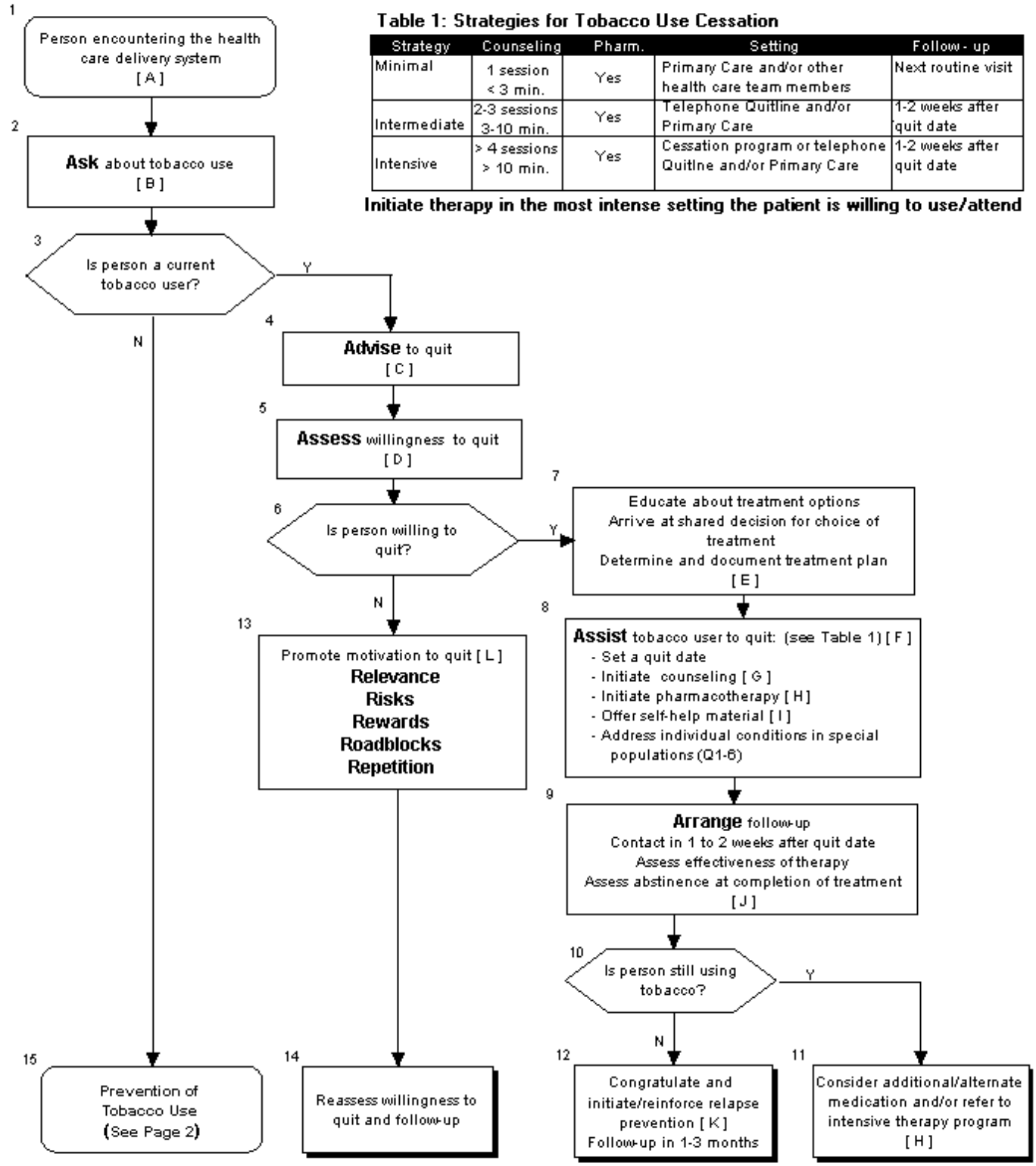


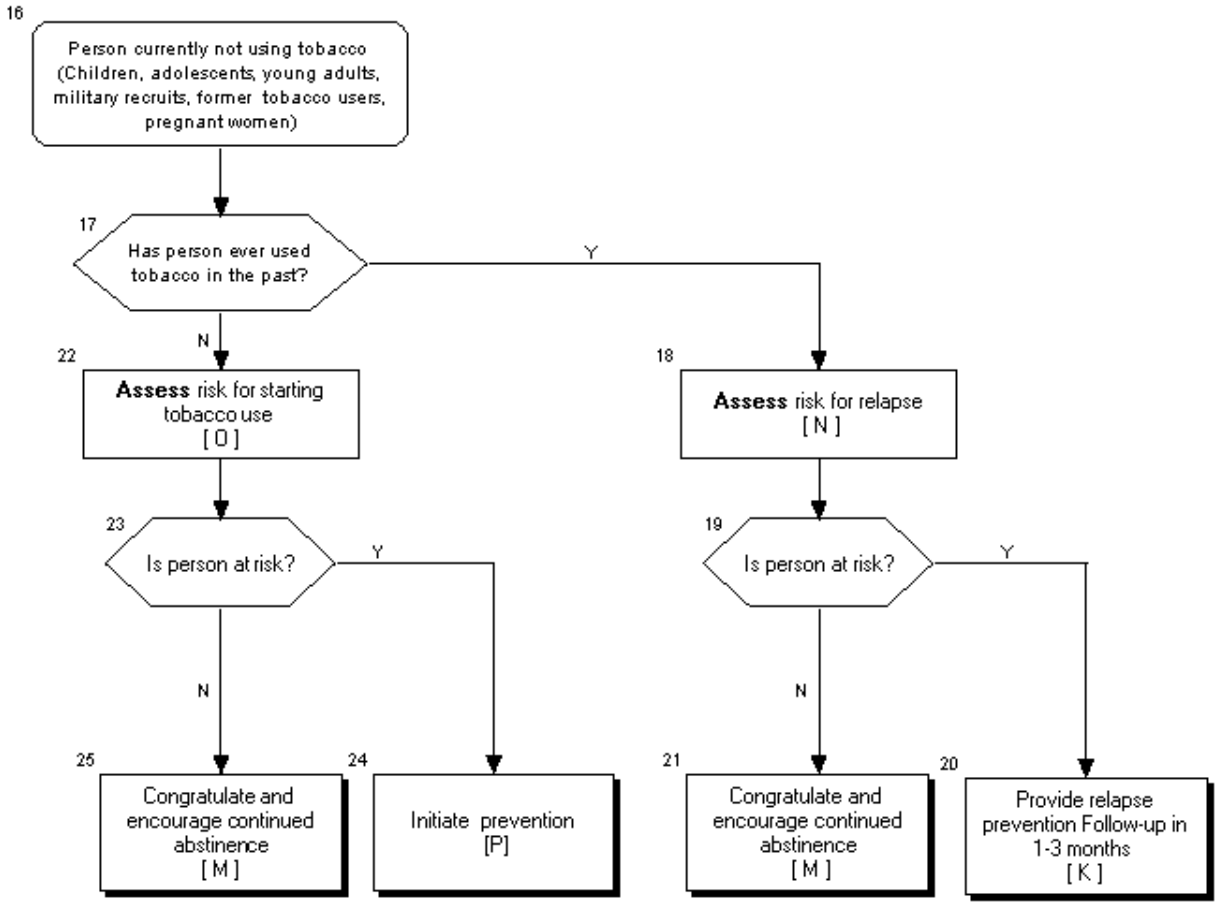
Table 1: Strategies for Tobacco Use Cessation

Strategy	Counseling	Pharm.	Setting	Follow - up
Minimal	1 session < 3 min.	Yes	Primary Care and/or other health care team members	Next routine visit
Intermediate	2-3 sessions 3-10 min.	Yes	Telephone Quitline and/or Primary Care	1-2 weeks after quit date
Intensive	> 4 sessions > 10 min.	Yes	Cessation program or telephone Quitline and/or Primary Care	1-2 weeks after quit date

Initiate therapy in the most intense setting the patient is willing to use/attend

VA/DoD Clinical Practice Guideline for the Management of Tobacco Use

Prevention



ANNOTATIONS

ASSESSMENT AND TREATMENT

A. Person Encountering The Health Care Delivery System

Any person (age >12) 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.

BACKGROUND

In order to assess tobacco use status, all patients should be asked about their use of tobacco (including the use of tobacco in any form) upon visiting any provider. This may be accomplished when the patient's vital signs are taken. The tobacco use status should be noted in the patient's record. If the medical record indicates that the patient has never used tobacco or has not used it for many years, repeated assessment is not necessary. The frequency of screening in the health care system (every visit, most visits, or only specific periodic visits) is a function of the balance between preventing tobacco use and over-burdening the system.

Tobacco use includes cigarette smoking as well as the use of other tobacco products (e.g., cigars, pipes, and smokeless tobacco) that are harmful.

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)

DISCUSSION

The meta-analysis of nine studies in PHS Table 8 demonstrated that having a screening system in place for tobacco use increases the rate of provider intervention with patients. However, three studies, summarized in PHS Table 9, suggest that having a screening system in place to identify tobacco users does not significantly increase the rates of tobacco cessation. Although screening increases the rate of provider intervention, there is insufficient evidence to make a specific recommendation on the incremental effectiveness of repeated screening or specific screening intervals.

Evidence from controlled trials shows that including tobacco-use status as a vital sign, using systematic prompts and reminders, increases the probability that tobacco use is consistently assessed and documented (Ahluwalia 1997; Ahluwalia et al., 1999; Chang et al., 1995; Fiore et al., 1995; Robinson et al., 1995; Yarnall et al., 1998). Although the data assessing this intervention were exclusively gathered from cigarette smokers, the panel felt that these results were generalizable to all tobacco users.

EVIDENCE

	Evidence	Sources of Evidence	QE	Overall Quality	R
1	Tobacco use screening system to identify smokers	PHS Table 8 PHS Table 9	I	Good	A

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

C. Advise to Quit

OBJECTIVE

Promote motivation to quit tobacco use.

BACKGROUND

Every health care team member should urge every tobacco user to quit. Repeated messages on the importance of quitting made over time have an accumulated effect on encouraging patients to quit. This message should be delivered in the brief "advice" format such that it is clear, (e.g., "I think it is important for you to quit tobacco use now and I can help you."), concise, strong, (e.g., "As your clinician I want you to know that quitting tobacco use is the most important thing you could do to protect your health.") and personalized (e.g., "Quitting your tobacco use will help improve your [health symptom or specific disease]").

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]

DISCUSSION

The Clinical Practice Guideline for Treating Tobacco Use and Dependence (Fiore et al., 2000) included the following:

> "…In the studies used in this analysis, the modal length of clinician intervention was 3 minutes or less. Two studies in this analysis used interventions lasting about 5 minutes. Results of the meta-analysis on physician advice are shown in PHS Table 11. This analysis shows that brief physician advice significantly increases long-term smoking abstinence rates."
>
> Physician advice is only examined in the PHS Table 11 meta-analysis because there were too few studies to examine advice delivered by other types of clinicians. The analysis for total amount of contact time (see PHS Table 13) indicates that minimal counseling (advice) delivered by a variety of clinician types increases long-term abstinence rates. Also, it should be noted that studies have shown that dentists and dental hygienists can be effective in assessing and advising patients who use smokeless/spit tobacco to quit. Given the large number of smokers who visit a clinician each year, the potential public health impact of universal advice to quit is substantial.

Rice and Stead (2001) reviewed 16 studies comparing nursing advice to control and found a significant increase in the odds of quitting (odds ratio [OR] 1.50; confidence interval [CI] 1.29-1.73). Results indicated a potential benefit of advice given by nurses to patients.

In the Cochrane Review, Silagy and Stead (2000) identified 34 trials. "Pooled data from 16 trials of brief advice versus no advice (or usual care) revealed a small but significant increase in the odds of quitting (OR

1.69, 95% CI 1.45 to 1.98). This equates to an absolute difference in the cessation rate of about 2.5 percent. There was insufficient evidence, from indirect comparisons, to establish a significant difference in the effectiveness of physician advice according to the intensity of the intervention, the amount of follow-up provided, and whether or not various aids were used at the time of the consultation in addition to providing advice. However, direct comparison of intensive versus minimal advice showed a small advantage of intensive advice (OR 1.44, 95% CI 1.23 to 1.68). Only one study evaluated the effect of advice to quit on mortality. It found no statistically significant differences in death rates at twenty years follow-up." The Cochrane reviewers concluded "simple advice has a small effect on cessation rates."

EVIDENCE

	Evidence	Sources of Evidence	QE	Overall Quality	R
1	Physician advice to quit smoking increases abstinence rates.	PHS Table 11 Silagy & Stead, 2000 U.S. PSTF, 1996	I	Good	A
2	Minimal contact time increases long-term abstinence.	PHS Table 13	I	Good	A
3	Advice to quit by all types of non-physician clinicians is effective in increasing patients' long-term quit rates.	Rice & Stead, 2001	I	Fair	B

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.

BACKGROUND

Tobacco users should be given advice appropriate to their level of interest in quitting. Approximately 70 percent of tobacco users want to quit. The patient's level of interest will determine subsequent steps to be taken. By knowing the person's stage of willingness to quit tobacco use, the health care provider can decide whether to provide motivational material to quit tobacco use, or alternatively, specific instructions to help the person quit.

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]

DISCUSSION

The Centers for Disease Control and Prevention (CDC) analyzed self-reported data from the 2000 National Health Interview Survey (NHIS) sample Adult Core questionnaire and Cancer Control module. This report indicated that, in the year 2000, approximately 23.3 percent of adults were current smokers compared with 25 percent in 1993, reflecting a modest but statistically significant decrease in prevalence among U.S. adults. In 2000, an estimated 70 percent of smokers said they wanted to quit, and 41 percent had tried to quit during the preceding year and only 4.1 percent actually remained abstinent for 12 months; however, marked differences in successful quitting were observed among demographic groups (CDC, MMWR 2002). Performance data

collected in the VHA have reported similar rates of patients willing to quit (Office of Quality and Performance, VHA, 1999).

There is little direct evidence supporting assessing readiness to quit tobacco use. Nonetheless, factors included in the Transtheoretical Model (DiClemente et al., 1991; Prochaska & DiClemente, 1983) are associated with higher abstinence rates. For advice to be credible, clinical experience suggests that it must address the patient's wishes or concerns.

E. Educate About Treatment Options; Arrive At Shared Decision For Choice Of Treatment; Determine And Document Treatment Plan

OBJECTIVES

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

BACKGROUND

Once the tobacco user has stated a willingness to quit, the provider and patient should discuss the available treatment options. It should be noted that the same modality of tobacco use treatment will not be appropriate or desirable for every patient – one size does not fit all. This is an important step, combining the provider's knowledge of the treatment options and their characteristics with the patient's preferences and individual needs. When ever possible, a more intensive treatment option should be available, as it has shown a higher success rate for patients who are willing to attend.
The provider should outline the different available treatment choices (treatment within primary care, telephone counseling, and referral to an intensive cessation program). The provider and patient may also want to take into account the patient's available social support and other psychosocial factors that may affect cessation success/relapse (e.g., major life changes or stressors or depression), as well as possible barriers to various treatment options/combinations (e.g., concerns about a time commitment, traveling to a group, or lack of access to the internet). In some cases, the provider may need to help the patient select program(s) that pertain(s) to their comorbid condition. Depending on the desires of the patient, level of training of the provider, the local resources of the health care setting, and the level of administrative support, the patient should be able to select from a variety of tobacco treatment options.

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, co-morbid 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]

DISCUSSION

Describing the treatment options and evidence of efficacy to the patient allows them to choose the most appropriate treatment option to meet their needs and preferences. For example, pharmacologic treatment appears more effective at preventing weight gain than counseling (Leischow & Stitzer, 1991). Research suggests differences exist between females and males regarding concerns about post-cessation weight gain.

While there has been considerable literature supporting a shared approach to decision-making (Edwards et al., 2003; O'Connor et al., 2001), there have been no studies examining this approach to choosing treatment for tobacco use cessation.

The selected strategy must be individualized for each patient based on the provider's appraisal of the patient's comorbidity, current tobacco use, level of dependence, daily schedule, relapse risk factors, concern about weight gain, available support, and willingness to quit. Following counseling, the patient's own preferences should be factored into the decision-making. The provider and the patient must mutually determine the goal of the proposed therapeutic regimen and patient preferences. The provider and patient should select the most intensive strategy that the patient is willing to use to maximize the likelihood for a successful quit. More contact time generally lead to increase likelihood for a successful quit.

EVIDENCE

	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.

BACKGROUND

Tobacco cessation treatment is effective and should be provided for all patients willing to quit. At a minimum, all treatment should include: 1) helping the patient set a quit date, 2) prescribing of pharmacotherapy, 3) providing brief counseling, 4) providing self-help materials and 5) addressing potential barriers to treatment.

Treatment using effective interventions appears to have a linear dose-response for successful tobacco cessation. Treatment could be conveniently categorized into three groups; minimal, intermediate and intensive (see Table 1). These treatment categories are discriminated by the treatment setting and intensity. Generally, tobacco users should be encouraged to choose the most intensive treatment available that they are willing to use/attend. Effective treatment can be delivered in primary care, specialty clinics for tobacco use cessation, or by telephone.

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]

DISCUSSION

Pharmacotherapy and counseling approaches have strong evidence of efficacy for tobacco use cessation: Each is effective by itself, but the two in combination achieve the highest rates of cessation. (Rigotti, 2002)

Randomized, controlled trials conducted in primary care practices demonstrate that a physician's advice to stop smoking increases the rates of smoking cessation among patients by approximately 30 percent. (Lancaster & Stead, 2002; PHS table 12;14) The efficacy of a treatment correlates with its intensity (Silagy & Stead, 2001; PHS Table 13), but even brief interventions by physicians during an office visit promote smoking cessation. Providing a brief period of counseling (three minutes or less) is more effective than simply advising the patient to quit and doubles the cessation rate, as compared with no intervention. (PHS Table 12)

Effective interventions in most clinical trials have a common approach that includes advising the patient to quit, and are followed by a combination of interventions that assist the patient in overcoming the nicotine dependency (craving for tobacco or cigarette), and modifying his/her behavior to maintain abstinence.

The components and intensity of the intervention were addressed by previous evidence-based guidelines. In a summary of selected evidence-based guidelines and reports, Hopkins et al. (2001b) quoted the following:

Guide to Clinical Preventive Services (U.S. PSTF, 1996)

- Tobacco cessation counseling on a regular basis is recommended for all patients who use tobacco products
- Tobacco cessation counseling is recommended for all patients who use tobacco products

Reducing Tobacco Use: A Report of the Surgeon General (CDC, 2000)

- Minimal clinical interventions foster smoking cessation
- Minimal interventions are effective in increasing smoker's motivation to quit and are cost-effective
- The success of counseling and advice increase as the intensity of intervention increases (i.e., increasing frequency and duration of contact)

Clinical Practice Guideline for Treating Tobacco Use and Dependence (Fiore et al., 2000)

- All physicians should strongly advise every patient who smokes to quit in that it increases abstinence rates (OR 1.3; 95% CI 1.1, 1.6) [PHS Table 11]

- There is a strong dose-response relationship between session length of person-to-person contact and successful treatment outcomes. More intensive interventions should be used when possible (OR of higher intensity counseling 2.3; 95% CI 2.0, 2.7) [PHS Table 13]

The U.S. PSTF Update to the Preventive Services guideline 2003 stated: (U.S. PSTF, 2003)

- The USPSTF strongly recommends that clinicians screen all adults for tobacco use and provide tobacco cessation interventions for those who use tobacco products **(A recommendation)**.

- Brief tobacco cessation counseling interventions, including screening, brief counseling (3 minutes or less), and/or pharmacotherapy, have proven to increase tobacco abstinence rates, although there is a dose-response relationship between quit rates and the intensity of counseling. Effective interventions may be delivered by a variety of primary care clinicians.

Based on trends showing increased efficacy for medication treatment and better outcomes when counseling is complemented by drug therapy, the Working Group opted to be consistent with the evidence and recommend that every tobacco user who is willing to quit should receive a combination of interventions that includes counseling, pharmacotherapy, and follow-up.

The dose response relationship, found by several of the studies, led the Working Group to construct the matrix in Table 1. Providers may refer to Table 1 for general guidance when individualizing treatment decisions and tailoring therapy for the specific patient.

Intensive cessation programs (regarded as the most effective treatment available), are currently used by only a small proportion of tobacco users. From a population health perspective, focusing on interventions that have broad reach and will help support all tobacco users' efforts to quit may have a greater impact on the final outcome (i.e., reducing the prevalence of tobacco use). Focusing on brief interventions that reach a larger proportion of the population may be a more cost effective approach.

Table 1. Strategies for Tobacco Use Cessation
Each strategy should include pharmacotherapy, counseling, and follow-up. Ensure counseling and pharmacotherapy in the most intense setting that the patient is willing to use/attend and consider patient education materials.

Strategy	Counseling	Pharmacotherapy (e.g., NRT or buproprion)	Typical Setting (individual or group)	Follow-up
Minimal	1 session <3 min	YES + Instructions print-out	Primary care provider *and/or* Other health care team members	Next routine visit
Intermediate	2 - 3 sessions 3-10 min	YES + Instructions print-out	Telephone Quitline**and/or* Primary care provider	1-2 weeks after quit date
Intensive program	≥4 sessions >10 min	YES + Instructions print-out	Cessation program *or* Telephone Quitline* *and/or* Primary care provider	1-2 weeks after quit date

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

Minimal level of interventions can (should) be provided in the primary care clinic. The "minimal" refers only to the duration of counseling, not to its effectiveness. The intervention should include offering smoking cessation medications (either nicotine replacement therapy or bupropion) in conjunction with brief counseling (typically less than 3 minutes in duration). When possible, providers should follow-up with the patient 1-2

weeks after the quit date to assess tolerance to the medication and provide additional brief advice, as this further increases rates of successful smoking cessation.

Intermediate interventions typically include 2-3 sessions of advice, often for somewhat longer duration (3-10 minutes) than that of minimal interventions. This should also be in conjunction with the use of smoking cessation medications. Follow-up can be by the primary care provider, but given time constraints, many experts suggest other approaches to follow-up, such as proactive telephone counseling.

Intensive counseling can be delivered effectively in person or by telephone. Group or individual counseling is effective when it is provided by trained counselors and includes repeated contacts over a longer period of time. Intensive counseling includes several sessions (at least four session) of longer duration (10 minutes or more), making this requirement beyond what most primary care providers are able to offer. The efficacy of this approach increases as the amount of time spent with the patient increases. If the patient and provider chose the intensive strategy, which also includes medications and requires more specialized counseling, the provider should refer the patient to existing intensive cessation program. These programs are offered as group or individual face-to-face program, or proactive telephone programs (Quitlines). Referrals to an intensive program generally have the highest success rate with patients who choose to enroll and are motivated to attend. Many smokers cannot, or do not follow through with referral and the provider should follow-up with the patient after the referral to ensure that they are enrolled in the intensive intervention.

Patient Education Material: Smoking-cessation counseling strategies are also summarized in pamphlets and booklets, audiotapes, videotapes, and computer programs. Written self-help material may increase quit rates compared to no intervention, but the effect is likely to be small (Lancaster & Stead 2002). While there is evidence that self-help materials are more effective than no intervention, there is no evidence that they offer any incremental benefit in patients who are receiving counseling and/or pharmacotherapy. Nevertheless, the working group consensus was to still recommend the use of self-help materials when feasible, for two reasons. First, the materials may have some effect in motivating smokers to make a quit attempt. Second, they save time for the provider, as he or she can provide brief counseling and then refer the patient to the self-help materials for additional details and advice.

Educational material should be made available for tobacco users and placed in various locations to make them more accessible:

- Generic brochure describing treatment options treatment options, strategies for quitting, self monitoring forms for recording tobacco use and plans for quitting. A brochure like that can be given to tobacco users as part of the brief intervention.
- A more detailed brochure (e.g., "You Can Quit") may include treatment strategies for quitting, self monitoring forms for recording tobacco use and plans for quitting, stress management and nutrition information, local resources available and web sites that may help with the quitting process. A brochure like that can be used a s a tool in assisting tobacco users in the quitting process as par tof intermediate strategy.
- The intensive programs for cessation incorporate several handouts focusing on specific problems/skills (e.g., weight gain and withdrawal symptoms). Some examples include 12-step programs (Nicotine Anonymous), computer-based tobacco intervention programs, internet web sites, and various community programs.

For more details on the different components of these interventions please see annotations G (Counseling) ,H (Pharmacotherapy) and I (Self help -education) and J (Follow-up)

Other Interventions:
Individual patients may opt choosing one of the following alternative therapies. Since there is insufficient evidence to support the use of the following strategies, they should be viewed as complimentary to evidence based intervention and not as replacement.

- **Acupuncture**:

From The Clinical Practice Guideline for Treating Tobacco Use and Dependence (Fiore et al., 2000):

> The acupuncture meta-analysis comparing "active" acupuncture with "control" acupuncture revealed no difference in efficacy between the two types of procedures. These results suggest that any effect of acupuncture might be produced by factors such as positive expectations about the procedure. PHS Table 24

A Cochrane Review (White et al., 2002) identified 22 studies that showed acupuncture was not superior to sham acupuncture in smoking cessation at any time point. Early outcomes odds ratio was 1.22, which increased to 1.5 at 6 months. However, at 12 months, odds ratio was 1.08. Similarly, when compared with other anti-smoking interventions there were no differences in outcome. Acupuncture appeared to be superior to no intervention in early results, but this difference was not sustained.

- **Hypnosis**:

From The Clinical Practice Guideline for Treating Tobacco Use and Dependence (Fiore et al., 2000):

> The original guideline did not conduct a separate meta-analysis on hypnosis because few studies met inclusion criteria, and those that did used very heterogeneous hypnotic procedures. There was no common or standard intervention technique to analyze. Literature screening for the updated guideline revealed no new published studies on the treatment of tobacco dependence by hypnosis that met the inclusion criteria; therefore, this topic did not warrant re-examination. Moreover, an independent review of hypnotherapy trials by the Cochrane Group found insufficient evidence to support hypnosis as a treatment for smoking cessation (Abbott et al., 1999).

A more recent update of the Cochrane by Abbot et al. (2001) showed that hypnotherapy had greater effect on 6 month quit rates in uncontrolled studies. This effect was not confirmed by randomized controlled trials (RCTs).

Stepped-Care Model:

There is not enough evidence to propose a recommendation regarding a stepped-care model for delivery of tobacco dependence treatment.

EVIDENCE

	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.	PHS Table 14	I	Good	A
3	Pharmacotherapy increases abstinence rates.	See Annotation H	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.

BACKGROUND

There is strong evidence that behavioral interventions work. More intense interventions, as defined by face-to-face contact, using a multidisciplinary approach and multiple formats, result in better cessation outcomes. However, even brief counseling increases overall abstinence rates. Effective counseling can also be provided by a wide variety of health care professionals, in addition to the patient's primary care physician. Tobacco use counseling and treatment can be provided in a variety of settings. It is crucial that the provider ensure that the tobacco user receives counseling and medication to assist him/her in quitting, regardless of the setting. For adolescent counseling, see Annotation Q-1 – Children and Adolescents.

Counseling tobacco users should start with having the patient set a quit date. Counseling and behavioral tobacco use cessation interventions should include: (1) providing practical counseling (problem-solving skills/skills training), (2) providing social support as part of treatment, and (3) helping tobacco users obtain social support outside of treatment. These three types of counseling and behavior therapies result in higher abstinence rates (see Appendix A-1 - Counseling: Brief Strategies and A-2 – Counseling: Techniques). Proactive telephone counseling, such as that provided by a Quitline, is another effective option for providing counseling to tobacco users

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 (Quit lines or intensive cessation program).

Quitlines

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

DISCUSSION

Cessation counseling is a fundamental part of any tobacco cessation treatment plan. Effective counseling options range from minimal counseling (such as would typically be received within a primary care setting) to intensive counseling (such as from an intensive cessation program).

PHS Table 20 summarizes the efficacy of various types of counseling and behavioral therapy.

Brief Counseling:
Minimal counseling (lasting less than 3 minutes) is effective at helping tobacco users quit. PHS Table 12 shows that counseling for less than 3 minutes was more effective than no contact (OR 1.3, 95% CI 1.01-1.6). Similarly, a recent Cochrane review of physician advice for smoking cessation found that brief advice (delivered within primary care in most studies) increased the odds of successfully quitting (OR 1.69, 95% CI 1.45-1.98) (Silagy & Stead, 2001). Intensive physician counseling (typically more than 10 minutes) *was marginally more* effective than brief advice (OR 1.44, 95% CI 1.23-1.68).

Counseling Intensity:
Counseling that occurs at multiple sessions is more effective than counseling that occurs at a single session. PHS Table 14 shows that there was increased success with 2-3 counseling sessions as compared with 0 or 1 counseling sessions (OR 1.4, 95% CI 1.1-1.7). The rate of success was even higher when there were at least 8 counseling sessions (OR 2.3, 95% CI 2.1-3.0). Additionally, a meta-analysis evaluating the total amount of contact time showed a dose response relationship between time spent in counseling and the rate of abstinence [PHS Table 13]. All patients should have reasonable access to minimal counseling as well as to either an intermediate or intensive cessation program.

Counseling Format:
Effective counseling for tobacco cessation can be delivered in a variety of methods and from a variety of different health care professionals. Minimal counseling and proactive telephone counseling are both effective, as is group counseling [PHS Table 17; Stead & Lancaster, Group behavior therapy, 2002]. Counseling delivered in multiple formats may be more effective than counseling delivered in a single format [PHS Table 18]. Many different clinician types have been shown to be effective at providing tobacco use cessation counseling when compared to intervention with no clinicians [PHS Table 15]. In a recent meta-regression of different provider types, the odds ratio was highest for physicians (OR 3.02, 95% CI 2.62-3.48), psychologists (OR 2.68, 95% CI 1.79-4.00), and nurses (OR 2.38, 95% CI 1.87-3.03).

Telephone Counseling:
Proactive telephone counseling, such as that provided by a Quitline, is another effective option for providing counseling to tobacco users. PHS Table 17 shows the effectiveness of proactive telephone counseling, as does a more recent Cochrane review (Stead & Lancaster, Telephone Counseling, 2001). A recent study by Zhu et al. (2002) of 3,282 tobacco users who called the California Smokers Helpline found that a telephone counseling protocol was effective when translated into a real-world setting, with abstinence rates in the telephone group approximately double those of the control group. Publicly funded Quitlines for tobacco use cessation are currently available in most states. While the content varies between different Quitlines, they provide another method to deliver multiple session counseling. Since most Quitlines do not provide medications, the provider still needs to coordinate prescribing and monitoring tobacco cessation medications. A review of the evidence (Hopkins et al., 2001a) in the Task Force on Community Preventive Services (TFCPS) has concluded that telephone cessation support is effective in increasing tobacco use cessation when implemented with other interventions (e.g., other educational approaches, clinical therapies, or a combination), in both clinical and community settings. The minimum intervention with sufficient evidence of effectiveness was proactive telephone support combined with patient cessation materials.

Training of Providers and System Support
A review of the evidence (Hopkins et al., 2001a) in the TFCPS has concluded that the available studies provide insufficient evidence to assess the effectiveness of provider education intervention when implemented alone. Only a few studies have measured outcomes (i.e., patient tobacco use cessation) or if done, reported inconsistent results. A number of trials have examined whether specific skills training for health professionals leads them to have greater success in helping their patients who smoke. Skills training included educational interventions on setting quit dates, providing advice and offering patient follow-up. A Cochrane review (Lancaster & Silagy, 2000) showed that health care professionals who received training were more likely to perform tasks of smoking cessation than untrained controls. Of eight studies that compared patient smoking behavior between trained professionals and controls, six found no effect of intervention. The effects of training on process outcomes increased if prompts and reminders were used. Training health professionals to provide smoking cessation interventions had a measurable effect on professional performance. There was no strong evidence that it changed smoking behavior (See appendix A-7: Promotion of Tobacco Cessation in the Health Care System).

EVIDENCE

	Evidence	Sources of Evidence	QE	Overall Quality	R
1	Dose response relationship between extent of counseling contact and rate of abstinence.	PHS Tables 13 & 14	I	Good	A

2	Minimal tobacco use cessation counseling (<3 minutes) is effective.	PHS Table 12 Silagy & Stead, 2001	I	Good	A
3	Proactive telephone counseling is effective.	PHS Table 17 Hopkins et al., 2001a Stead and Lancaster, Telephone Counseling, 2001	I	Good	A
4	Multiple formats (e.g., group, telephone, individual) are effective.	PHS Table18	I	Good	A
5	- Counseling by a variety clinician types is effective. - Counseling by nurses is effective.	PHS Table15 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.

BACKGROUND

Pharmacotherapy has been shown to double quit rates compared to placebo and should be a vital element of a multi-component approach to treatment. First-line pharmacotherapies (i.e., nicotine patch, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, and bupropion sustained release [SR]) for tobacco use and dependence are safe, have been empirically proven to be effective, and should always be considered part of a tobacco treatment intervention program unless contraindicated. Studies published subsequent to the literature synthesized in The Clinical Practice Guideline for Treating Tobacco Use and Dependence (Fiore et al., 2000) support previously determined efficacy of first-line pharmacologic medications for treatment of tobacco use and dependence. The specific pharmacotherapy selected should be based on patient characteristics with consideration of individual patient preferences. Providers seeking to use pharmacotherapy for their patients should be familiar with the methods for use, effectiveness, precautions/contraindications, potential adverse effects of these medications, and precautions for adolescents and geriatrics (see Appendix A-3 - Pharmacotherapy).

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 therapy (NRT) [transdermal patch, gum, nasal spray, lozenges, or vapor inhaler] and non nicotine replacement [bupropion IR or SR]. [A]
    - Pharmacotherapy should be combined with minimal counseling (<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 8-12 weeks, and for bupropion 7-12 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, revaluate 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]

DISCUSSION

Both NRT and bupropion SR have been found to be more effective than placebo in clinical studies. NRT and bupropion SR have been proven to be safe in most populations treated and should be used first-line [PHS Tables 25-29].

Most clinical trials assessing the efficacy of drug therapy combine drug therapy with counseling. Both NRT and bupropion SR are effective with minimal counseling, as would be expected in a typical primary care setting. In the past, the consensus was that medications for tobacco cessation were only effective when combined with behavior modification counseling. Many experts questioned whether there would be sufficient counseling from primary care providers to allow the medications to be effective. More recent evidence shows that both medicines are effective with the level of counseling that would typically be received within primary care (Hall et al., 2002). A recent Cochrane review of NRT found that the "effectiveness of NRT appears to be largely independent of the intensity of additional support provided to the tobacco user. Provision of more intense levels of support, although beneficial in facilitating the likelihood of quitting, is not essential to the success of NRT" (Silagy et al., 2002). While there is not as much evidence available for bupropion SR, Hall et al. (2002) found that bupropion SR with minimal counseling was effective and that adding intensive counseling did not increase quit rates.

***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

Selection of the NRT should be based on the person's level of addiction to tobacco, motivation to quit, and concomitant medical conditions. The higher the person's level of dependence to nicotine, the more likely he or she is to benefit from NRT as an aid to tobacco cessation. Persons with higher nicotine dependence (i.e., tobacco use equivalent to greater than or equal to 25 cigarettes per day OR tobacco use less than 30 minutes after awakening) may require higher NRT dosing. Pooled abstinence data in trials of patients with a higher nicotine dependence comparing 4 mg gum to 2 mg gum showed an OR of 2.67 (95% CI 1.69, 4.22). Studies comparing high patch doses to standard therapy suggest a small benefit from higher doses in patients with a higher nicotine dependence (OR 1.21; 95% CI 1.03, 1.42) (Silagy et al., 2002).

Although there are no absolute contraindications to the use of NRT, caution should be used with concomitant cardiovascular disease. It is recommended that NRT not be prescribed within two weeks of a myocardial infarction, but otherwise, it is safe to use with cardiac patients (Joseph et al., 1996; Rigotti, 2002). Separate analyses have now documented the lack of an association between the nicotine patch and acute cardiovascular events (Benowitz et al., 1997, Joseph et al., 1996, Mahmarian et al., 1997) even in patients who continued to smoke intermittently while on the nicotine patch (Working Group for the Study of Transdermal Nicotine in Patients with Coronary Artery Disease, 1994). It may be important to inform patients who are reluctant to use NRTs that there is no evidence of increased cardiovascular risk with these medications.

***First Line* - NON-NRT**

The only non-nicotine product currently U.S. Food and Drug Administration (FDA) approved is bupropion SR (Hughes et al., 2002; Hurt et al., 1997; Jorenby et al., 1999). It is chemically unrelated to tricyclic, tetracyclic, selective serotonin reuptake inhibitor, or other known antidepressant agents. The mechanism by which bupropion SR enhances the ability of persons to abstain from smoking is unknown. Bupropion SR has been proven to be effective in clinical trials, with a recent meta-analysis showing that it increases the likelihood of abstinence compared to placebo (OR 2.1; 95% CI 1.5, 3.0) [PHS Table 25].

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]

Combination Therapy

Providing a background nicotine replacement level with a patch and using faster acting NRT products for controlling cravings may be useful. Pooled results from 5 trials comparing the combination of patch with another form of NRT to each NRT agent alone suggests a benefit to combination NRT therapy (OR 1.55; 95% CI 1.17, 2.05) (Silagy et al., 2002; PHS Table 32). In one large trial, NRT was used safely in combination with bupropion SR for selected healthy, non-depressed smokers (Jorenby et al., 1999). The combination of a patch and bupropion SR was better than patch alone, but not better than bupropion SR alone.

Second Line Agents

Second-line therapies include clonidine and nortriptyline and should be considered on a case-by-case basis after first-line treatments have been used or considered [PHS Tables 30 - 31]. There is evidence that these agents are effective in tobacco cessation (Glassman et al., 1988; Hall et al., 1998; Hilleman et al., 1993; Niaura et al., 1996; Prochazka et al., 1998); however, these agents are associated with more severe adverse effects (significant drug-drug interactions) than either 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.

Use in Depression

Both bupropion SR and nortriptyline are effective for treatment of tobacco dependence in tobacco users with a current or past history of depression. Hall and colleagues (1998) studied patients who attempted to quit smoking with nortriptyline and found the drug to be effective in tobacco cessation without relapse of depressive symptoms. Likewise, Hayford and colleagues (1999) studied bupropion SR in smokers and found it to be efficacious. Since the publication of The Clinical Practice Guideline for Treating Tobacco Use and Dependence (Fiore et al., 2000), Hayford et al. (1999) used a randomized, double-blind, placebo-controlled multi-dose study of bupropion SR to evaluate efficacy in smokers with a former history of major depression or alcoholism. Doses included 100 mg/d, 150 mg/d, and 300 mg/d, with treatment duration of 7 weeks including physician quit advice with counseling components according to the National Cancer Institute guidelines. Point prevalence smoking abstinence for each dose (i.e., 100 mg/d, 150 mg/d, and 300 mg/d) and placebo at 7 weeks was 29 percent, 38 percent, 44 percent, and 18 percent. The numbers needed to treat with each respective dose of bupropion SR were 9.1 using 100 mg/d, 5 using 150 mg/d, and 3.9 using 300 mg/d. At 12 months, follow-up point prevalence smoking abstinence was 20 percent using 100 mg/d and 23 percent using both 150 mg/d and 300 mg/d. Using placebo, the abstinence rate was 12 percent. The number needed to treat using 12-month point prevalence abstinence rates were 12.5 (100 mg/d), 9.1 (150 mg/d), and 9.1 (300 mg/d). No continuous abstinence rates were reported. The efficacy of bupropion SR was independent of having a former history of major depression or alcoholism. These patients were predominately white, highly educated, and seeking treatment for smoking cessation.

Extended use of Pharmacotherapy

Limited evidence suggests that bupropion SR, when prescribed for extended periods, can reduce craving and delay but not prevent relapse to tobacco use. Three studies examined the outcome of extended pharmacotherapy for smoking cessation. Durcan et al. (2002) and Hays et al. (2001) reported the outcome of 45 weeks of bupropion SR therapy, and Shiffman et al. (2000) reviewed the effectiveness of extending nicotine patch treatment to 10 weeks rather than the usual 6 weeks. In Durcan et al.'s study, the treatment appeared to reduce cravings: "Results from patients' diaries showed no differences between bupropion SR and placebo in terms of 'craving in the past 24 hours' but significantly lower scores for 'craving right now' for bupropion SR at weeks 11 and 12 ($P < 0.05$). Results at scheduled visits showed that 'craving in the past 24 hours' was significantly less with bupropion SR compared with placebo at weeks 12, 20, and 48, and 'craving right now' was significantly less with bupropion SR compared with placebo at weeks 12, 16, 20, 24, 48, and 52 ($P < 0.05$)." Although bupropion SR reduced cravings, it did not prevent relapse in the long run: "The continuous abstinence rate was higher in the bupropion SR group than in the placebo group at study week 24 (17 weeks after randomization) (52.3% vs. 42.3%; $P = 0.037$) but did not differ between groups after week 24."

Limited evidence suggests that extending nicotine patch therapy to a longer duration can be beneficial for some patients attempting to quit tobacco use. In the Shiffman et al. (2000) study, the additional four weeks of nicotine patch treatment resulted in a significant improvement in participants' reported mood, and the patches significantly reduced participants' cravings. The authors did not state whether these improvements translated into a higher rate of continuous abstinence.

EVIDENCE

	Evidence	Sources of Evidence	QE	Overall Quality	R
1	Pharmacotherapy (NRT, bupropion) are effective in increasing abstinence rates	PHS Tables 25 - 29 Hughes et al., 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	PHS Tables 25 - 29 Silagy et al., 2002	I	Good	A
3	Bupropion SR is an effective first-line medication for smoking cessation.	PHS Tables 25 - 29 Hughes et al., 2002	I	Good	A
4	Pharmacotherapy is more effective when combined with counseling.	Silagy et al., 2002 Stead et al., 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.	PHS Table 32 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.	PHS Tables 25 & 31 Hughes et al., 2002 Hayford et al., 1999	I	Good	A
7	Prescriptions for effective pharmacotherapies for smoking cessation should be considered in adolescents with higher degrees of dependence and willingness to quit.	Hurt et al., 2000 Smith et al., 1996 Sussman et al., 1999	II II III	Fair Fair Poor	C
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

BACKGROUND

In addition to counseling and medication, there are a wide range of materials and resources to support an individual's tobacco use cessation attempt. Some examples include 12-step programs (Nicotine Anonymous), computer-based tobacco intervention programs, internet web sites, and various community programs.

A variety of patient education materials should be available for tobacco users and placed in various locations to make them more accessible. Examples of sites would include health care provider offices, sites within the clinic area, patient education libraries, and community libraries. Placing the materials on the internet or an intranet allows for easy access by patients and providers.

Self-help materials can be individually tailored, as some materials will work more effectively than others with individual tobacco users. Basic information should include treatment options, strategies for quitting, self monitoring forms for recording tobacco use and plans for quitting, stress management and nutrition information, local resources available and web sites that may help with the quitting process. Samples of self-help materials may be found in the VA/DoD Management of Tobacco Use Tool Kit. Tobacco treatment team members should be informed of available self-help materials so they can understand their role in assisting the patient to quit tobacco use.

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]

DISCUSSION

A recent Cochrane review found that when used alone, self-help materials were more effective than no intervention (OR 1.24, 95% CI 1.07-1.45) (Lancaster & Stead, Self-Help Interventions, 2002). However, there was no evidence that self-help materials were effective when used in addition to face-to-face advice or NRT. There was some evidence that personalizing the materials increased their effectiveness as compared to standard manuals (OR 1.36, 95% CI 1.13-1.64) or no materials (OR 1.80, 95% CI 1.46-2.23).

EVIDENCE

	Evidence	Sources of Evidence	QE	Overall Quality	R
1	Self-help materials are more effective than no intervention.	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.

BACKGROUND

Tobacco dependence is a chronic disease that often requires repeated interventions. Tobacco addiction is a chronic disorder that carries with it the vulnerability to relapse persisting for weeks, months, and perhaps even years. Therefore, consistent follow-up is necessary to ensure optimal care.

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]

DISCUSSION

The majority of all relapse occurs within the first 3 months after quitting, and relapse is less common after 6 months of abstinence. Assessments soon after quitting (optimally 1 to 2 weeks) are recommended. Evidence is strongest from two independent, randomized, double-blind, placebo-controlled studies using the nicotine patch that were evaluated for predictors of successful quitting of tobacco use (Kenford et al., 1994; Reid & Pipe, 1999). In this context, any smoking during the first 2 weeks of NRT was highly associated with a poor prognosis, and smoking or abstinence during week 2 was the most accurate predictor of outcome. Based largely on this information, prior expert opinion (Fiore et al., 2000) has supported a systematic follow-up plan, including within the first 2 weeks after quit date, in order to maximize the chance for early success and hopefully improve long-term abstinence. This particular hypothesis remains unproven.

Abstinent patients should receive relapse prevention treatment including reinforcement for the decision to quit, congratulations on the success of quitting, and encouragement to remain abstinent (Carroll, 1996).

Similar evidence, supported by a larger number of independent studies (Hopkins et al., 2001b), suggests that a provider reminder system helps to increase the systematic delivery of minimal clinical interventions for tobacco cessation and may increase the likelihood of quitters remaining abstinent.

EVIDENCE

	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, 1999	I	Fair	B
2	Assessment for abstinence at the completion of treatment.	Fiore 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., 2001b	I	Fair	B

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

PREVENTION

K. Initiate/Reinforce Relapse Prevention

OBJECTIVE

Prevent relapse to nicotine.

BACKGROUND

Tobacco use is characterized as a chronic relapsing disorder due to the high number of relapses after a single quit attempt. Studies have documented that smokers may make between 3 and 7 serious quit attempts before successfully quitting. Relapse frequently occurs within a few hours or up to 3 months after quitting, and may even occur after a year or more of abstinence. Addressing the issue of relapse before it occurs and identifying risk factors has been helpful in devising coping strategies to help the tobacco user to quit and prepare them to accept relapse as a learning experience and not a failure.

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). [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]

DISCUSSION

Researching the question of relapse prevention through pharmacotherapy is complicated by the lack of consensus on the meaning of the term “relapse.” For some researchers, relapse may occur as quickly as one day after a patient begins a quit attempt. Thus, it is difficult to distinguish “relapse” from “failure to maintain abstinence,” which is an outcome measure in countless tobacco cessation studies.

Patients with multiple relapses or those who express a great deal of trouble in quitting/staying quit, should be encouraged to consider a more intensive form of treatment. Additional consideration must also be given to the “quitter” who expresses deep emotional problems while quitting. These patients should be encouraged to seek counseling with their mental health provider, as this may be a sign of undiagnosed depression.

Telephone calls, clinic visits, or any time the provider encounters a former tobacco user can be appropriate times to institute intervention for relapse prevention. The purpose of relapse prevention may need to be individualized, especially during the first three months of abstinence (Hatziandreu et al., 1990; U.S. DHHS, 1994). 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 provider, specialized clinic, or program.

The majority of tobacco users who quit gain weight. Most will gain fewer than 10 pounds, but there is a broad range of weight gain. The Clinical Practice Guideline for Treating Tobacco Use and Dependence (Fiore et al., 2000) cites the following:

Some evidence suggests that attempts to prevent weight gain (e.g., strict dieting) may undermine the attempt to quit smoking (Hall et al., 1992; Perkins, 1994; Pirie et al., 1992). Other evidence suggests that weight gain is reduced if smoking cessation is accompanied by a moderate increase in physical activity (Kawachi et al., 1996). One recent study showed that an exercise program, occurring in three 45-minute sessions per week, increases

long-term smoking abstinence in women and delays weight gain when it is combined with a cognitive-behavioral smoking cessation program (Marcus et al., 1999).

Nicotine replacement—in particular, nicotine gum—appears to be effective in delaying post-cessation weight gain. Moreover, there appears to be a dose-response relation between gum use and weight suppression (i.e., the greater the gum use, the less weight gain occurs). However, once nicotine gum use ceases, the quitting smoker gains an amount of weight that is about the same as if she or he had never used gum (Dale et al., 1998; Doherty et al., 1996; Emont & Cummings, 1987; Gross et al., 1989; Nides et al., 1994).

Bupropion SR also appears to be effective in delaying post-cessation weight gain. However, once bupropion SR therapy is stopped, the quitting smoker, on average, gains an amount of weight that is about the same as if she/he had not used bupropion SR (Hurt et al. 1997; Jorenby et al., 1999).

A few pharmacological therapies have been shown to increase abstinence among spit tobacco users. A recent RCT has shown that bupropion has a short-term effect on abstinence of spit tobacco users (Chengappa et al., 2001; Dale et al., 2002; Nordstrom et al., 1999). The mean weight change at the end of treatment was much lower in the treatment group and continued to be lower at 6 months after treatment. Bupropion appears to attenuate weight gain during spit tobacco abstinence.

See Appendix A-5 – Relapse Prevention for components of minimal practice relapse prevention and prescriptive relapse prevention.

EVIDENCE

	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 CDC, 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. DHHS, 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.	U.S. DHHS, 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.

BACKGROUND

Even when advised to stop tobacco use, many tobacco users may be unwilling to do so at the present time. It is widely acknowledged that one of the biggest challenges in treating tobacco users is addressing the lack of motivation to seek and remain in treatment. Lack of motivation can be attributed to the tobacco user's personal, enduring characteristics. In the past, motivation was commonly viewed as a static trait that the tobacco user either did or did not have. However, psychological research (in particular, research addressing patients with substance use disorders) has shown that motivation can be increased through motivational interventions.

Changing behavior:
Research suggests that changes in health behavior (such as quitting tobacco use) happen through five stages. The "Transtheoretical Model" of changing behavior developed by Prochaska and DiClemente (1983) is widely accepted as an effective tool for lifestyle change intervention. This model is being used by the Centers for Disease Control and Prevention (CDC), National Cancer Institute, National Institute of Alcohol Abuse and Alcoholism, and American Lung Association, among others. The five major stages of change are:

1. Precontemplation – no intention to change
2. Contemplation – considering a change
3. Preparation – preparatory actions following the decision to change a behavior
4. Action – currently engaged in behavior change activities
5. Maintenance – the continuation of a changed behavior beyond six months

Stopping tobacco use may involve a behavioral cycle of change. Health care providers employ motivational strategies to help move the tobacco user through this cycle:

1. Thinking about stopping
2. Deciding to try
3. Trying to stop
4. Stopping
5. Maintaining the change or relapsing

Motivational intervention strategies/techniques:
Motivational intervention is any clinical strategy designed to enhance a patient's motivation to change (see Appendix A-4 – Motivational Techniques and Interviewing).

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

The "five Rs" include *Relevance, Risks, Rewards, Repetition, and Roadblocks*. Counseling that is delivered in a non-judgmental and non-argumentative manner is considered to be more effective. Differential emphasis upon various aspects of these techniques may be applied depending upon whether the person indicates a willingness to attempt quitting sometime in the future, versus no willingness to consider quitting at any time. Tobacco users who express an unwillingness to quit at any time may benefit more from an emphasis upon *Relevance, Risks, Rewards, and Repetition*. Tobacco users who express a willingness to consider quitting at some future time may respond most favorably to a discussion of *Roadblocks* (barriers) and potential solutions. All discussions should be followed by an offer to help when the person is "ready" to attempt cessation.

Motivational interviewing (MI), developed by Miller and Rollnick, views motivation as a result of *interpersonal processes* rather than of personal characteristics (1991). Miller's approach de-emphasizes labeling, encourages individual responsibility, and increases the patient's dissonance (dissatisfaction) between their ideal goal and their present behavior. MI emphasizes a combination of discrepancy and self-efficacy in order to better motivate people for change. In MI, the *therapist's behavior* directly affects the patient's motivation for change.

The Working Group believes that several of the different motivational interventions that can be used at all stages of the change process and the tools and assessment instruments related to motivation should be incorporated into the treatment of tobacco use.

Providers can increase motivation by using the assessment of comorbidities to point out the "Relevance" of tobacco use to the patient's health status. Primary care providers should tailor the tobacco cessation message to the individual's increased risk of development of a diseases or exacerbation of preexisting diseases. There are a generally well-known variety of disease states related to, associated with, and/or exacerbated by the use of tobacco. These include, but are not limited to:

- Cardiovascular disease
- Pulmonary disease
- Cancer
- Diabetes
- Periodontal & other dental diseases
- Pregnancy & childbirth problems
- Male sexual functioning
- Depression, schizophrenia, & other mental health disorders

Relevance can also be addressed by pointing out the potential harm a tobacco user may cause to family members and loved ones through second-hand smoke in the home.

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]:
    - **R**elevance: connection between tobacco use and current symptoms, disease and medical history.
    - **R**isks: risks of continued tobacco use and tailor the message to individual risk / relevance of cardiovascular disease or exacerbation of preexisting disease.
    - **R**ewards: potential benefits for quitting tobacco use to their medical, financial, and psychosocial well-being
    - **R**oadblocks: barriers to quitting and discuss options and strategies to address patient's barriers.
    - **R**epetition: 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]

DISCUSSION

Motivational interventions have been demonstrated to influence patients' readiness to change health behaviors. Research has shown positive outcomes in applying MI in patients with substance use (i.e., alcohol). A complete bibliography for studies evaluating the use of MI for motivating substance users to quit can be found in www.motivationalinterview.org . Some researchers have applied this technique in treating tobacco users. The following RCTs examined the use of MI for tobacco use cessation:

Cigrang et al. (2002) identified 60 *active-duty male participants as smokeless tobacco (ST)* users during their annual preventive health screening and randomly assigned them to minimal-contact intervention or usual care. Intervention participants were proactively contacted by phone and recruited, using a motivational interviewing style, for a cessation program consisting of a treatment manual, video, and two supportive phone calls from a cessation counselor. Sixty-five per cent (20/31) agreed to participate in the minimal-contact intervention. Three- and 6-month follow-up contacts found that the cessation rates reported by intervention participants were double those reported by participants receiving usual care (41% vs. 17% at 3 months, 37% vs. 19% at 6 months). These pilot study data suggest that proactive recruitment, using a motivational interviewing approach to offer a treatment, provides a good opportunity to reduce the use of ST in military settings.

Stotts et al. (2002) applied a motivational interviewing intervention to 269 *pregnant women* smokers who had failed to stop smoking after a minimal intervention. The more intense experimental intervention consisted of a 20-30 minute motivational telephone interview, a personalized stage-based feedback letter after the first phone contact, and a follow up motivational telephone interview. These subjects were compared to a usual care control group. Many of the intervention group received only part of the full intervention due to logistical difficulties. The intervention group was significantly heavier smokers than were the control group at baseline. Initial comparison showed no differences between the control and intervention groups. Adjusting for baseline smoking rates yielded significant differences in smoking cessation, favoring the intervention group. Further, those subjects who received the full motivational intervention, rather than just parts of it, also demonstrated higher rates of abstinence.

Emmons et al. (2001) studied a large sample of racially and ethnically diverse low-income families to determine whether a motivational intervention for *smoking parents of young children* would lead to reduced household passive smoke exposure. Participants were randomly assigned to either the MI or a self-help intervention group. The MI group received a 30- to 45-minute motivational interviewing session at the participant's home with a trained health educator and 4 follow-up telephone counseling calls. Participants in the self-help group received a copy of the smoking cessation manual, the passive smoke reduction tip sheet, and the resource guide in the mail. Household nicotine levels were measured and found to be significantly lower in MI households. Repeated measures analysis of variance across baseline, 3-month, and 6-month time points showed a significant time-by-treatment interaction, whereby nicotine levels for the MI group decreased significantly and nicotine levels for the self-help group increased but were not significantly different from baseline. These findings suggest that pediatric health care providers can help parents work toward reducing household passive smoke exposure by using motivational strategies and providing a menu of approaches regardless of whether the parents are ready to quit.

Hajek et al. (2001) studied 1,120 *pregnant women* in their third month of pregnancy (249 recent ex-smokers and 871 current smokers) to evaluate the efficacy of a brief smoking cessation intervention provided by midwives. The 10-15 minute intervention was based on brief counseling, written materials, arrangements for continuing self-help support and feedback on expired-air carbon monoxide levels. The intervention and usual care groups differed in post-delivery point prevalence abstinence rates for recent ex-smokers (65% vs. 53%, $p < 0.05$, one-tailed), but not in other outcome measures. Overall, 54 percent of "recent ex-smokers" at booking and 7 percent of "current smokers" at booking had been abstinent for at least 3 months at the time of delivery, and 23 percent and 3 percent, respectively, were still abstinent by the time the child was 6 months old (i.e., 12 months post-intervention). The authors concluded that a brief "one-off" smoking cessation intervention by midwives does not seem to be a practicable or effective method of helping pregnant smokers to stop.

Smith et al. (2001) compared the efficacies of two group counseling step-up treatments for smoking cessation, cognitive-behavioral/skill training therapy (CBT) and motivational interviewing/supportive (MIS) therapy with brief intervention (BI) treatment in a sample of 677 *smokers*. All participants received 8 weeks of nicotine patch therapy. BI consisted of three brief individual cessation counseling sessions; CBT and MIS participants received BI treatment and 6 group counseling sessions. Neither CBT nor MIS treatment improved long-term abstinence rates relative to BI. Limited support was found for the hypothesis that high-risk smokers would benefit more from MIS than CBT.

McHugh et al. (2001) provided nurse-delivered patient education and motivational interventions to 49 *patients on a waiting list for coronary artery bypass surgery*, compared to 49 patients receiving usual care.

Interventions were conducted both at patients' homes and in a clinic setting on a monthly basis while patients awaited surgery, and were variable in number and focus. The motivational interventions targeted smoking, diet, physical activity, anxiety, depression, blood pressure, and cholesterol, differing according to the needs of each patient. Results demonstrated significant reductions among the intervention group in smoking, obesity, anxiety, depression, and blood pressure, and an increase in physical activity, compared to the control group. There were no significant reductions in cholesterol.

Ershoff et al. (1999) examined whether outcomes achieved with *brief counseling from prenatal care providers* and a self-help booklet could be improved by adding a more resource-intensive cognitive-behavioral program. 390 women >18 years of age who were active smokers at their initial prenatal appointment were randomized to one of three groups: (1) a self-help booklet tailored to smoking patterns, stage of change, and lifestyle of pregnant smokers; (2) the booklet plus access to a computerized telephone cessation program based on interactive voice response technology; or (3) the booklet plus proactive telephone counseling from nurse educators using MI techniques and strategies. Twenty percent of participants were confirmed as abstinent at approximately the 34th week of pregnancy, with no significant differences found between intervention groups. The authors concluded that neither a computerized telephone cessation program nor systematic provision of motivational counseling improved cessation rates over a tailored self-help booklet delivered within the context of brief advice from prenatal providers.

Colby et al. (1998) tested the feasibility and efficacy of a brief smoking intervention for *adolescents in a hospital setting*. Forty adolescent patients were randomized to receive either brief advice or a motivational interview, a nonconfrontational therapeutic intervention. Feasibility of brief smoking interventions with teen patients was supported by high rates of recruitment, retention, and quit attempts and long periods of continuous abstinence. Although between-groups differences on smoking measures were not significant at 3-month follow-up, an effect size of h = .28 was noted. The sample showed significant decreases in smoking dependence and number of days smoked. Baseline stage of change, smoking rate, and depression were significant prospective predictors of smoking outcome.

Tappin et al. (2000) conducted a pilot study of midwife home-based motivational interviewing to determine how *pregnant women* could be helped to stop smoking. 100 self-reported smokers received routine smoking guidance at their "booking" in the clinic. In addition, intervention clients received a median of four home-based MI sessions from one specially trained midwife. All sessions (n = 171) were audio-taped and interviews (n = 49) from 13 randomly selected clients were transcribed for content analysis. Cotinine measurement on routine blood samples confirmed self- reported smoking change from late pregnancy telephone interview. Motivational interviewing was satisfactory in more than 75% of transcribed interviews. In this pilot study, self-reported smoking at booking (100 of 100 available) corroborated by cotinine (93 of 100) compared with late pregnancy self-reports (intervention 47 of 48; control 49 of 49) and cotinine (intervention 46 of 48; control 47 of 49) showed no significant difference between groups.

EVIDENCE

	Evidence	Sources of Evidence	QE	Overall Quality	R
1	Use of brief motivational intervention.	Cigrang et al., 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 et al., 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.

BACKGROUND

Nicotine dependence is a primary, chronic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. The disease is often progressive and fatal, because tobacco use causes coronary artery disease, chronic lung disease, and cancer. It is characterized by impaired control over tobacco use, preoccupation with the drug nicotine, use of tobacco despite adverse consequences, and distortion in thinking, including denial of addiction. Therefore, congratulating those who do not use tobacco for maintaining their health is an important element in primary prevention.

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]

DISCUSSION

Primary care reinforcement of not using tobacco among young non-smokers has been shown to prevent the onset of smoking, especially in boys (Fidler & Lambert, 2001). Brief motivational interventions promote positive behavior changes in tobacco users. Positive reinforcement of a behavior (not using tobacco) generally encourages its continuation. A simple, brief, congratulatory statement may serve this purpose.

EVIDENCE

	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.

BACKGROUND

Most relapse occurs in the first three months after a quit attempt, but people making a quit attempt continue to be at-risk beyond this point. Individuals who have been abstinent for less than three months should be considered at high-risk for relapse and 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 is a predictor for relapse. Although relapse frequently occurs, the average adult is able to successfully quit tobacco use after multiple attempts; so repeated quit attempts should be encouraged.

Persons fitting any of the following parameters should be considered candidates in need of relapse prevention counseling and medication (Brownell et al., 1998):

1. Individual factors relate to an increased likelihood for relapse:
    - Negative emotional states (e.g., stress, depression, and anxiety)
    - Concern about post-cessation weight gain
    - Presence of significant craving and/or withdrawal symptoms
    - Present or past history of substance use disorder
    - Previous quit attempts
    - Unaware or unconcerned about issues related to relapse
    - Failure to modify his or her environment
    - Engagement in "risky behavior" such as consumption of alcohol or other mind-altering substances
    - Attends establishments where tobacco use is tolerated, even encouraged (e.g., bars)
2. Social and environmental factors related to relapse:
    - Tobacco use is socially accepted and legal in the area where prior tobacco user lives or works
    - Presence of other tobacco users at home or work
    - Lack of social support for quitting
    - Visual cues related to the advertising of tobacco products
    - Easy access to tobacco products

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]

DISCUSSION

Tobacco use is characterized as a chronic relapsing disorder due to the high frequency of relapse after a single quit attempt. Relapse rates are highest within the first three months of attempted quitting and fall significantly after three months (U.S. Department of Health and Human Services [DHHS], 1994; Westman et al., 1997; Zhu et al., 1996). Relapse has been seen even after one or more years of abstinence (Brandon et al., 1990;

Hatziandreu et al., 1990). Multiple psychosocial and environmental risk factors for relapse have been identified (Brownell et al., 1998) and should be used to identify those at greatest risk for relapse. Psychological factors such as history of depression or depressive symptoms at initiation of quit attempt may significantly contribute to increased rates of relapse (Niaura et al., 2001) and should specifically be identified and treated.

The management of tobacco use carries with it the vulnerability to lapse and relapse. The actual process of establishing long term abstinence takes many months. Knowing the factors that often precipitate a lapse or relapse, such as emotional distress, may help people focus on the problem that needs to be addressed.

"Relapse prevention skills" are critical. Because emotional distress is a primary factor in lapses and relapses (Brownell et al., 1986), learning to cope effectively with stress is invaluable for the individual trying to effect a major change in behavior, which is a major stressor unto itself. Stress management skills may minimize counterproductive negative emotions. For example, cognitive restructuring or modifying self-talk to decrease negative thinking can be learned with practice (Seaward, 1997). Other relevant skills worth developing relate to time management, conflict resolution, assertiveness, and decision making. An individual planning to change behavior should practice recognizing high-risk situations for a lapse or relapse and specific coping skills for those situations. Plans for effectively responding to a lapse or relapse are advisable.

EVIDENCE

	Evidence	Sources of Evidence	QE	Overall Quality	R
1	Assessment for relapse in patient's abstinent < 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 environmental risk factors for relapse.	Brownell et al., 1998	III	Poor	I
4	Assessment for willingness for another quit attempt in relapsed patients.	Brandon et al., 1990 Westman et al., 1997 Zhu et al., 1996 Fiore et al., 2000	III	Poor	C

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

O. Assess Risk For Starting Tobacco Use

OBJECTIVE

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

BACKGROUND

Over 80 percent of those who will become regular smokers start smoking before age 18 years. Young people report experiencing symptoms of dependence very early. Children, adolescents, and young adults are the highest risk group for initiating tobacco use.

Nicotine dependence is a primary, chronic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. As nicotine dependence is often fatal, identifying those at-risk for initiation of tobacco use should be a primary prevention goal for all health care providers, especially those who treat children, adolescents, and young adults.

RECOMMENDATIONS

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)

DISCUSSION

Intention to smoke in the future is a predictor of smoking status and is inversely related to quitting. Self-efficacy regarding ability to abstain or avoid tobacco has been shown to be a predictor of future smoking. Therefore, asking the patient about intention to smoke in the future is likely to be a strong predictor of future use or non-use (Adelman et al., 2001; Ary & Biglan, 1998).

The provider can help identify risk factors for initiation of smoking in the following areas, derived from the history and physical:

1. *Individual risks:* Personal characteristics correlated with child and teen cigarette smoking include low self-esteem, poor self-image, susceptibility to peer pressure, novelty seeking and rebelliousness, ignorance of smoking-related adverse effects, depression, and anxiety (American Academy of Pediatrics [AAP] Committee on Substance Abuse Tobacco, 1998). Genetic factors appear to influence the pharmacologic reaction to nicotine; some of these appear to be linked to genes that influence the expression of alcoholism (Lynch & Bonnie, 1994).
2. *The role of the family:* Adolescents with parents or siblings who smoke are at increased risk for initiation of smoking. Qualitative data suggest that parental messages about smoking influence teenage behavior (AAP Committee on Substance Abuse, 1998 & 2001; Lynch & Bonnie, 1994).
3. *Low educational attainment:* The prevalence of smoking is highest in those with less than 12 years education. Smoking is often associated with poor school performance, low aspirations, school absences, and anticipated dropping out (Elders et al., 1994).
4. *Societal/cultural/environmental influences:*
    - Adolescents with friends who smoke are at increased risk for initiation of smoking. Tobacco use is associated with alcohol and other drug use. Nicotine is frequently the first substance of abuse used by children and youth. Those who use tobacco are 15 times more likely to progress to other drug use than those who have never smoked (AAP Committee on Substance Abuse, 2001).
    - Smoking is associated with exposure to tobacco advertising, and the positive portrayal of tobacco in the media. Tobacco advertising appears to be a more potent influence than parents or peers, perhaps, because it affects perceptions of the pervasiveness, image, and benefits of smoking. Tobacco advertising and promotion are appealing to young people and make a powerful

impression, influencing them to experiment with cigarettes, cigars, and smokeless tobacco (AAP Committee on Substance Abuse, 2001).

- White females may be at increased risk for smoking because of expectations created by socio-cultural beliefs, e.g., smoking helps to control weight, control mood, and enhance one's image of being independent and sophisticated (Camp et al., 1993; Charlton, 1984; French et al., 1994).

5. *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 (1998) found that at one year after boot camp:
   - Eight percent of those who had "never used tobacco" before enlistment were using tobacco
   - Twenty-six percent of those who had been "experimental tobacco users" were using tobacco
   - Forty-three percent of those who had been "ex-tobacco users" were using tobacco

Protective factors in the individual, family, and environment that can guard against risky behaviors such as tobacco use include close communication with parents, positive parental support, high self-esteem, assertiveness, social competence, school success, regular church attendance, and a strong sense of right and wrong—factors that can be encouraged in the context of a pediatric office visit (Belcher & Shinitzky, 1998).

EVIDENCE

	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.	AAP Committee on Substance Abuse, 1998 & 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).

BACKGROUND

Tobacco use typically begins in early adolescence, usually by age 16, and before young people graduate from high school. If adolescents and young adults can be kept tobacco-free, most will remain tobacco-free for the rest of their lives (Mittelmark et al., 1987). Therefore, primary prevention of tobacco use targeted toward children, adolescents, and young adults is critical to improved health in the community. As it is uncommon for adults to begin smoking after age 25 or after two years in the workforce, primary prevention should focus on children, adolescents and young adults. The most effective preventive programs are community-wide ones that combine education and public policy approaches. There is conflicting evidence regarding the role of the primary care provider in provision of 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]

DISCUSSION

A multitude of approaches to primary prevention of tobacco use have been evaluated. Approaches with the largest span of impact (i.e., economic, regulatory, and comprehensive) are likely to have the greatest long-term, population impact. Those with a smaller span of impact (i.e., educational and clinical) are of greater importance in helping individuals resist the use of tobacco (CDC, 2000). The most effective strategy for primary prevention is the combination of educational strategies, conducted in conjunction with community-and media-based activities, which can postpone or prevent smoking onset in 20 to 40 percent of adolescents. Regulation of advertising and promotion of tobacco products, clean air regulations, restriction of minors' access to tobacco products, and increased price of tobacco products all have evidence of effectiveness in primary prevention of tobacco use (CDC, 2000). Overall, community interventions are modestly effective for tobacco use prevention.

Community and school-based prevention programs have been shown to teach usable skills, be easy to implement, and improve short-term outcomes (Biglan et al., 2000; Dent, 1998; Schinke et al., 1985; Sowden et al., 2003; Sussman et al., 1999). One randomized clinical study has evaluated office-based interventions for tobacco prevention (Stevens et al., 2002). In this study, no impact was found on initiation of tobacco use. However, no long-term outcomes were evaluated, so the impact of an office-based approach on continued or long-term use is unknown. On the other hand, primary care reinforcement of not using tobacco among young non-smokers, through mailed congratulatory letters, has been shown to prevent onset of smoking, especially in boys (Fidler & Lambert, 2001). Other research, as reviewed and supported by prior expert opinion, shows that provider reinforcement of preventive community interventions may be beneficial (U.S. DHHS, 1994). More research is needed to determine the effectiveness of office-based interventions targeted toward primary prevention of tobacco use. It is clear that any preventive intervention is best delivered before the onset of smoking experimentation and should therefore occur by the fifth or sixth grade. Interventions, in individuals as young as first grade (age 6), have shown a positive effect (Storr et al., 2002).

Suggested focused interventions for primary care managers or providers to prevent initiation of tobacco use among young adults can be found in Appendix A-6 – Primary Prevention in Young Adults and Adolescents.

EVIDENCE

	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 CDC, 1994 & 2000 Dent, 1998 Fiore et al., 2000 Schinke et al., 1985 Sowden et al., 2003 Sussman, 1999	I III II-2 III II I II-3	Fair Poor Fair Poor Fair Fair Fair	B
2	Office-based reinforcement and primary prevention may be beneficial.	Fidler & Lambert, 2001 Fiore et al., 2000 Stevens et al., 2002 U.S. DHHS, 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.

BACKGROUND

Forty-three percent of children in the United States are exposed to environmental tobacco smoke. Children exposed to adult tobacco use are at increased risk for: sudden infant death syndrome, low birth weight, asthma, middle ear disease, pneumonia, cough, and upper respiratory infection. Providers who see children and adolescents play a crucial role in reducing both exposure to tobacco smoke and tobacco use by children, adolescents, and their parents (AAP, 2001).

The disease of tobacco dependence begins in childhood and adolescence. Every day in the United States over 6,000 children and adolescents try their first cigarette (CDC, 1998). Over 80 percent of smokers begin before age 18, and those who start tobacco use at an early age are most likely to continue to smoke into adult life. Adolescent smokers are unique, as effective adult interventions, such as nicotine replacement, have not been shown to be effective in this age group; however, increasing evidence demonstrates that developmentally appropriate interventions are effective for adolescent smoking cessation.

Adolescents are defined in this guideline as being 12 - 17 years old.

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]

DISCUSSION

Multiple studies have demonstrated that delivery of information to parents regarding the harms of exposing children to second-hand smoke reduces childhood exposure to second-hand smoke. This was demonstrated during the postpartum period (Greenberg et al., 1994, Greenberg et al., 1991), among parents of children with asthma (Hovell et al., 1994; Wahlgren et al., 1997), in minority populations (Emmons et al., 2001; Hovell, 2002), and in the outpatient setting (Hovell et al., 2000). The feasibility of engaging parents in smoking cessation in the inpatient setting has recently been shown (Winickoff et al., 2003). Few interventions have been shown to reduce parental smoking rates (Severson et al., 1997; Wall et al., 1995). Therefore, all parents who use tobacco should be informed of the detrimental effects of passive smoking upon children, and the provider should consider adult tobacco use interventions with all parents who use tobacco.

Throughout the United States, a variety of interventions have been developed for adolescents who wish to stop using tobacco. Overall, these programs are better than controls or naturally occurring quit rates, but there is much variability in their success, as well as the methods in which they were evaluated (Sussman et al., 1999). A rigorous, randomized controlled clinical trial with biochemical validation of outcomes and school year long follow-up (Adelman et al., 2001) demonstrated that an adolescent-specific, school-based intervention are greatly superior to self-help materials alone among teens motivated to quit. The largest controlled study of adolescent smoking cessation (Sussman, 2001), also school-based, in a different population, using a different intervention, also showed significant cessation rates in the intervention versus control group five months after program quit day. Therefore, all adolescents interested in quitting smoking should be offered an adolescent-specific intervention, recognizing that often these are community or school-based. Although there is a paucity of evidence to support the effectiveness of adult programs for adolescents, there is no evidence of harm in considering adult programs for adolescents (Fiore et al., 2000). Similarly, early nicotine replacement trials have shown little benefit for teen smokers, but have also shown no harm. Therefore, prescriptions for nicotine replacement or bupropion SR may be considered for adolescents, but only in the case where nicotine dependence exists, which may optimally be evaluated with a nicotine dependence score validated for adolescents (Prokhorov et al., 1996).

EVIDENCE

	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, 2002 Hovell et al., 2000 & 1994 Severson et al., 1997	I	Good	A
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.

BACKGROUND

Smoking in pregnancy presents risks for both the woman and the fetus. Tobacco use by pregnant women has been shown to cause adverse fetal outcomes, including stillbirths, spontaneous abortions, decreased fetal growth, premature births, low birth weight, placental abruption, sudden infant death syndrome (SIDS), cleft palates and cleft lips, and childhood cancers. Many women are motivated to quit during pregnancy, and health care professionals can take advantage of this motivation by reinforcing the knowledge that cessation will reduce health risks to the fetus and that there are postpartum benefits for both the mother and child (Wisborg et al., 1999).

Even women who have maintained total abstinence from tobacco for 6 or more months during pregnancy have a high rate of relapse in the postpartum period (Edwards & Sims-Jones, 1998; Ko & Schulken, 1998). Postpartum relapse may be decreased by continued emphasis on the relationship between maternal smoking and

poor health outcomes in infants and children (i.e., SIDS, respiratory infections, asthma, and middle ear disease) (Edwards & Sims-Jones, 1998; Ko & Schulken, 1998; McBride & Pirie, 1990; Severson et al., 1997).

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.

BACKGROUND

Effective in 1986, basic military training in the DoD prohibited all forms of tobacco use. This decision was based on many factors, including those dealing with health, safety, and readiness. After completing basic military training, varying in length from 6 to 12 weeks, military trainees attend a variety of advanced training programs where tobacco control policies are less restrictive.

RECOMMENDATIONS

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

DISCUSSION

During 1993-2000, substantial reductions in current smoking prevalence were reported in the United States for all age groups, except those aged 18 to 24. An additional issue of tobacco use in this age group is the fact that this group has shown a 13 percent use of smokeless tobacco (CDC, 2002). According to military demographic data, the age of military recruits falls within this age range (Haddock et al., 2001). Studies show that between 34 to 60 percent of recruits entering the military utilized some form of tobacco prior to entering the initial phase of military training (Chisick et al., 1998; Haddock et al., 1998; Williams, 2001a). Studies have also shown that the enforced abstinence during basic military training resulted in a 26 percent rate of abstinence after basic training for those previous users of tobacco. Three studies found that approximately 74 percent of graduated recruits resumed their tobacco use, with approximately 6 to 11 percent initiation of tobacco use after graduation among previous non-tobacco users (Haddock et al., 1998; Hurtado & Conway, 1996; Williams et al., 1996).

One promising DoD program designed to take advantage of the tobacco-free recruit environment is the Navy's **R**einforcing **E**ducation to **AC**hieve **H**ealth (REACH) Program. This program introduces recruits to the impact of tobacco use on military readiness, health benefits to not using tobacco, and financial benefits of being tobacco-free that will result from graduated trainees continuing their tobacco-free lifestyle. This multifaceted program has resulted in a 50 percent reduction in tobacco use resumption within 30 days of recruit graduation and a 67 percent reduction of tobacco-use initiation (Williams, 2001a; Williams, 2001b).

Q-4. Hospitalized Patients

OBJECTIVE

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

BACKGROUND

Hospitalized patients may be particularly motivated to make a quit attempt for two reasons. First, the illness resulting in hospitalization may have been caused or exacerbated by using tobacco, highlighting the patient's vulnerability to the health risks of tobacco. Second, every hospital in the United States must now be smoke free if it is to be accredited by the Joint Commission on Accreditation of Health-Care Organizations.

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]

DISCUSSION

The Clinical Practice Guideline for Treating Tobacco Use and Dependence (Fiore et al., 2000) cites the following:

> It is vital that hospitalized patients attempt to quit smoking, because smoking may interfere with their recovery. Among cardiac patients, second heart attacks are more common in those who continue to smoke (Lightwood & Glantz, 1997; Multiple Risk Factor Intervention Trial Research Group, 1982). Lung, head, and neck cancer patients who are successfully treated, but who continue to smoke, are at elevated risk for a second cancer (Browman et al., 1993; Fujisawa et al., 1999, Gritz, 1991; Kawahara et al., 1998; Richardson et al., 1993). Additionally, smoking negatively affects bone and wound healing (Chang et al., 1996; Grossi et al., 1995; Jones, 1985).
>
> …For these reasons, clinicians should use hospitalization as an opportunity to promote smoking cessation in their patients who smoke (Hurt et al., 1992; Stevens et al., 1993). Patients in long-term care facilities also should receive tobacco dependence interventions identified as efficacious in this guideline. Suggested interventions for hospitalized patients can be found in PHS Table 45.
>
> Four studies met the selection criteria and were relevant to the analysis comparing augmented smoking cessation treatment with usual care for hospitalized patients. Because the analysis was limited to four studies, no attempt was made to categorize the augmented treatment with respect to intensity or type for the purpose of the meta-analysis. For reference only, the augmented interventions in the analyzed studies included elements such as self-help via brochure or audio/videotape, chart prompt reminding physician to advise smoking cessation, pharmacotherapy, hospital counseling, and post-discharge counseling telephone calls. As can be seen from the data in PHS Table 44, augmented smoking cessation interventions among hospitalized patients increase rates of smoking abstinence.

EVIDENCE

	Evidence	Sources of Evidence	QE	Overall Quality	R
1	Augmented interventions among hospitalized tobacco users are effective.	PHS Table 44	I	Fair	B

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

Q-5. Older Patients

OBJECTIVE

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

BACKGROUND

Tobacco cessation treatments have been shown to be effective for older adults. It is estimated that 13 million Americans ages 50 and older and 4.5 million adults over age 65 smoke cigarettes (Rimer et al., 1994). Smokers over the age of 65 can both quit tobacco use and benefit from abstinence (Cohen & Fowlie, 1992; Lightwood & Glantz, 1997).

RECOMMENDATION

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]

DISCUSSION

Age does not appear to diminish the benefits of quitting tobacco use (Hermanson et al., 1988).

The Clinical Practice Guideline for Treating Tobacco Use and Dependence (Fiore et al., 2000) cites the following:

> The tobacco treatment interventions that have been shown to be effective in the general population also have been shown to be effective with older tobacco users. Research has demonstrated the efficacy of the "4 A's" (ask, advise, assist, and arrange follow-up) in patients ages 50 and older (Boyd, 1996). Counseling interventions (Burton et al., 1995; Morgan et al., 1996; Vetter & Ford, 1990), physician advice (Morgan et al., 1996), buddy support programs (Kviz et al., 1994), age-tailored self-help materials (Morgan et al., 1996; Ossip-Klein et al., 1997; Rimer et al., 1994), telephone counseling (Ossip-Klein et al., 1997; Rimer et al., 1994), and the nicotine patch (Orleans et al., 1994) have all been shown to be effective in treating tobacco use in adults ages 50 and older.

EVIDENCE

	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.

BACKGROUND

The Clinical Practice Guideline for Treating Tobacco Use and Dependence (Fiore et al., 2000) cites the following:

The term "psychiatric comorbidity" refers to the co-occurrence of tobacco use with a psychiatric disorder. Although it is not necessary to assess for psychiatric comorbidity prior to initiating tobacco dependence treatment, psychiatric comorbidity is important to the assessment and treatment of tobacco users for several reasons:

- Psychiatric disorders are more common among smokers than in the general population. For instance, as many as 30 percent of patients seeking smoking cessation services may have a history of depression (Anda et al., 1990), and 20 percent or more may have a history of alcohol abuse or dependence (Brandon, 1994; Breslau, 1995; Breslau et al., 1994; Glassman et al., 1988; Hall et al., 1993). Among abusers of alcohol and drugs, smoking occurs at rates well above population average (e.g., greater than 70 percent) (Budney et al., 1993; Clemmey et al., 1997; DiFranza & Guerrera, 1990). These individuals may infrequently present themselves for tobacco dependence treatment. However, such treatments could be conveniently delivered within the context of chemical dependence clinics.
- Smoking cessation or nicotine withdrawal may exacerbate a patient's comorbid condition. For instance, smoking cessation may elicit or exacerbate depression among patients with a prior history of affective disorder (Covey et al., 1998; Ginsberg et al., 1997; Glassman, 1993; Glassman et al., 1993).
- Smokers with psychiatric comorbidities have heightened risk for relapse to smoking after a cessation attempt (Brandon, 1994; Gilbert et al., 1999; Glassman et al., 1993; Hall et al., 1993).

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]

DISCUSSION

Although psychiatric comorbidity places smokers at increased risk for relapse, such smokers can be helped by smoking cessation treatments (Breckenridge, 1990; Burling et al., 1991; Hall et al., 1993; Hartman et al., 1989; Hartman et al., 1991; Ziedonis & George, 1997). Currently, there is insufficient evidence to determine whether smokers with psychiatric comorbidity benefit more from specialized or tailored cessation treatments than from standard treatments (Hall et al., 1994; Zelman et al., 1992). There is also insufficient evidence regarding treatment of smokeless tobacco dependence in patients with psychiatric comorbidities. However, it may be reasonable to extrapolate from the data about smoking cessation treatment among those with psychiatric comorbidities, and would suggest that results would be similar. Even though some smokers may experience exacerbation of a comorbid condition upon quitting smoking, most evidence suggests that abstinence entails little adverse impact. For instance, patients in inpatient psychiatric units are able to stop smoking with few adverse effects (e.g., little increase in aggression) (Hurt et al., 1993; Resnick, 1993; Smith et al., 1999).

With respect to specific psychiatric conditions, data suggests that patients with schizophrenia may respond favorably to smoking cessation treatment using either NRT or bupropion SR, in combination with group therapy or cognitive behavioral counseling. Bupropion SR may help stabilize psychiatric symptoms in schizophrenic patients during a quit attempt. Further, schizophrenic patients taking atypical antipsychotic medications may have more favorable outcomes than those taking typical antipsychotics (Dalack & Meador-Woodruff, 1999; Evins et al., 2001; George et al., 2000; George et al., 2002). The use of bupropion SR, NRT, and cognitive behavioral counseling have all been found to be effective in smoking cessation treatment with patients who are depressed, or who have a history of depression (Brown et al., 2001; Hayford et al., 1999; Hughes et al, 2002; Thorsteinsson et al., 2001;). The use of bupropion SR may also be effective for smoking cessation treatment with patients having posttraumatic stress disorder (PTSD) (Hertzberg et al., 2001). Nortriptyline is also efficacious for both depression and smoking cessation, but its side-effect profile renders it a second-line medication [PHS Table 31]. Other antidepressant medications have not been found to be effective for smoking cessation, nor have anxiolytic medications been found effective for smoking cessation treatment of those with anxiety disorders. Although still controversial, evidence suggests that treatment for tobacco dependence can be effectively provided concurrent to treating patients for alcohol or other chemical dependencies (Burling et al., 2001; Patten et al., 2000; Patten et al., 2001; Patten et al., 2002; Shoptaw et al., 2002). With patients in treatment for chemical dependency, there is little evidence that patients with other chemical dependencies relapse to other drug use when they stop smoking (Bobo et al., 1998; Ellingstad et al., 1999; Hurt et al., 1993). However, such patients should be followed closely for substance use after they stop smoking, for reasons related to the substance use treatment itself.

Stopping smoking may affect the pharmacokinetics of certain psychiatric medications (Hughes, 1993). Therefore, clinicians may wish to monitor closely the actions or side effects of psychiatric medications in smokers making a quit attempt.

EVIDENCE

	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 et al., 2002 Thorsteinssonet al., 2001	I	Fair	B
2	Bupropion SR and nortriptyline are effective in treating tobacco dependence in patients with current/ past history of	PHS Tables 25 & 31 Hughes et al., 2002 Hayford et al., 1999	I	Good	A

	depression.				
3	Smoking cessation for substance abuse patients is recommended.	Bobo et al., 1998 Burling et al., 2001 Ellingstad et al., 1999 Hurt et al., 1993 Patten et al., 2002; 2001; 2000 Shoptaw et al., 2002	I	Fair	C

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

APPENDICES

APPENDIX A-1:
Counseling: Brief Strategies

Advise - Strongly urge all tobacco users to quit	
Action	**Strategies for implementation**
In a *clear*, *strong*, and *personalized* manner, urge every tobacco user to quit.	Advice should be: • *Clear* - "I think it is important for you to quit smoking now and I can help you." "Cutting down while you are ill is not enough." • *Strong* - "As your clinician, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you." • *Personalized* - Tie tobacco use to current health/illness, and/or its social and economic costs, motivation level/readiness to quit, and/or the impact of tobacco use on children and others in the household.
Assist - aid the patient in quitting	
Action	**Strategies for implementation**
Help the patient with a quit plan.	*A patient's preparations for quitting:* • ***S**et a quit date* - ideally, the quit date should be within 2 weeks. • ***T**ell* family, friends, and coworkers about quitting and request understanding and support. • ***A**nticipate* challenges to planned quit attempt, particularly during the critical first few weeks. These include nicotine withdrawal symptoms. • ***R**emove* tobacco products from your environment. Prior to quitting, avoid smoking in places where you spend a lot of time (e.g., work, home, car).
Provide practical counseling (problem solving/skills training).	*Abstinence* - Total abstinence is essential. "Not even a single puff after the quit date." *Past quit experience* - Identify what helped and what hurt in previous quit attempts. *Anticipate triggers or challenges in upcoming attempt* - Discuss challenges/triggers and how patient will successfully overcome them. *Alcohol* - Since alcohol can cause relapse, the patient should consider limiting/abstaining from alcohol while quitting. *Other smokers in the household* - Quitting is more difficult when there is another smoker in the household. Patients should encourage housemates to quit with them or not smoke in their presence.
Provide intra-treatment social support	Provide a supportive clinical environment while encouraging the patient in his or her quit attempt. "My office staff and I are available to assist you." (See PHS Table 22)
Help patient obtain extra-treatment social support.	Help patient develop social support for his or her quit attempt in his or her environments outside of treatment. "Ask your spouse/partner, friends, and coworkers to support you in your quit attempt." (See PHS Table 23)
Recommend the use of approved pharmacotherapy, except in special circumstances.	Recommend the use of pharmacotherapies found to be effective in this guideline (see PHS Table 4 for clinical guidelines and PHS Tables 33-39 for specific instructions and precautions). Explain how these medications increase smoking cessation success and reduce withdrawal symptoms. The first-line pharmacotherapy medications include: bupropion SR, nicotine gum, nicotine inhaler, nicotine nasal spray, and nicotine patch.
Provide supplementary	*Sources* - Federal agencies, nonprofit agencies, or local/state health departments

materials.	(see PHS Appendix A for Web site addresses). *Type* - Culturally/racially/educationally/age appropriate for the patient. *Location* - Readily available at every clinician's workstation.

Arrange - schedule follow-up contact	
Action	**Strategies for implementation**
Schedule follow-up contact, either in person or via telephone.	*Timing* – Follow-up contact should occur soon after the quit date, preferably during the first week. A second follow-up contact is recommended within the first month. Schedule further follow-up contacts as indicated.
	Actions during follow-up contact - Congratulate success. If tobacco use has occurred, review circumstances and elicit recommitment to total abstinence. Remind patient that a lapse can be used as a learning experience. Identify problems already encountered and anticipate challenges in the immediate future. Assess pharmacotherapy use and problems. Consider use or referral to more intensive treatment (see PHS Chapter 4).

Fiore MC, Bailey WC, Cohen SJ et al. Treating Tobacco Use and Dependence. Clinical Practice Guideline. Rockville, MD: US Department of Health and Human Services, Public Health Service; 2000.

APPENDIX A-2:
Counseling: Techniques

Counseling and behavioral smoking cessation interventions should include:

(1) Providing tobacco users with practical counseling (problem-solving skills/skills training)
(2) Providing social support as part of treatment
(3) Helping tobacco users obtain social support outside of treatment

PHS Table 21. Common Elements of Practical Counseling (Problem Solving/Skills Training)

Practical Counseling (Problem Solving/Skills Training) Treatment Component	Examples
Recognize danger situations - identify events, internal states, or activities that increase the risk of smoking or relapse.	• Negative affect • Being around other smokers • Drinking alcohol • Experiencing urges • Being under time pressure
Develop coping skills - identify and practice coping or problem solving skills. Typically, these skills are intended to cope with danger situations.	• Learning to anticipate and avoid temptation • Learning cognitive strategies that will reduce negative moods • Accomplishing lifestyle changes that reduce stress, improve quality of life, or produce pleasure • Learning cognitive and behavioral activities to cope with smoking urges (e.g., distracting attention)
Provide basic information - provide basic information about smoking and successful quitting.	• The fact that any smoking (even a single puff) increases the likelihood of a full relapse • Withdrawal typically peaks within 1-3 weeks after quitting • Withdrawal symptoms include negative mood, urges to smoke, and difficulty concentrating • The addictive nature of smoking

PHS Table 22. Common Elements of Intra-Treatment Supportive Interventions

Supportive Treatment Components	Examples
Encourage the patient in the quit attempt	• Note that effective tobacco dependence treatments are now available • Note that one-half of all people who have ever smoked have now quit

	• Communicate belief in patient's ability to quit
Communicate caring and concern	• Ask how patient feels about quitting • Directly express concern and willingness to help • Be open to the patient's expression of fears of quitting, difficulties experienced, and ambivalent feelings
Encourage the patient to talk about the quitting process	**Ask about:** • Reasons the patient wants to quit • Concerns or worries about quitting • Success the patient has achieved • Difficulties encountered while quitting

PHS Table 23. Common Elements of Extra-Treatment Supportive Interventions

Supportive treatment component	Examples
Train patient in support solicitation skills	• Show videotapes that model support skills • Practice requesting social support from family, friends, and coworkers • Aid patient in establishing a smoke-free home
Prompt support seeking	• Help patient identify supportive others • Call the patient to remind him or her to seek support • Inform patients of community resources such as hotlines and helplines
Clinician arranges outside support	• Mail letters to supportive others • Call supportive others • Invite others to cessation sessions • Assign patients to be "buddies" for one another

Fiore MC, Bailey WC, Cohen SJ et al. Treating Tobacco Use and Dependence. Clinical Practice Guideline. Rockville, MD: US Department of Health and Human Services, Public Health Service; 2000.

APPENDIX A-3: Pharmacotherapy

There are several medications currently marketed and used as pharmacotherapy to promote cessation of tobacco use. First line agents are those drugs approved for tobacco cessation, which include nicotine replacement therapy (NRT) and bupropion, a non-NRT agent. Practitioners seeking to use pharmacotherapy for their patients should be familiar with the methods for use, effectiveness, precautions/contraindications, potential adverse effects of these medications, and precautions for adolescents and geriatrics.

First Line - NRT

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

1. 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.
2. Treat withdrawal symptoms - the nicotine replacement dose should be sufficient to prevent or minimize craving for tobacco products.
3. 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.
4. Advice patient not to use tobacco while using NRT. Encourage patient to report to provider if they have severe craving, which may indicate reevaluation of dosage and type of NRT (e.g., consider adding oral to the use of transdermal)

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

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

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. There is pharmacokinetic data showing bioequivalence between bupropion Immediate Release (IR) and Sustained Release (SR). Bupropion IR is an alternative dosage form that can be utilized. Factors to be considered in choosing candidates for bupropion therapy include:

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]

Second Line Agents

Prescription and use of the second-line agents, which include clonidine and nortriptyline, should only occur under the supervision of a physician.

DRUG DETAILS TABLE PRIMARY CARE**

Agent	Sample Regiments	Typical Duration	Contraindications/ Relative Contraindications	Common Adverse Effects
Nicotine-Replacement Therapy				
Transdermal patch ①③ 24 hr (e.g., Nicoderm ® CQ) (may be worn for 16 or 24 hours)	High dependence*: 21mg patch for 4-6 weeks, then 14mg patch for 2 weeks, then 7mg patch for 2 weeks Low dependence* 14 mg patch for 6-8 weeks, then 7mg patch for 2 weeks	8 – 12 weeks	Relative Contraindications • Hypersensitivity • Pregnancy: Category D • Coronary artery disease (within 14 days post myocardial infarction)	• Sleep disturbance • Local irritation • Bone pain • Headache • Nausea
Nicotine polacrilex gum ①③	High dependence*: 4mg gum every 1-2 hours for 6 weeks then every 2-4 hours for 4 weeks then every 4-6 hours for 2 weeks Low dependence* 2 mg gum every 1-2 hours for 6 weeks then every 2-4 hours for 4 weeks then every 4-6 hours for 2 weeks	8 – 12 weeks	Relative Contraindications • Hypersensitivity • Pregnancy: Category D • Coronary artery disease (within 14 days post myocardial infarction)	• Local mouth irritation • Jaw pain • Rhinitis • Nausea
Nicotine polacrilex lozenge ③	High dependence*: 4 mg Low dependence*: 2mg Suck 1 lozenge every 1-2 hours for 6 weeks then 1 every 2-4 hours for 3 weeks then 1 every 4-8 hours for 3 weeks	8 – 12 weeks	Relative Contraindications • Hypersensitivity • Pregnancy: Category D • Coronary artery disease (within 14 days post myocardial infarction)	• Local mouth irritation • Headache • Nausea • Diarrhea • Flatulence • Hiccup • Heartburn • Cough
Vapor inhaler (Nicotrol® Inhaler)	Inhale deeply or puff on cartridge for about 20 minutes (delivered dose 4mg/cartridge) Use 6-16 cartridges a day for 6 weeks then 4-8 cartridges a day for 2 weeks then 2–6 cartridges a day for 2 weeks	8 – 12 weeks	Relative Contraindications • Hypersensitivity • Pregnancy: Category D • Coronary artery disease (within 14 days post myocardial infarction)	• Local irritation • Cough • Rhinitis • Headache • Dyspepsia
Nasal spray (Nicotrol® NS)	1 spray in each nostril = 1 dose (0.5mg each, 1 mg total) Use 1–2 doses/hr up to a maximum of 40 doses per day (80 sprays) for 6 weeks then 1-2 doses every 2-4 hours up to a maximum	8 – 12 weeks	Relative Contraindications • Hypersensitivity • Pregnancy: Category D • Coronary artery disease (within 14 days post myocardial infarction)	• Headache • Nausea • Confusion • Palpitations • Nasal irritation

	of 20 doses per day (40 sprays) for 2-4 weeks then 1 dose every 4-6 hours for 2 weeks			
Non-Nicotine Therapy				
Sustained-release bupropion ①,②	150 mg/day for 3 days, then 150 mg twice a day¶	7 – 12 weeks	• History of seizures • Predisposition to seizures Severe head trauma • Recent stroke • Abrupt withdrawal from heavy, daily alcohol or other sedative • MAO inhibitor within 14 days • Bulimia, anorexia nervosa Relative contraindication: • Hypersensitivity • Pregnancy: category B	• Anxiety • Disturbed concentration • Dizziness • Insomnia • Constipation • Dry mouth • Nausea
Bupropion IR ①	100mg/ day for 3 days, then 100mg three times a day to complete 7-12 weeks	7 – 12 weeks		

* High dependence definition varies based on manufacturer's labeling and expert consensus. In general, use of tobacco greater than or equal to 20 cigarettes (one package) per day are considered high dependence or use of tobacco less than 30 minutes after awakening. If these criteria do not apply the patient is consider low dependent.
** For complete drug information, refer to manufacturer's drug information sheets.

① Currently on formulary in the VA
② Currently on basic core formulary in the DoD, may be available on local formulary
③ Available over the counter

General
Adolescents are usually not addicted to nicotine and therefore are not usually candidates for NRT. However, NRT may be considered in adolescents with nicotine dependence and willingness to quit.

Oral forms
Do not eat or drink for 15 minutes before, during or after using.

Gum
Chew (gently) until a peppery taste, and then park between teeth and gums to facilitate nicotine absorption through the oral mucosa. Gum should be chewed slowly and intermittently "chewed and parked" for about 30 minutes or until the taste dissipates. No more than 24 pieces per 24 hours.

Lozenge
Place in mouth and allow to dissolve slowly over 20-30 minutes. Do not chew or swallow. Consuming too quickly may cause heartburn and nausea. Shift in mouth occasionally. No more than 5 in 6 hours or 20 per 24 hours. Tingling feeling in mouth on release of medication is normal and expected.

Nasal Spray
Patients should not sniff, swallow, or inhale through the nose while administering doses as this increases irritating effects. The spray is best delivered with the head tilted slightly back.

Inhaler
Delivery of nicotine from the inhaler declines significantly at temperatures below 40°F; do not eat or drink for 15 minutes before and after using.

Bupropion
May be considered in adolescents with nicotine dependence and willingness to quit.

Key Points For Using NRT Agents:

1. Miscellaneous conditions — Use of NRT must be carefully assessed and monitored in persons with hyperthyroidism, peptic ulcer disease, insulin-dependent diabetes mellitus, TMJ syndrome (nicotine gum), severe renal impairment, and certain peripheral vascular diseases.
2. Nicotine from any NRT product may be harmful to children and pets if taken orally.
3. Unstable coronary artery disease — NRT is relatively contraindicated in persons with unstable coronary artery disease.
4. Stable coronary artery disease — NRT can be initiated at intermediate doses with careful monitoring.
5. Pregnancy — The U.S. Food and Drug Administration (FDA) has developed a uniform warning for all non-prescription NRT. They warn against the risks of nicotine in pregnancy. They believe that NRT is safer than smoking in pregnancy; however, the risk to the fetus from this medicine in not fully known. The risk of fetal harm due to nicotine must be weighed against the benefit of abstinence from tobacco.
6. Geriatrics — The safety of NRT in the elderly has not been systematically evaluated. However, one small pharmacokinetic study concluded that though there were statistically significant differences, the disposition of nicotine does not seem to be changed to a clinically important extent in the elderly compared to younger subjects (Molander et al., 2001)

Available NRT Agents:

1. **Nicotine Transdermal (patch)** (Dale et al., 1995; Greenland et al., 1998; Henningfield, 1995; Hurt et al., 1997; Setter & Johnson, 1998)
    - Should be rotated to different areas of the upper arms and torso to minimize dermatological impact, and should not be occluded.
    - Produce 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.
    - Steady-state concentration is not reached until 2 to 3 days after placement of first patch.

- Tobacco users using fewer than the equivalent of 10 cigarettes a day may not have developed tolerance to nicotine and should therefore be started on a reduced dose of NRT.
- Adolescents (Hurt et al., 2000; Smith et al., 1996) — Use of patches with minimal and intensive counseling produced long-term tobacco cessation rates of 5 percent. Side effects were similar to adults, the most common being localized skin reactions.

2. **Nicotine Polacrilex Resin (gum)** (Lam et al., 1987; Murray et al., 1996)
    - Allows tobacco users to take an active coping response to nicotine withdrawal symptoms.
    - Provides plasma nicotine concentrations approximately 30 to 64 percent of pre-cessation levels.
    - Is not associated with as much weight gain as placebo during treatment.
    - Acidic beverages (i.e., coffee and juice) inhibit the absorption of nicotine and should be avoided within 15 – 20 minutes of gum use (Fiore et al., 2000).
    - 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.
    - Sticks to dentures, may dislodge fillings and inlays because of its density.
    - TMJ syndrome is a relative contraindication.

3. **Nicotine Polacrilex Lozenge** (Shiffman et al., 2002)
    - Allows tobacco users to take an active coping response to nicotine withdrawal symptoms.
    - Doesn't stick to dentures.
    - Not contraindicated in TMJ syndrome.
    - Easier to use than gum.
    - Potential to consume too quickly may cause symptoms of high nicotine levels.
    - Acidic beverages (i.e., coffee and juice) inhibit the absorption of nicotine and should be avoided within 15 – 20 minutes of gum use (Fiore et al., 2000).

4. **Nicotine Nasal Spray** (Hjalmarson et al., 1994; Hurt et al., 1998)
    - 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.
    - Peak concentrations occur more rapidly than other NRT products (within 15 minutes) resembling the kinetics of nicotine seen with cigarette use.
    - May be better tolerated by those who have had dermatological effects from the patch or dental side effects from the gum.
    - Local irritant adverse effects, including nasal and throat irritation, runny nose, sneezing, watery eyes, and cough may occur. These effects frequently dissipate after several days of use.

5. **Nicotine Oral Vapor Inhaler** (Tonnesen et al., 1993)
    - Absorption of nicotine occurs through the buccal mucosa, not through the lungs.
    - Peak plasma concentrations occur in 15 minutes, as seen with nicotine nasal spray.
    - Need for hand-mouth action can be substituted with this product.
    - High incidence (about 66 percent) of mouth and throat irritation.
    - High residual level of nicotine in discarded cartridge (danger to children and pets).
    - Persons should be told to stop smoking completely before using this product and not to exceed the recommended maximum dosage (16 mg/day).

Key Points For Non-NRT Agents:

1. Can be started while the person is still smoking without adverse effects.
2. Bupropion is nonaddicting and nicotine-free; therefore, no withdrawal symptoms occur after discontinuation.
3. Potential to lower the seizure threshold in some individuals.
4. Pregnancy Category B, may be preferable to NRT in pregnant women.
5. Comparative pharmacokinetic data at equal doses shows equivalent absorption between the IR and SR products. At steady state, peak levels are lower and trough levels are higher with the SR product versus the

IR product. However, average concentrations of the parent drug and metabolites, AUC's, and peak metabolite concentrations are equivalent between the IR and SR, making them bioequivalent at steady state.

6. Adolescents — Use for tobacco cessation has not been evaluated in this population. Bupropion IR has been studied in a small number of adolescents with depression and attention deficit hyperactivity disorder (ADHD) and appears to be safe and well tolerated. It should be used with caution for adolescents motivated to quit who are highly addicted (Davis et al., 2001; Glod et al., 2000; Hudziak et al., 2000; Solhkhan et al., 2001).
7. Geriatrics — Use for tobacco cessation has not been systematically evaluated in this population. One small pharmacokinetic study found drug accumulation in older patients. Other studies show increased risk of falls in elderly taking bupropion SR (Joo et al., 2002; Sweet et al., 1995, Szuba & Leuchter, 1992).
8. Military flight status — While first-line pharmacotherapy is generally safe and effective, military prescribers should consult their service-specific recommendations governing the use of these medications (Zastawny, 2002).

Available Non-NRT Agents – Bupropion SR and Bupropion IR:

1. Bupropion is contraindicated under the following circumstances: (Hughes et al., 1998)
    - In persons with a seizure disorder, bupropion can potentially lower the seizure threshold in these persons.
    - Persons who are predisposed to seizures due to a current or prior diagnosis or bulimia or anorexia nervosa.
    - 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.

2. Bupropion should be used with caution (careful evaluation, monitoring) under the following circumstances (Jorenby et al., 1999):
    - Persons who are taking a noradrenergic antidepressant agent.
    - Persons with medical conditions that may predispose them to seizures:
        - Severe head trauma
        - Central nervous system tumor
        - History of seizures
        - Abrupt withdrawal from heavy, daily alcohol or other sedatives
        - Addiction to opiates, cocaine, or stimulants
        - Diabetics treated with oral hypoglycemics or insulin at-risk for hypoglycemic induced seizures
    - Persons with hepatic dysfunction or end stage cirrhosis.
    - Caution in patients with insomnia.

EVIDENCE

Drug	Efficacy OR=Odds Ratio CI = 95% Confidence Interval Abstinence Rate (% vs. placebo)	Source of Evidence	DBPC Trials (n)	QE	Overall Quality	Net Effect	R
Nicotine Replacement Therapy (NRT)							
Transdermal nicotine patch	OR 1.74 (CI 1.57-1.93) Estimated abstinence rate 17% (CI 14.0-21.0) vs. 8.4%	Silagy et al., 2002 PHS Table 29	34	I	Good	Moderate	A
Nicotine polacrilex gum	OR 1.66 (CI 1.52-1.81) Estimated abstinence rate 18% (CI 17.0-19.0) vs. 11.6%	Silagy et al., 2002 PHS Table 26	51	I	Good	Moderate	A
Nicotine polacrilex lozenges	(a) 2 mg: OR 2.08 (CI 1.63-2.65) 4mg:OR 2.67 (CI 1.69–4.22) (b) 2mg:OR 2.10 (CI 1.59–2.79) 4mg:OR 3.69 (CI 2.74-4.96) Estimated abstinence rate 2 mg:46% vs. 29.7% 4 mg: 48.7% vs. 20.8%	(a) Silagy et al., 2002 (b) Shiffman et al., 2002	3 1	I II	Good Fair	Moderate Substantial	A B
Nicotine nasal spray	OR 2.27 (CI 1.61-3.2) Estimated abstinence rate 24% (CI 20.0-28.0) vs. 11.8%	Silagy et al., 2002 PHS Table 28	4	I	Good	Moderate	A
Nicotine oral inhaler	OR 2.08 (CI 1.43-3.04) Estimated abstinence rate 17% (CI 14.0-21.0) vs 9.0%	Silagy et al., 2002 PHS Table 27	4	I	Good	Moderate	A
FDA Approved Anti-Depressant Cessation Aid							
Bupropion SR (Zyban)	OR 2.1 (CI 1.5-3.0) Estimated abstinence rate 30.5% (CI 23.2-37.8) vs. 17.3%	PHS Table 25	2	I	Good	Moderate	A

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

TABLE OF DRUG COSTS

Drug and Dose	Cost/Unit[1]	Cost/Month	Rank/Cost[2]
Nicotine patch	$1.95 per patch Dose 1 patch/day (varied mg)	Average price for initial therapy 30 days = $58.50/month	$
Nicotine gum	2mg = $0.21 each 4mg = $0.29 each	12/day x 30 days = $75.60/month 12/day x 30 days = $104.40/month	$$
Nicotine spray	$0.21 per dose Up to 40 doses/day	$94.50 – $252.00/first month	$$$$$
Nicotine lozenge	2 mg & 4mg = $0.41 each†	$159.25 – $246.00/month	$$$
Nicotine inhaler	$0.48 - 0.60 each cartridge Dose 8 - 16 cartridges/day	$115.20 – $288.00/month	$$$$$
Bupropion SR 150 mg (Zyban)	$1.09 each Dose 2 tablets/day	BID = $65.40/month	$
Bupropion IR 100mg	$0.1332 each One three times a day	$11.99/month	$

1 *- Federal Supply Schedule (FSS) and contract as of 3-15-04*
2 *-**R**elative ranking by acquisition costs only*
† FSS price not available at current time

APPENDIX A-4:
A. Motivational Techniques

The "Five R's"- A Counseling Sequence

Relevance	Encourage the patient to indicate why quitting is personally relevant, being as specific as possible. Motivational information has the greatest impact if it is relevant to a patient's disease status or risk, family or social situation (e.g., having children in the home), health concerns, age, gender, and other important patient characteristics (e.g., prior quitting experience, personal barriers to cessation).
Risks	The clinician should ask the patient to identify potential negative consequences of tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient. The clinician should emphasize that smoking low-tar/low-nicotine cigarettes or use of other forms of tobacco (e.g., smokeless tobacco, cigars, and pipes) will not eliminate these risks. Examples of risks are: • *Acute risks*: Shortness of breath, exacerbation of asthma, chronic cough, acute bronchitis, harm to pregnancy, impotence, infertility, increased serum carbon monoxide, loss of smell and taste. • *Long-term risks*: Heart attacks, strokes, vascular disease, lung and other cancers (larynx, oral cavity, pharynx, esophagus, pancreas, bladder, cervix, leukemia), chronic obstructive pulmonary diseases (chronic bronchitis and emphysema), long-term disability and need for extended care. • *Environmental risks*: Increased risk of lung cancer and heart disease in household family members; higher rates of smoking by children of tobacco users; increased risk for low birth weight, sudden infant death syndrome (SIDS), asthma, middle ear disease, and respiratory infections in children of smokers; fires.
Rewards	The clinician should ask the patient to identify potential benefits of stopping tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient. Examples of rewards follow: • Improved personal and family health • Breathe more easily • Food will taste better • Improved sense of smell • Significant money savings • Feel better about self • Home, car, clothing, breath will smell better • Can stop worrying about quitting- feel free from addiction • Set a good example for children • Have healthier babies and children • Not worry about exposing others to smoke • Feel better physically • Improved performance at work and in physical activities • Reduced wrinkling/aging of skin
Roadblocks	The clinician should ask the patient to identify barriers or impediments to quitting and note elements of treatment (problem solving, pharmacotherapy) that could address barriers. Typical barriers might include: • Withdrawal symptoms • Fear of failure • Weight gain • Lack of support

	• Depression • Enjoyment of tobacco
Repetition	The motivational intervention should be repeated every time an unmotivated patient visits the clinic setting. Tobacco users who have failed in previous quit attempts should be told that most people make repeated quit attempts before they are successful.

B. Motivational Interviewing

"Motivational Interviewing"- A general counseling style:

Treatment Improvement Protocol (TIP), based on consensus of clinicians and experts in substance abuse treatment, was developed under the sponsorship of the U.S. DHHS. The TIP is based on fundamental rethinking of the concept of motivation and shows how substance abuse treatment staff can influence change by developing therapeutic relationships that respect and build on the patient's autonomy, and at the same time, make the treatment clinician a partner in the change process. The Working Group believes that several of the different motivational interventions that can be used at all stages of the change process and the tools and assessment instruments related to motivation should be incorporated into the treatment of tobacco use.

Counseling interventions to increase motivation are most likely to be effective if "motivational interviewing" strategies are utilized. "Motivational interviewing" describes a set of techniques that are designed to advance the process of behavior change. The interviewing techniques are client centered, empathic, non-judgmental, non-argumentative, and promote patient autonomy and self-efficacy. The counseling acknowledges the tobacco user's ambivalence about stopping such use, helps create a discrepancy for the patient between their current situation and their desired situation, assists the user in examining the pros and cons of continued use versus quitting, and encourages the patient to create their own solutions and to make their own decisions.

Motivational interviewing is a therapeutic style intended to help clinicians work with clients to address their ambivalence. While conducting a motivational interview, the clinician is directive yet client centered, with a clear goal of eliciting self-motivational statements and behavioral change from the client, and seeking to create client discrepancy to enhance motivation for positive change. Motivational interviewing may be seen not as a set of techniques or tools, but rather as a way of interacting with clients. Motivational interviewing is supported by the following principles:

- Ambivalence about substance use and change is normal and constitutes an important motivational obstacle in recovery.
- Ambivalence can be resolved by working with the client's intrinsic motivations and values.
- The alliance between patient and clinician is a collaborative partnership to which each brings important expertise.
- An empathic, supportive, yet directive counseling style provides conditions within which change can occur. (Direct argument and aggressive confrontation tend to increase client defensiveness, reducing the likelihood of change.)

The motivational interviewing style facilitates an exploration of stage-specific motivational conflicts that can potentially hinder further progress. However, each dilemma also offers an opportunity to use the motivational style as a way of helping clients explore and resolve opposing attitudes.

The Consensus Panel recognizes that successful motivational interviewing will entail being able to:

- Express empathy through reflective listening.
- Communicate respect for and acceptance of patients and their feelings.
- Establish a nonjudgmental, collaborative relationship.
- Be a supportive and knowledgeable consultant.
- Compliment rather than denigrate.
- Listen rather than tell.

- Gently persuade, with the understanding that change is up to the client.
- Provide support throughout the process of recovery.
- Develop discrepancy between clients' goals or values and current behavior, helping clients recognize the discrepancies between where they are and where they hope to be.
- Avoid argument and direct confrontation, which can degenerate into a power struggle.
- Adjust to, rather than oppose, client resistance.
- Support self-efficacy and optimism: that is, focus on clients' strengths to support the hope and optimism needed to make change.

Clinicians who adopt motivational interviewing as a preferred style have found that the following five strategies are particularly useful in the early stages of treatment:

1. *Ask open-ended questions.* Open-ended questions cannot be answered with a single word or phrase. For example, rather than asking, "Do you like to drink?" ask, "What are some of the things that you like about drinking?"
2. *Listen reflectively.* Demonstrate that you have heard and understood the client by reflecting what the client said.
3. *Summarize.* It is useful to summarize periodically what has transpired up to that point in a counseling session.
4. *Affirm.* Support and comment on the client's strengths, motivation, intentions, and progress.
5. *Elicit self-motivational statements.* Have the client voice personal concerns and intentions, rather than try to persuade the client that change is necessary.

See more details for tailoring the motivational intervention to the stages of change model in [http://motivationalinterview.org/library/TIP35/TIP35.htm]

Reference:

Miller W, et al. TIP - Treatment Improvement Protocol; Enhancing Motivation For Change In Substance Abuse Treatment. U.S. DHHS, Center for Substance Abuse Treatment; Rockville, MD, 1999.

Motivational Interviewing and Smoking

Adapted from Brad Cheek (1999): http://www.wellclosesquare.co.uk/training/consult/motiv.htm

APPENDIX A-5:
Relapse Prevention

PHS Brief Strategy C-1. Components of Minimal Practice Relapse Prevention

These interventions should be part of every encounter with a patient who has quit recently:

Every ex-tobacco user undergoing relapse prevention should receive congratulations on any success and strong encouragement to remain abstinent.

When encountering a recent quitter, use open-ended questions designed to initiate patient problem solving (e.g., How has stopping tobacco use helped you?) The clinician should encourage the patients' active discussion of the topics below:
The benefits, including potential health benefits, the patient may derive from cessation.
Any success the patient has had in quitting (duration of abstinence, reduction in withdrawal, etc.).
The problems encountered or anticipated threats to maintaining abstinence (e.g., depression, weight gain, alcohol, other tobacco users in the household).

PHS Brief Strategy C-2. Components of Prescriptive Relapse Prevention

During prescriptive relapse prevention, a patient might identify a problem that threatens his or her abstinence. Specific problems likely to be reported by patients and potential responses follow:

Problems	**Responses**
Lack of support for cessation	Schedule follow-up visits or telephone calls with the patient. Help the patient identify sources of support within his or her environment. Refer the patient to an appropriate organization that offers cessation counseling or support.
Negative mood or depression	If significant, provide counseling, prescribe appropriate medications, or refer the patient to a specialist.
Strong or prolonged withdrawal symptoms	If the patient reports prolonged craving or other withdrawal symptoms, consider extending the use of an approved pharmacotherapy or adding/combining pharmacologic medications to reduce strong withdrawal symptoms.
Weight gain	Recommend starting or increasing physical activity; discourage strict dieting. Reassure the patient that some weight gain after quitting is common and appears to be self-limiting. Emphasize the importance of a healthy diet. Maintain the patient on pharmacotherapy known to delay weight gain (e.g., bupropion SR, NRTs, particularly nicotine gum). Refer the patient to a specialist or program.
Flagging motivation/feeling deprived	Reassure the patient that these feelings are common. Recommend rewarding activities. Probe to ensure that the patient is not engaged in periodic tobacco use. Emphasize that beginning to smoke (even a puff) will increase urges and make quitting more difficult.

Adapted from the Clinical Practice Guideline for Treating Tobacco Use and Dependence (Fiore et al., 2000)

Strategies to Address Factors Associated with Relapse

	Anticipated Factors/Conditions	**Suggested Actions/Interventions**
1	High-risk for relapse (e.g., patient with multiple relapses)	- Initiate a telephone follow-up - Encourage rewarding activities to enhance motivation
2	Ineffective medication regimen or non-adherence	- Assess the effectiveness of pharmacotherapy and increase/adjust medication - Address barriers to non-adherence or consider other therapies
3	Lack of social support for abstinence	- Help identify sources of support within the person's environment or refer the person to an appropriate organization offering cessation counseling or support - Address barriers and support
4	Prolonged withdrawal symptoms	- Educate about symptoms and expectations - Prescribe pharmacological therapy, as appropriate
5	Weight gain	- Reassure that some weight gain is common - Treat for weight gain (dietary/exercise/lifestyle recommendations) - Consider bupropion or NRT to delay weight gain
6	Substance use and other risky behaviors (e.g., gambling and compulsiveness)	- Consider referral to specialists for treatment of substance use dependence - Refer to the VA/DoD Clinical Practice Guideline for the Treatment of Substance Use Disorders
7	Negative mood, stress, depression, or anxiety	- Prescribe appropriate medications or refer to a mental health specialist

APPENDIX A-6:
Primary Prevention in Young Adults and Adolescents

Suggested focused interventions for Primary Care providers to prevent initiation of tobacco use include the following:

Elementary School (through 6th grade):

1. Ask the child if he or she has experimented with tobacco.
2. Reinforce positive health choices.
3. Provide anticipatory guidance regarding the likelihood that he or she may encounter peers who use tobacco and discuss ways in which he or she might address peer pressure to try tobacco.

Middle School and High School (7 to 12th grade):

1. Reassure that most kids do not use tobacco.
2. Educate that all forms of tobacco (including snuff, cigarettes, dip, etc.) are equally dangerous and extremely addictive, and once you are hooked, it is very hard to quit.
3. Readdress issues of peer pressure.
4. Introduce the idea that addiction to tobacco takes away one's independence.
5. Point out that tobacco use leads to:
    - Bad breath
    - Brittle and smelly hair
    - Smelly clothes
    - Stained teeth and finger nails
    - Stained and burned clothes
    - More colds, shortness of breath, and minor illnesses
    - Decreased athletic performance
    - Fire and deaths
6. Tobacco companies market to teenagers that smoking is rugged, sexy and cool. Eighty-five percent of all teenagers say they would prefer a boyfriend or girlfriend who does NOT smoke.
7. Addiction to nicotine may make a person more susceptible to trying other dangerous drugs.
8. The rule of 4s: There are over 4000 chemicals in every cigarette; 400 are toxic, at least 40 are known to cause cancer, and they are the same chemicals as are found in dead bodies (formaldehyde), moth balls or urinal cakes (naphthalene), gas chambers (hydrocyanide), fertilizer (phosphatides), and decaying fish (methylamine).

APPENDIX B: Guideline Development Process

The development process of the VA/DoD Clinical Practice Guideline for the Management of Tobacco Use followed the steps described in "Guideline for Guideline," an internal working document of VHA's National Clinical Practice Guideline Council, which requires an ongoing review of the work in progress.

Target Audience

- Tobacco use as the targeted behavior and tobacco users as the clinical population of interest.
- Interventions for the primary prevention of tobacco use only if they are directly relevant to clinical practice. The guideline does not include community level intervention (mass media, education, workplace) which are important components of the effort to reduce the prevalence of tobacco use in the general population.
- The guideline is designed for three main audiences: primary care providers/managers; tobacco dependence treatment specialists; and health care team members and administrators across the health care systems of the VA and DoD.

Focus of the Update

1. Update any recommendations from the original guideline likely to be affected by new research findings.
2. Summarize the literature and make recommendations regarding special populations.
3. Address content areas and models of treatment for which new data has been published since the development of the original guideline.
4. Provide information and recommendations on health systems changes relevant to tobacco cessation.
5. Evaluate tobacco dependence treatments for efficacy of interventions aimed at modifying both clinician and health care delivery system behavior.

Guideline Development Process

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 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 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.

Clinical experts in the VA and DoD reviewed the final draft. Their feedback was integrated into the final draft. Nonetheless, this document is a work in progress. It will be updated every two years, or when significant new evidence is published.

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. The list of participants is included in the introduction to the guideline.

Formulating of Questions

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.

Selection of Evidence

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. The Working Group made this decision recognizing the limitations of RCTs, particularly considerations of generalizability with respect to patient selection and treatment quality. Meta-analyses that included random controlled studies were also considered to be the strongest level of evidence, as well as reports of evidence-based systematic reviews.

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. The literature search for the guideline development was validated by: (1) comparing the results to a search conducted by the independent research and appraisal team; (2) a review of the database by the expert panel; and (3) requesting articles pertaining to special topics from the experts in the working group.

Preparation of Evidence Tables (reports)

Five of the researchable questions have been 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

Rating of Evidence – Consensus of Experts

Following the independent review of the evidence, a consensus meeting was held to discuss discrepancies in ratings and formulate recommendations. The Working Group graded the recommendations based on the evidence reviews. These gradings are indicated in the Recommendations sections of the annotations. Where scientific data was lacking on an issue, recommendations were based on the clinical experience of the Working Group. These recommendations are marked as "Expert Consensus".

Recommendation and Overall Quality Rating

Evidence-based practice involves integrating clinical expertise with the best available clinical evidence derived from systematic research. The Working Group reviewed the evidence and graded it using the rating scheme developed by the United States Preventive Service Task Force (U.S. PSTF) (2001). The experts themselves, after an orientation and tutorial on the evidence grading process, formulated Quality of Evidence ratings (see Table 1), a rating of Overall Quality (see Table 2), a rating of the Net Effect of the Intervention (see Table 3), and an overall Recommendation (see Table 4).

Evidence Grading System

TABLE 1: Quality of Evidence (QE)

I	At least one properly done RCT
II-1	Well designed controlled trial without randomization
II-2	Well designed cohort or case-control analytic study
II-3	Multiple time series, dramatic results of uncontrolled experiment
III	Opinion of respected authorities, case reports, and expert committees

TABLE 2: 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

TABLE 3: Net Effect of the 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.

TABLE 4: Final Grade of Recommendation

	The net benefit of the intervention			
Quality of Evidence	**Substantial**	**Moderate**	**Small**	**Zero or Negative**
Good	*A*	*B*	*C*	*D*
Fair	*B*	*B*	*C*	*D*
Poor	*I*	*I*	*I*	*I*

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

Abstract of the USPSTF:

- Once assembled, admissible evidence is reviewed at three strata: (1) the individual study, (2) the body of evidence concerning a single linkage in the analytic framework, and (3) the body of evidence concerning the entire preventive service. For each stratum, the Task Force uses explicit criteria as general guidelines to assign one of three grades of evidence: good, fair, or poor.

- Good or fair quality evidence for the entire preventive service must include studies of sufficient design and quality to provide an unbroken chain of evidence-supported linkages that generalize to the general primary care population and connect the preventive service with health outcomes. Poor evidence contains a formidable break in the evidence chain, such that the connection between the preventive service and health outcomes is uncertain.

- For services supported by overall good or fair evidence, the Task Force uses outcomes tables to help categorize the magnitude of benefits, harms, and net benefit from implementation of the preventive service into one of four categories: substantial, moderate, small, or zero/negative.

The Task Force uses its assessment of the evidence and magnitude of net benefit to make a recommendation, coded as a letter: from A (strongly recommended) to D (recommend against). It gives an "I" recommendation in situations in which the evidence is insufficient to determine net benefit (Harris et al., 2001).

Algorithm Format

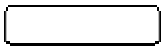
The goal in developing the guideline for Management of Tobacco Use was to incorporate the information from several existing reports, recommendations, and statements into a format which would maximally facilitate clinical decision making. The use of the algorithm format was chosen because of the evidence that such a format improves data collection, diagnostic and therapeutic decision-making and changes patterns of resource use. The algorithm format may help the clinician sort out the logic and sequence of the decision-making process for choosing the appropriate interventions to help survivors during the disorientation that often follows a trauma.

The algorithmic format allows the provider to follow a linear approach to critical information needed at the major decision points in the clinical process, and includes:

- An ordered sequence of steps of care
- Recommended observations
- Decisions to be considered

- Actions to be taken.

A clinical algorithm diagrams a guideline into a step-by-step decision tree. Standardized symbols are used to display each step in the algorithm (Society for Medical Decision-Making Committee [SMDMC], 1992). Arrows connect the numbered boxes indicating the order in which the steps should be followed.



Rounded rectangles represent a clinical state or condition.

Hexagons represent a decision point in the guideline, formulated as a question that can be answered Yes or No. A horizontal arrow points to the next step if the answer is YES. A vertical arrow continues to the next step for a negative answer.

Rectangles represent an action in the process of care.

Ovals represent a link to another section within the guideline.

A letter within a box of an algorithm refers the reader to the corresponding annotation. The annotations elaborate on the recommendations and statements that are found within each box of the algorithm. Included in the annotations are brief discussions that provide the underlying rationale and specific evidence tables. Annotations indicate whether each recommendation is based on scientific data or expert opinion. A complete bibliography is included in the guideline.

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APPENDIX C:
Acronym List

AAP	American Academy of Pediatrics
ADHD	Attention deficit hyperactivity disorder
APA	American Psychiatric Association
BI	Brief intervention
CBT	Cognitive behavioral training
CDC	Centers for Disease Control and Prevention
CI	Confidence interval
DARE	Database of Abstracts of Reviews of Effectiveness
DHHS	Department of Health and Human Services
CMS	Center for Medicare & Medicaid Services
DoD	Department of Defense
EBM	Evidence-based medicine
FSS	Federal supply schedule
MAOI	Monoamine oxidase inhibitor
MI	Motivational interviewing
MIS	Motivational interviewing/supportive therapy
MTF	Medical treatment facility
NHIS	National Health Interview Survey
NRT	Nicotine replacement therapy
OR	Odds ratio
PE	Physical examination
PHS	Public Health Service
PTSD	Posttraumatic stress disorder
QE	Quality of evidence
RCT	Randomized controlled trial
REACH	Navy's Reinforcing Education to Achieve Health Program
SMDMC	Society for Medical Decision-Making Committee
SIDS	Sudden infant death syndrome
SR	Strength of recommendation [in evidence tables]
SR	Sustained release [in reference to medication]
ST	Smokeless tobacco
SUNY	State University of New York
TFCPS	Task Force on Community Preventive Services
TMJ	Temporomandibular joint syndrome
U.S. FDA	U. S. Food and Drug Administration
U.S. PSTF	U.S. Preventive Service Task Force
VA	Veterans Affairs
VAMC	Veterans Affairs Medical Center
VHA	Veterans Health Administration
VISN	Veterans Integrated Services Network

APPENDIX D:
Participant List

MAJ William P. Adelman, MD
Chief, Adolescent Medicine Service
National Naval Medical Center
8901 Wisconsin Avenue
Bethesda, MD 20889
Phone: 301-295-4915
E-mail: wpadelman@bethesda.med.navy.mil

Peter L. Almenoff, MD
Acting Network Director
VISN 15
4801 E. Linwood Blvd.
Kansas City, MO 64128
Phone: 816-922-2908
Fax: 816-922-3392
E-mail: Peter.Almenoff@med.va.gov

Oneil J. Brown
Administrative Assistant
ACS Federal Healthcare, Inc.
5270 Shawnee Road
Alexandria, VA 22312
Phone: 703-310-0158
Fax: 703-310-0126
E-mail: oneil.brown@acs-inc.com

MAJ Geralyn K. Cherry, MSN, RN
USA MEDCOM
Quality Management, MCHO-Q, Room 111
2050 Worth Road
Fort Sam Houston, TX 78234-6026
Phone: 210-221-8971
Fax: 210-221-8478
E-mail: Geralyn.Cherry2@cen.amedd.army.mil

Lynn Clark, JD
Project Manager
ACS Federal Healthcare, Inc.
5270 Shawnee Road
Alexandria, VA 22312
Phone: 703-310-0025
Fax: 703-310-0126
E-mail: lynn.clark@acs-inc.com

Linda H. Ferry, MD, MPH
Chief, Preventive Medicine Section
Jerry L. Pettis VAMC
11201 Benton Street
Loma Linda, CA 92357
Phone: 909-777-3290
Fax: 909-777-3281
E-mail: LHFerry@aol.com

Mark C. Geraci, PharmD BCOP
Pharmacy Benefits Management Strategic
Healthcare Group (119D)
1st Avenue- 1 Block North of Cermak Road
Building 37, Room 139
Hines, IL 60141
Phone: 708-786-7866
Fax (708) 786- 7891
E-mail: Mark.Geraci@med.va.gov

Ronald Goldman, PhD, MPH
Research Specialist
Department of Veterans Affairs
810 Vermont Avenue
Washington, DC 20043
Phone: 202-273-8330
Fax: 202-273-9097
E-mail: Ronald.Goldman@hq.med.va.gov

Kim W. Hamlett-Berry, PhD
Director, Public Health National Prevention
Program
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420
Phone: 202-273-8929
Fax: 202-273-6243
E-mail: Kim.hamlet@hq.med.va.gov

Richard T. Harvey, PhD
Asst. Director, Preventive Behavior
VA National Center for Health Promotion and
Disease Prevention
3000 Croasdaile Dr.
Durham, NC 27705
Phone: 919-383-7874, ext. 223
Fax: 919-383-7598
E-mail: Richard.harvey3@med.va.gov

Steve Heaston, RN, CS, MPH
Public Health Educator, Population Health
Navy Environmental Health Center
Program Manager for Clinical Prevention
Phone: 757 953-0962 (DSN 377)
Email: heastons@nehc.med.navy.mil

MAJ Donald E.Hicks, PA-C, MPH
Instructor
Interservice Physician Assistant Program
Ft. Sam Houston, TX
Phone: 210-221-6684
E-mail: Donald.Hicks@AMEDD.ARMY.MIL

Sarah Ingersoll
Project Manager
ACS Federal Healthcare, Inc.
5270 Shawnee Road
Alexandria, VA 22312
Phone: 703-310-0176
Fax: 703-310-0126
E-mail: sarah.ingersoll@acs-inc.com

Mark A. Long, EdD
Health Promotion Program Manager for Tobacco Cessation
Navy Environmental Health Center
620 John Paul Jones Circle, Suite 1100
Portsmouth, VA 23708-2103
Phone: 757-953-0959
Fax: 757-953-0658
E-mail: Long2@nehc.med.navy.mil

Joanne Marko, MS, CCC-SLP
ACS Federal Healthcare, Inc.
5270 Shawnee Road
Alexandria, VA 22312
Phone: 703-310-0184
Fax: 703-310-0126
E-mail: joanne.marko@acs-inc.com

Eugene Moore, PharmD
Clinical Pharmacist
DoD Pharmacoeconomic Center
2421 Dickman Rd, Suite310
Fort Sam Houston, TX 78234-5081
Phone: 210-295-2792
Fax: 210-295-2789
E-mail: Eugene.Moore@amedd.army.mil

LTC Sharon E. Reese, BSN, MPH
Program Manager
USACHPPM
5158 Blackhawk Rd
Aberdeen Proving Ground, MD 21010-5403
Phone: 410-436-7151
Fax: 410-436-7381
E-mail: Sharon.Reese@apg.amedd.army.mil

Pamila Richter, RDH
Health Promotion Director
USA Dental Command
2050 Worth Road, Ste 4
Fort Sam Houston, TX 78234-6026
Phone: 210-221-8241
Fax: 210-221-8810
E-mail: Pamila.Richter@cen.amedd.army.mil

Abby C. Rosenthal, MPH
Office on Smoking and Health
Centers for Disease Control and Prevention,
4770 Buford Highway, NE
Atlanta, GA 30341
Phone: 770-488-5159
Fax: 770-488-5848
E-mail: alr7@cdc.gov

Joanne Schmith, RNC, MPH
OH Nurse Consultant
USACHPPM
Bldg. 1570
APG, MD 21010
Phone: 410-436-1002
Fax: 410-436-4637
E-mail: Joanne. Schmith@amedd.army.mil

Maj Lisa Schmidt, BSN, MSA
Chief, Health Promotion Operations
Air Force Medical Operation Agency
110 Luke Ave., Room 405
Bolling AFB, Washington DC, 20032
Phone: 202-767-0187
Fax: 202-404-8089
E-mail: Lisa.Schmidt@pentagon.af.mil

Diana M. Settles, MAT, ATC
Program Manager, Injury Prev. & Physical Fitness
Navy Environmental Health Center
620 John Paul Jones Circle, Suite 1100
Portsmouth, VA 23708-2197
Phone: 757-953-0977 DSN (377)
E-mail: settlesd@nehc.med.navy.mil

Scott Sherman, MD, MPH
Smoking Cessation Coordinator
VA Greater Los Angeles Healthcare System
16111 Plummer Street
Sepulveda, CA 91343
Phone: 818-891-7711, ext.9909
Fax: 818-894-5838
E-mail: scott.Sherman@med.va.gov

Oded Susskind, MPH
Medical Education Consultant
PO Box 112
Brookline, MA 02446
Phone: 617-232-3558
Fax: 617-713-4431
E-mail: oded@tiac.net

Col Gerald Talcott, PhD
Chief, Community Prevention Division
AFMOA/SGZF
2664 Flight Nurse, B801
Brooks, AFB 78235
Phone: 210-536-6771
Fax: 210-536-9032
E-mail: Wayne.Talcott@brooks.af.mil

Sara Thomas
Consultant
ACS Federal Healthcare, Inc.
5270 Shawnee Road
Alexandria, VA 22312
E-mail: sara.thomas@acs-inc.com

Debby Walder, RN, MSN
Director of Quality and Performance
Department of Veterans Affairs
810 Vermont Avenue
Washington, DC 20420
Phone: 202-273-8336
Fax: 202-273-9030
E-mail: debby.walder@hq.med.va.gov

CAPT Larry N. Williams, DDS
Head, Dental Department
Military Medical Support Office
320A "B" Street
PO Box 886999
Great Lakes, Illinois 60088
Phone: 847-688-3950, ext. 723
Fax: 847-688-7394
E-mail:lnwilliams@mmso.med.navy.mil

Steven Yevich, MD
Director
VA National Center for Health Promotion and Disease Prevention
3000 Croasdaile Dr.
Durham, NC 27705
Phone: 919-383-7874
E-mail: Steven.Yevich@med.va.gov

LTC Stacey Young-McCaughan RN, PhD
Chief, Performance Improvement & Outcomes Management
USA MEDCOM, Quality Management
2050 Worth Road, Suite 26
Fort Sam Houston, TX 78234-6026
Phone: 210-221-8297
Fax: 210-221-8478
E-mail: stacey.young-mccaughan@cen.amedd.army.mil

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