

US Public Health Service Clinical Practice Guideline: Treating Tobacco Use and Dependence

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for the Guideline Panel and Staff

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Abstract

Treating Tobacco Use and Dependence, a Public Health Service-sponsored Clinical Practice Guideline, is a product of the Tobacco Use and Dependence Guideline Panel ("the panel"), consortium representatives, consultants, and staff. These 30 individuals were charged with the responsibility of identifying effective, experimentally validated tobacco dependence treatments and practices. The updated guideline was sponsored by a consortium of seven Federal Government and nonprofit organizations: the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), National Cancer Institute (NCI), National Heart, Lung, and Blood Institute, National Institute on Drug Abuse, Robert Wood Johnson Foundation, and University of Wisconsin Medical School's Center for Tobacco Research and Intervention. This guideline is an updated version of the 1996 *Smoking Cessation Clinical Practice Guideline No. 18* that was sponsored by the Agency for Health Care Policy and Research (now the AHRQ), United States Department of Health and Human Services. The original guideline reflected the extant scientific research literature published between 1975 and 1994.

The updated guideline was written because new, effective clinical treatments for tobacco dependence have been identified since 1994. The accelerating pace of tobacco research that prompted the update is reflected in the fact that 3,000 articles on tobacco were identified as published between 1975 and 1994, contributing to the original guideline. Another 3,000 were published between 1995 and 1999 and contributed to the updated guideline. These 6,000 articles were screened and reviewed to identify a much smaller group of articles that served as the basis for guideline data analyses and panel opinion.

This guideline contains strategies and recommendations designed to assist clinicians, tobacco dependence treatment specialists, and health care administrators, insurers, and purchasers in delivering and supporting effective treatments for tobacco use and dependence. The recommendations were made as a result of a systematic review and analysis of the extant scientific literature, using meta-analysis as the primary analytic technique. The strength of evidence that served as the basis for each recommendation is clearly indicated in the guideline. A draft of the guideline was peer-reviewed prior to publication, and the comments of 70 external reviewers were incorporated into the final document. The key recommendations of the updated guideline, *Treating Tobacco Use and Dependence*, based on the literature review and expert panel opinion, are as follows:

1. Tobacco dependence is a chronic condition that often requires repeated intervention. However, effective treatments exist that can produce long-term or even permanent abstinence.
2. Because effective tobacco dependence treatments are available, every patient who uses tobacco should be offered at least one of these treatments:
 - Patients *willing* to try to quit tobacco use should be provided with treatments identified as effective in this guideline.
 - Patients *unwilling* to try to quit tobacco use should be provided with a brief intervention designed to increase their motivation to quit.

3. It is essential that clinicians and health care delivery systems (including administrators, insurers, and purchasers) institutionalize the consistent identification, documentation, and treatment of every tobacco user seen in a health care setting.
4. Brief tobacco dependence treatment is effective, and every patient who uses tobacco should be offered at least brief treatment.
5. There is a strong dose-response relation between the intensity of tobacco dependence counseling and its effectiveness. Treatments involving person-to-person contact (via individual, group, or proactive telephone counseling) are consistently effective, and their effectiveness increases with treatment intensity (eg, minutes of contact).
6. Three types of counseling and behavioral therapies were found to be especially effective and should be used with all patients attempting tobacco cessation:
 - Provision of practical counseling (problem-solving/skills training);
 - Provision of social support as part of treatment (intra-treatment social support); and
 - Help in securing social support outside of treatment (extra-treatment social support).
7. Numerous effective pharmacotherapies for smoking cessation now exist. Except in the presence of contraindications, these should be used with all patients attempting to quit smoking.
 - Five *first-line* pharmacotherapies were identified that reliably increase long-term smoking abstinence rates:
 - Bupropion SR
 - Nicotine gum
 - Nicotine inhaler
 - Nicotine nasal spray
 - Nicotine patch
 - Two *second-line* pharmacotherapies were identified as efficacious and may be considered by clinicians if first-line pharmacotherapies are not effective:
 - Clonidine
 - Nortriptyline
 - Over-the-counter nicotine patches are effective relative to placebo, and their use should be encouraged.
8. Tobacco dependence treatments are both clinically effective and cost-effective relative to other medical and disease prevention interventions. As such, insurers and purchasers should ensure that:
 - All insurance plans include as a reimbursed benefit the counseling and pharmacotherapeutic treatments identified as effective in this guideline, and
 - Clinicians are reimbursed for providing tobacco dependence treatment just as they are reimbursed for treating other chronic conditions.

The updated guideline is divided into eight chapters that provide an overview including methods (Chapter 1), information on the assessment of tobacco use (Chapter 2), brief clinical interventions, both for patients willing and unwilling to make a quit attempt at this time (Chapter 3), intensive clinical interventions (Chapter 4), systems interventions for health care administrators, insurers, and purchasers (Chapter 5), the scientific evidence supporting the guideline recommendations (Chapter 6), and special populations and topics (Chapters 7 and 8).

A comparison of the findings of the updated guideline with the original guideline reveals the considerable progress made in tobacco research over the brief period separating these two publications. Tobacco dependence is now increasingly recognized as a chronic disease, one that typically requires ongoing assessment and repeated intervention. In addition, the updated guideline offers the clinician many more efficacious treatment strategies than were identified in the original guideline. There are now seven different efficacious agents in the smoking cessation pharmacopoeia, allowing the clinician and patient many different medication options. In addition, recent evidence has identified new, efficacious counseling strategies. In particular, proactive telephone counseling is efficacious, as is counseling that helps smokers attain social support outside of the treatment context. The updated guideline also reveals greater evidence of the strong dose-response relation between counseling intensity and the likelihood of long-term abstinence from tobacco. Indeed, the data are compelling that pharmacologic and counseling treatment each independently boost cessation success; these data suggest that optimal cessation outcomes may require the combined use of both counseling and pharmacotherapy.

Finally, there is increasing evidence that the success of any tobacco dependence treatment strategy or

effort cannot be divorced from the health care system in which it is embedded. Data strongly indicate that effective tobacco interventions require *coordinated interventions*. Just as the clinician must intervene with his or her patient, so must the health care administrator, insurer, and purchaser foster and support tobacco intervention as an integral element of health care delivery. Health care administrators and insurers should ensure that clinicians have the training and support, and receive the reimbursement necessary to achieve consistent, effective intervention with tobacco users.

One important conclusion of this guideline is that the most effective way to move clinicians to intervene is to provide them with information regarding multiple efficacious treatment options and to ensure that they have ample institutional support to use these options. Indeed, in this guideline, the panel encourages a culture of health care in which failure to treat tobacco use—the chief cause of preventable disease and death—constitutes an inappropriate standard of care. *Key words: tobacco, dependence, addiction, nicotine, cessation, Bupropion, Nortriptyline, patch.* [Respir Care 2000;45(10):1200–1262]

1. Overview and Methods

Introduction

Tobacco use has been cited as the chief avoidable cause of illness and death in our society, responsible for more than 430,000 deaths in the United States each year.¹ Smoking is a known cause of cancer, heart disease, stroke, complications of pregnancy, and chronic obstructive pulmonary disease (COPD).² Given the health dangers it presents and the public's awareness of those dangers, tobacco use remains surprisingly prevalent. Recent estimates are that 25% of adult Americans smoke.^{3–5} Moreover, smoking prevalence among adolescents has risen dramatically since 1990,⁶ with more than 3,000 additional children and adolescents becoming regular users of tobacco each day.^{7,8} As a result, a new generation of Americans has become dependent upon tobacco and is at risk for the extraordinarily harmful consequences of tobacco use.

Tobacco use is not only dangerous to individuals, it also results in staggering societal costs. The estimated smoking-attributable cost for medical care in 1993 was more than \$50 billion,⁹ and the cost of lost productivity and

forfeited earnings due to smoking-related disability was estimated at \$47 billion per year.¹⁰

Despite the tragic health consequences of using tobacco, clinicians often fail to assess and treat tobacco use consistently and effectively. For instance, in 1995 smoking status was identified in only about 67% of clinic visits, and smoking cessation counseling was provided in only 21% of smokers' clinic visits.¹¹ Moreover, treatment is typically offered only to patients already suffering from tobacco-related diseases.¹¹ This failure to assess and intervene consistently with tobacco users exists in the face of substantial evidence that even brief smoking cessation treatments can be effective.^{12–15}

This guideline concludes that tobacco use presents a rare confluence of circumstances: (1) a highly significant health threat, (2) a disinclination among clinicians to intervene consistently, and (3) the presence of effective interventions. This last point is buttressed by evidence that smoking cessation interventions, if delivered in a timely and effective manner, significantly reduce the smoker's risk of suffering from smoking-related disease.^{16,17} Indeed, it is difficult to identify any other condition that presents such a mix of lethality, prevalence, and neglect, despite effective and readily available interventions.

Finally, significant barriers exist that interfere with clinicians' assessment and treatment of smokers. Many clinicians lack knowledge about how to identify smokers quickly and easily, which treatments are efficacious, how such treatments can be delivered, and the relative efficacies of different treatments.¹⁸ Additionally, they may fail to intervene because of inadequate clinic or institutional support for routine assessment and treatment of tobacco use^{11,19,20} and for other reasons such as time constraints.^{21,22}

Rationale for Initial Guideline Development and Year 2000 Update

In the early 1990s, the Agency for Health Care Research and Policy (now the Agency for Healthcare Research and

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Parts of the original document are not reprinted herein but are available at <http://www.osophs.dhhs.gov/tobacco>. The omitted sections are: Appendix A: Helpful Web site addresses. Appendix B: Coding information regarding the diagnosis of and billing for tobacco dependence treatment. Appendix C: Financial disclosures for panel members, consultants, and senior project staff. Glossary. Index.

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Quality [AHRQ]) convened an expert panel to develop the *Smoking Cessation Clinical Practice Guideline No. 18* (the "guideline") in the AHCPR series of Clinical Practice Guidelines. The need for this guideline was based on several factors, including tobacco use prevalence, related morbidity and mortality, the economic burden imposed by tobacco use, variation in clinical practice, availability of methods for improvement of care, and availability of data upon which to base recommendations for care.

Since the guideline was published in 1996, it has become a popular document. More than 1 million copies of the guideline and its affiliated products have been disseminated. Guideline recommendations have inspired changes in diverse health care settings such as health maintenance organizations and Veteran's Administration hospitals. The original guideline continues to provide a framework for educating clinicians, administrators, and policy makers about the importance of tobacco dependence and its treatment. It has stimulated discussions that address the development of tobacco dependence treatment programs at the federal and state levels and by professional medical organizations.

Significant new research on tobacco use and its treatment has appeared since the publication of the original guideline. As a result of this new research, as well as an increasing recognition that tobacco interventions must become an integral part of health care delivery, the expert panel that developed the 1996 *Smoking Cessation Clinical Practice Guideline No. 18* was reconvened in 1998 to conduct an update. This guideline update is sponsored by a consortium of private and public partners, including the AHRQ, National Cancer Institute (NCI), National Heart, Lung, & Blood Institute, National Institute on Drug Abuse, Office on Smoking and Health at the Centers for Disease Control and Prevention (CDC), Robert Wood Johnson Foundation, and University of Wisconsin Medical School's Center for Tobacco Research and Intervention.

The original guideline addressed barriers to effective smoking cessation intervention on the basis of a careful evaluation and synthesis of relevant scientific evidence. The guideline comprised specific evidence-based recommendations to guide clinicians and smoking cessation specialists in their tobacco intervention efforts. Additional specific recommendations guided insurers, purchasers, and health care administrators in their efforts to develop and implement institutional and policy changes that support the reliable assessment and treatment of tobacco dependence.

The updated guideline, *Treating Tobacco Use and Dependence*, a Public Health Service-sponsored Clinical Practice Guideline, provides recommendations based on evidence published through January 1, 1999. This new title underscores three truths about tobacco use.²³ First, all tobacco products, not just cigarettes, exact devastating costs on the Nation's health and welfare. Second, for most users,

tobacco use results in true drug dependence, one comparable to the dependence caused by opiates, amphetamines, and cocaine.²⁴ Third, chronic tobacco use warrants clinical intervention just as do other addictive disorders.^{18,25}

Most tobacco users in the United States are cigarette smokers. As a result, the majority of clinician attention and research in the field has focused on the treatment and assessment of smoking. However, clinicians should intervene with all tobacco users, not just with smokers. To foster a broad implementation of this guideline, every effort has been made to describe interventions so that they are relevant to all forms of tobacco use. In some sections of this guideline (eg, sections of Chapter 6), the term "smoker" is used instead of "tobacco user." The use of the term "smoker" merely means that all relevant evidence for a recommendation arises exclusively from studies of cigarette smokers. Additional discussion of noncigarette forms of tobacco use is found in Chapter 8.

It is important to note that other guidelines and analyses on the treatment of tobacco dependence have been published, including those from the American Psychiatric Association,²⁶ the American Medical Association,²⁷ the United Kingdom Guideline,²⁸ and those published by the Cochrane Collaboration.²⁹

Tobacco Dependence as a Chronic Disease

Tobacco dependence shows many features of a chronic disease. Although a minority of tobacco users achieves permanent abstinence in an initial quit attempt, the majority persist in tobacco use for many years and typically cycle through multiple periods of relapse and remission. A failure to appreciate the chronic nature of tobacco dependence may undercut clinicians' motivation to treat tobacco use consistently.

Epidemiologic data suggest that more than 70% of the 50 million smokers in the United States today have made at least one prior quit attempt, and approximately 46% try to quit each year.⁴ Unfortunately, most of these efforts are unsuccessful; among the 17 million adults who attempted cessation in 1991, only about 7% were still abstinent 1 year later.^{30,31} These discouraging statistics have led many clinicians to report that they feel ineffective in the treatment of tobacco dependence.

Moreover, as described in a recent editorial,³² much smoking cessation research and clinical practice over the last three decades has focused on identifying the ideal intervention that would turn all smokers into permanent nonsmokers. This effort may have inadvertently communicated two messages of dubious validity: first, that there is one treatment that will be effective for virtually all smokers, and, second, that success should be defined only on the basis of permanent abstinence. These messages may have masked the true nature of tobacco addiction; it is

typically a chronic disorder that carries with it a vulnerability to relapse that persists for weeks, months, and perhaps years.

A more productive approach is to recognize the chronicity of tobacco dependence. A chronic disease model has many appealing aspects. It recognizes the long-term nature of the disorder with an expectation that patients may have periods of relapse and remission. If tobacco dependence is recognized as a chronic condition, clinicians will better understand the relapsing nature of the ailment and the requirement for ongoing, rather than just acute, care. Clinicians also should recognize that despite the potential for relapse, numerous effective treatments are now available and described in this guideline.

A chronic disease model emphasizes for clinicians the importance of counseling and advice. Although most clinicians are comfortable in counseling their patients about diabetes, hypertension, or hyperlipidemia, many believe that they are ineffective in providing counseling to patients who use tobacco. As with these chronic disorders, clinicians encountering a patient dependent on tobacco must be encouraged to provide that patient with simple counseling advice, support, and appropriate pharmacotherapy. In updating the guideline, the panel has presented evidence-based analytic findings in a format accessible and familiar to practicing clinicians. Although this should aid clinicians in the assessment and treatment of tobacco users, clinicians should remain cognizant that relapse is likely and that it reflects the chronic nature of dependence, not their personal failure, nor a failure of their patients.

Guideline Development Methodology

Introduction. Panel recommendations are intended to provide clinicians with effective strategies for treating patients who use tobacco. Recommendations were influenced by two goals. The first was to identify clearly efficacious treatment strategies. The second was to formulate and present recommendations so that they can be implemented easily across diverse clinical settings and patient populations.

The guideline is based on two systematic reviews of the available scientific literature. The first review occurred during the creation of the original guideline published in 1996 and included literature published from 1975 through 1994. The second review was conducted for the updated guideline and included literature from 1995 through January 1, 1999. The two reviews were then combined into a single database.

The panel identified randomized placebo/comparison controlled trials as the strongest level of evidence for evaluation of treatment efficacy. Thus, evidence derived from randomized controlled trials serves as the basis for meta-analyses and for almost all recommendations contained in this guideline. However, the panel occasionally made rec-

ommendations in the absence of randomized controlled trials. It did so when faced with an important clinical practice issue for which persuasive evidence existed. When the panel considered evidence other than randomized controlled trials, it did not restrict itself to articles that otherwise met the inclusion criteria. For example, for recommendations that were not based on meta-analyses, the panel reviewed some articles published after January 1, 1999. This guideline clearly identifies the level or strength of evidence that serves as the basis for each of its recommendations.

Topics Included in the Guideline. The panel identified tobacco use as the targeted behavior and tobacco users as the clinical population of interest. Tobacco dependence treatments were evaluated for efficacy as were interventions aimed at modifying both clinician and health care delivery system behavior.

Interventions for the primary prevention of tobacco use were not examined in detail, with the exception of interventions directly relevant to clinical practice. Because of the importance and complexity of the primary prevention of tobacco initiation, the panel recommends that primary prevention be addressed in a separate clinical practice guideline. Readers may also refer to the 1994 Surgeon General's Report, *Preventing Tobacco Use Among Young People*.⁶³ In addition, community-level interventions (eg, mass media campaigns) that are not usually implemented in primary care practice settings are not addressed. For more information on community-based tobacco use prevention, refer to the *Centers for Disease Control and Prevention Guide to Community Preventive Services* (available in 2000).

This guideline is designed for three main audiences: primary care clinicians, tobacco dependence treatment specialists, and health care administrators, insurers, and purchasers. Additionally, the guideline is designed to be used in a wide variety of clinical practice settings, including private practices, academic health centers, managed care settings and health maintenance organizations, public health department clinics, hospitals, and school or work site clinics.

At the start of the update process, guideline panel members, outside experts, and consortium representatives were consulted to determine those aspects of the original guideline that required updating. These consultations resulted in the following chief recommendations that guided the update efforts: (1) to update any recommendations from the original guideline likely to be affected by new research findings, (2) to provide information and recommendations on health systems changes relevant to tobacco cessation including the cost-effectiveness of tobacco cessation, (3) to summarize the literature and make recommendations regarding special populations, and (4) to address content

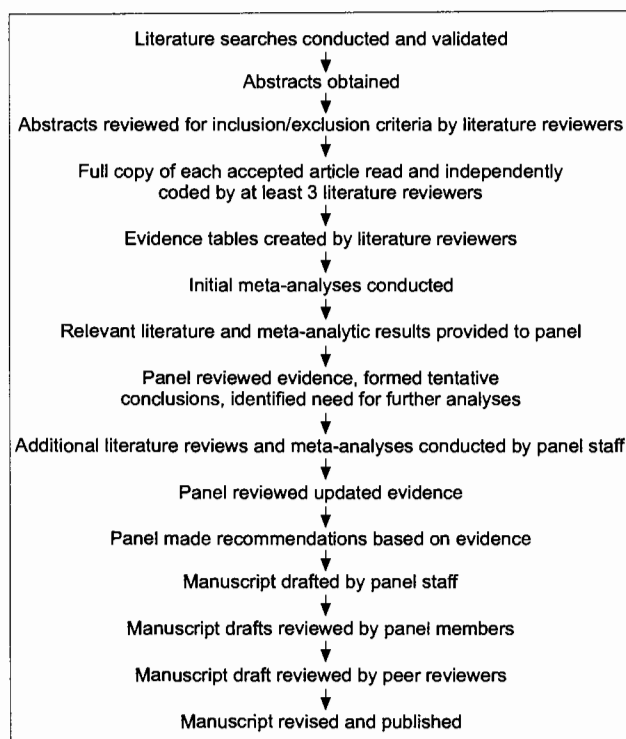


Fig. 1. Guideline development process. These steps were taken in drafting both the original and updated guidelines.

areas and models of treatment for which little data existed during the development of the original guideline.

Guideline Development Process. The original guideline development process was initiated in late 1993. This update was initiated in mid-1998. The methodology was consistent between the two efforts except where specifically identified below (Fig. 1).

Selection of Evidence. Published, peer-reviewed, randomized controlled studies were considered to constitute the strongest level of evidence in support of guideline recommendations. This decision was based on the judgment that randomized controlled trials provide the clearest, scientifically sound basis for judging comparative efficacy. The panel made this decision recognizing the limitations of randomized controlled trials, particularly considerations of generalizability with respect to patient selection and treatment quality.

Literature Review and Inclusion Criteria. Approximately 6,000 articles were reviewed to identify evaluable literature—3,000 during the original project and another 3,000 during the update. These articles were obtained through searches of electronic databases and reviews of published abstracts and bibliographies. An article was deemed appropriate for meta-analysis if it met the criteria

for inclusion established *a priori* by the panel. These criteria were that the article: (A) reported the results of a randomized, placebo/comparison controlled trial of a tobacco-use treatment intervention randomized on the patient level, (B) provided follow-up results at a time point at least 5 months after the quit date, (C) was published in a peer-reviewed journal, (D) was published between January 1, 1975 and January 1, 1999, and (E) was published in English. Additionally, articles screened during the update were screened for relevance to economic or health systems issues. As a result of the original and updated literature reviews, more than 180 articles were identified for possible inclusion in a meta-analysis, and more than 500 additional articles were examined by the panel. These articles were used in the consideration and formulation of panel recommendations that were not supported by meta-analyses. The literature search for the update project was validated by comparing the results against a search conducted by the CDC, by a review of the database by the expert panel, and by requesting articles pertaining to special topics from experts in the field.

It is important to note that because of a faithful application of article screening criteria in the updated guideline, some of the studies that were included in the original guideline were not included in the updated analyses. This resulted in an inability to perform certain analyses that had previously been conducted (eg, analysis of the different types of self-help).

When individual authors published multiple articles meeting the meta-analytic inclusion criteria, the articles were screened to determine whether they contained unique data. Where two articles reported data from the same group of subjects, both articles were used to elicit the complete trial data for the analyses.

Preparation of Evidence Tables. Three reviewers independently read and coded each article that met inclusion criteria. The reviewers coded the treatment characteristics that were used in data analyses (see Table 6 in Chapter 6). The same general coding procedure employed during the original guideline process was employed during the update. Where adjustments to the coding process were made, articles from the original process were re-coded to reflect the changed coding (eg, more refined counseling and behavioral therapy designations were used during the update to capture more specific counseling practices.) The reviewers then met and compared coding. Any discrepancies that could not be resolved were adjudicated by the project director, panel chair, and/or senior scientific consultant. The data were then compiled and used in relevant analyses. As a test of the coding process for the update, interrater reliability analyses were conducted on four coded intervention categories: type of format, type of clinician, type of counseling and behavioral therapies, and level of

person-to-person contact. Using the proportional overlap method³³ for format, clinician and counseling and behavioral therapies, and the nominal response method³⁴ for level of person-to-person contact, reliability analyses were conducted on 16 studies that had all been coded by the same three reviewers. Coded data were sampled from the preadjudicated ratings made by the three reviewers who coded the greatest number of articles. Studies and intervention categories were selected after coding, so reviewers were unaware of the data to be analyzed for reliability. Results revealed the following chance-corrected inter-rater reliabilities for each of the tested categories: $\kappa = 0.73$ for format, $\kappa = 0.72$ for clinician, $\kappa = 0.77$ for counseling and behavioral therapies, and $\kappa = 0.78$ for level of person-to-person contact.

Outcome Data. To meet inclusion criteria for the meta-analyses, a study was required to provide outcome data with follow-up at least 5 months after the designated quit day. Five months was chosen to balance the needs for (A) a large pool of studies for meta-analyses and (B) the desire to examine only clinically important outcomes (ie, long-term abstinence). When quit rates were provided for multiple long-term end points, efficacy data from the end point closest to 6 months were used, so long as they did not exceed 3 years. Virtually all cessation analyses in this guideline were done on these long-term outcome data. (One exception is that the meta-analysis of cessation treatments in pregnant women allowed somewhat shorter follow-up periods because of the desire for preparturition data.)

Panel staff also coded biochemical confirmation of self-reported abstinence. Previous guideline analyses show that studies with and without biochemical confirmation yield similar meta-analysis results. Therefore, meta-analyses presented in the guideline reflect a pooling of these studies. The only exception to this was in the pregnancy analyses. Data suggest that self-reported abstinence rates may be less reliable in pregnant women; therefore, the pregnancy meta-analysis included only abstinence data that were biochemically confirmed.³⁵⁻³⁷

Two types of follow-up data were included in the analyses to index treatment efficacy. The first and preferred type of data were intent-to-treat data, in which the denominator was the number of patients randomized to treatment and the numerator was the number of abstinent patients contacted at follow-up. The second type of acceptable data were similar, except that the denominator consisted only of patients who had completed treatment. Other types of follow-up data were not included in analyses (eg, studies in which the denominator included only those subjects contacted during follow-up).

Studies were coded for how the outcome measures were reported, "point prevalence," "continuous," or "unknown."

If abstinence data were based on smoking occurrence within a set time period (usually 7 d) prior to a follow-up assessment, the outcome measure was coded as "point prevalence." "Continuous" was used when a study reported abstinence based on whether study subjects were continuously abstinent from tobacco use since their quit day. "Unknown" was used when it was not possible to discern from the study report whether the authors used a point prevalence or continuous measure for abstinence.

As in the original guideline, a point prevalence outcome measure (1-week point prevalence, when available) rather than continuous abstinence was used as the chief outcome variable. Point prevalence was preferred for several reasons. First, among the 180 randomized controlled trials available for meta-analysis, the majority presented their primary outcome data as point prevalence. Second, continuous abstinence data underestimate the percentage of individuals who are abstinent at particular follow-up time points. They might, therefore, suggest that the likelihood of cessation is lower than in actuality. Finally, most relapse begins early in a quit attempt and persists. A point prevalence measure taken at 5 months would certainly capture the great majority of those relapse events. Therefore, wherever possible, 1-week point prevalence abstinence data were used. If point prevalence data were not available, the preferred alternative was continuous abstinence data. Data of an unknown or unspecified nature were used otherwise.

Meta-Analytic Techniques. The principal analytic technique used in this guideline was meta-analysis. This statistical technique estimates the impact of a treatment or variable across a set of related investigations. The primary meta-analytic model used in this and the original guideline was logistic regression using random effects modeling. The modeling was done at the level of the treatment arm, and study effects were treated as fixed. The panel methodologists chose to employ random effects modeling, assuming that both the subject populations and the treatment elements analyzed would vary from study to study (eg, "general problem-solving" counseling might be done somewhat differently at two different sites). Random effects modeling is well suited to accommodate such variation among studies.³⁸ The statistician used the EGRET Logistic Normal Model (Statistics and Epidemiology Research Corporation, *EGRET Reference Manual*, Revision 4, Seattle, 1993). A complete and detailed review of the meta-analytic methods used in the guideline can be found in the *Smoking Cessation Guideline Technical Report No. 18* available from AHRQ as AHCPR Publication No. 97-N004.

The meta-analytic technique assumed randomization of subjects to treatment conditions. Moreover, studies that randomized at another level (eg, clinician, clinic, etc) typically did not provide data on nonindependence. There-

fore, only studies that randomized at the level of the subject were submitted to meta-analysis. To reduce the likelihood that this selection criterion would bias results, some test analyses were performed that included studies randomized by clinic or clinician. In all cases, these analyses were consistent with the results of studies using subject-based randomization.

The initial step in meta-analysis was the selection of studies that were relevant to the treatment characteristic being evaluated. After relevant studies were identified (eg, those that contained a self-help intervention if self-help treatments were being evaluated), panel staff reviewed the studies to ensure that they passed screening criteria. Some screening criteria were general (eg, study presents greater than 5 mo follow-up data), whereas other criteria were specific to the type of treatment characteristic evaluated (eg, in the analysis of clinicians, screening ensured that differences in type of clinician were not confounded by differences in use of pharmacotherapy). In most cases, there was no attempt to control for the effects of variables that were potentially correlated with an analyzed treatment dimension (eg, controlling for overall treatment intensity in the analysis of number of types of formats and number of types of clinicians).

The separate arms (treatment or control groups) in each study were then inspected to identify confounders that could compromise interpretation. Seriously confounded arms were excluded from analysis. Relevant characteristics of each arm were then coded to produce meaningful analytic comparisons. Criteria for performing a meta-analysis included: (1) the guideline panel judged the topic to be addressed in the meta-analysis as having substantial clinical importance, (2) at least two studies meeting selection criteria existed on the topic and the studies contained suitable within-study control or comparison conditions, and (3) there was acceptable inter-study homogeneity in the analyzed variable or treatment to permit meaningful inference (eg, an analyzed treatment was sufficiently similar across various studies so that combining studies was meaningful).

Limitations of Meta-Analytic Techniques. Several factors can compromise the internal validity of meta-analyses. For example, publication biases (particularly the tendency to publish only those studies with positive findings) may result in biased summary statistics. The complement to publication bias is the "file-drawer effect," in which negative or neutral findings are not submitted for publication. In addition, either the magnitude or the significance of the effects of meta-analyses may be influenced by factors such as the frequency with which treatments occurred in the data set, and by the extent to which treatments co-occurred with other treatments. All else being equal, a treatment that occurs infrequently in the data set is less likely to be found significant than a more frequently oc-

curing treatment. Also, when two treatments co-occur frequently in the same groups of subjects, it is difficult to apportion statistically the impact of each. In addition, comparability biases can exist when substantially different groups or treatments are coded as being the same (eg, when treatments are similar only on a superficial attribute).

Stability of meta-analytic findings was determined with respect to only one population characteristic: that is whether patients sought cessation treatment ("self-selected") or whether treatment was delivered without the patient seeking it ("all-comers," as when cessation treatment occurred as an integral part of health care). Conducting separate meta-analyses in these different subject populations yielded very similar findings across a variety of treatment dimensions (eg, treatment format, treatment intensity). No other population characteristic (eg, years smoked, severity of dependence) was explored in meta-analyses.

Interpretation of Meta-analysis Results. The meta-analyses yielded logistic regression coefficients that were converted to odds ratios. The meaning or interpretation of an odds ratio can be seen most easily by means of an example depicted in a 2×2 table. Table 1 contains data showing the relation between maternal smoking and low birthweight in infants. Data are extracted from Hosmer and Lemeshow.³⁹ The odds of a low birthweight infant if the mother smokes are 30:44, or 0.68 to 1. The odds of a low birthweight infant if the mother does not smoke are 29:86, or 0.34 to 1. The odds ratio is thus $(30/44)/(29/86) = 2.02$ to 1. Therefore, the odds ratio can be seen roughly as the odds of an outcome on one variable, given a certain status on another variable(s). In the case above, the odds of a low birthweight infant is about double for women who smoke compared with those who do not.

Once odds ratios were obtained from meta-analyses, 95% confidence intervals (CIs) were estimated around the odds ratios. An odds ratio is only an estimate of a relation between variables. The 95% CI presents an estimate of the accuracy of the particular odds ratio obtained. If the 95% CI for a given odds ratio does not include "1," then the odds ratio represents a statistically significant effect at the 0.05 level. The CIs will generally not be perfectly symmetrical around an odds ratio because of the distributional properties of the odds ratio. Comparisons of the relative

Table 1. Relation Between Maternal Smoking and Low Birth Weight in Infants

		Maternal Smoking		Totals
		Yes	No	
Low Birth Weight	Yes	30	29	59
	No	44	86	130
Totals		74	115	189

Table 2. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Various Types of Format (*n* = 58 studies)

Format	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
No format	20	1.0	10.8
Self-help	93	1.2 (1.02, 1.3)	12.3 (10.9, 13.6)
Proactive telephone counseling	26	1.2 (1.1, 1.4)	13.1 (11.4, 14.8)
Group counseling	52	1.3 (1.1, 1.6)	13.9 (11.6, 16.1)
Individual counseling	67	1.7 (1.4, 2.0)	16.8 (14.7, 19.1)

CI = confidence interval

sizes of odds ratios is meaningful only for those odds ratios yielded by the same meta-analysis (listed in the same data table).

After computing the odds ratios and their CIs, the odds ratios were converted to abstinence percentages and their 95% CIs (based on reference category abstinence rates). Abstinence percentages indicate the estimated long-term abstinence rate achieved under the tested treatment or treatment characteristic. The abstinence percentage results are approximate estimates derived from the odds ratio data.⁴⁰ Therefore, they essentially duplicate the odds ratio results but are presented because their meaning may be clearer for some readers. Because the placebo/control abstinence percentage for a particular analysis is calculated exclusively from the studies included within that meta-analysis, these abstinence percentages vary across the different analyses.

How To Read the Data Tables. Table 2 depicts a table of results from one of the meta-analyses reported in this guideline. This table presents results from the analysis of the effects of different treatment formats on outcome (see Formats of Psychosocial Treatments in Chapter 6B). In this table, the comparison condition, or "reference group," for determining the impact of different treatment options, was smokers who had no contact with a provider. The "Estimated odds ratio" column reveals that treatment groups receiving self-help treatment had an odds ratio of 1.2. The odds ratio indicates a significant effect, because the lower boundary of the CI did not include "1." Proactive telephone counseling had an odds ratio of 1.2, and group counseling had an odds ratio of 1.3. Both of these are statistically significant because the lower bounds of their CIs do not include "1." Individual counseling had the largest odds ratio of 1.7. This odds ratio means that when a smoker receives individual counseling, he or she is more than one and one-half times more likely to remain abstinent than if he or she had received no counseling.

The column labeled "Estimated abstinence rate" shows the abstinence percentages for the various treatment for-

mat. For instance, the reference group conditions (no contact) in the analyzed data set were associated with an abstinence rate of 10.8%. Consistent with the odds ratio data reviewed above, self-help treatments produced modest increases in abstinence rates (12.3%), proactive telephone counseling and group counseling produced somewhat larger increases in abstinence rates (13.1% and 13.9%, respectively), and individual counseling produced the largest increase (16.8%).

The total number of studies included in each meta-analysis is provided within the title of the corresponding table. A list of published articles used in each meta-analysis is available from AHRQ via the AHRQ Web site at www.ahrq.gov.

The column labeled "Number of arms" lists the number of treatment conditions or groups across all analyzed studies that contributed data to the various treatment format categories (eg, self-help treatment was provided in 93 treatment arms). Therefore, this column depicts the number of treatment conditions or groups relevant to each analyzed category. Frequently, the number of treatment groups or arms exceeds the number of studies included in a meta-analysis.

The outcome data in the tables include studies with "all-comers" (individuals who did not seek a treatment intervention) and "self-selected" populations, studies using point-prevalence and continuous abstinence end points, and studies with and without biochemical confirmation, except where otherwise described. Some meta-analyses (such as those evaluating pharmacotherapies) included predominantly studies with "self-selected" populations. In addition, in pharmacotherapy studies both experimental and control subjects typically received substantial counseling. Both of these factors tend to produce higher abstinence rates in reference or placebo subjects than are typically observed among self-quitters.

Strength of Evidence. Every recommendation made by the panel bears a strength-of-evidence rating that indicates the quality and quantity of empirical support for the recommendation. Each recommendation and its strength of evidence reflect consensus of the guideline panel. The three strength of evidence ratings are described below:

- A** Multiple well-designed randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings.
- B** Some evidence from randomized clinical trials supported the recommendation, but the scientific support was not optimal. For instance, few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation.

C Reserved for important clinical situations where the panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.

The availability of randomized clinical trials was not considered in economic recommendations. The existence of such trials was thought to be a less germane criterion for evaluating economic studies. In such cases, the strength of evidence is based primarily on the consistency of findings among different studies. Finally, the panel declined to make recommendations when there was no relevant evidence or the evidence was too weak or inconsistent to support a recommendation.

Caveats Regarding Recommendations. The reader should note some caveats regarding guideline recommendations. First, an absence of studies should not be confused with proven lack of efficacy. In certain situations, there was little direct evidence regarding the efficacy of some treatments, and in these cases the panel usually rendered no opinion. Second, even when there were enough studies to perform a meta-analysis, a nonsignificant result does not prove inefficacy. Rather, nonsignificance merely indicates that efficacy was not demonstrated given the data available.

The emphasis of this guideline was to identify efficacious interventions, not to rank-order interventions in terms of efficacy. The panel chose not to emphasize comparisons among efficacious interventions, for several reasons. First, the most important goal of the analytic process was to identify all efficacious interventions. Second, selection or use of particular intervention techniques or strategies is usually a function of practical factors: patient preference, time available, training of the clinician, cost, and so on. The panel believed clinicians should choose the most appropriate intervention from among the efficacious interventions, given existing circumstances. An excessive emphasis on relative efficacy might discourage clinicians from using interventions that have a small, but reliable, impact on smoking cessation. Finally, data were often inadequate or unavailable to make adequate statistical comparisons of different types of interventions. For example, there were insufficient studies testing head-to-head comparisons of the different pharmacotherapies to allow a rank-ordering of the different pharmacotherapies.

Despite a lack of emphasis on the rank-ordering of interventions, some interventions were so superior to control or no-treatment conditions that the panel clearly identified them as superior to another intervention. For instance, although minimal person-to-person contact can increase smoking abstinence rates over no-treatment conditions, there is little doubt that longer person-to-person interventions have greater impact.

External Review of the Guideline. The panel and AHRQ invited 155 outside reviewers to review the draft of the 1996 guideline. In addition, AHRQ placed a notice in the *Federal Register* inviting individuals to review and comment on this original draft guideline. A total of 71 reviewers provided comments. Panel and consortium members invited 175 outside reviewers to review the updated guideline. A total of 70 provided comments. Peer reviewers included clinicians, health care administrators, social workers, counselors, health educators, researchers, consumers, key personnel at selected federal agencies, and others. Reviewers were asked to evaluate the guideline based on five criteria: validity, reliability, clarity, clinical applicability, and utility. Comments of the peer reviewers were incorporated into the guideline when appropriate.

Guideline Products

Accompanying the original guideline were four products intended to aid in the dissemination and translation of the guideline's evidence-based recommendations. These products were intended to address consumers as well as the three target audiences: primary care clinicians, specialists, and health care administrators, insurers, and purchasers. These products were: (1) *You Can Quit Smoking. Consumer Guide*, (2) *Helping Smokers Quit. A Guide for Primary Care Clinicians*, (3) *Smoking Cessation: Information for Specialists. Quick Reference Guide*, and (4) *Smoking Cessation, A Systems Approach: A Guide for Health Care Administrators, Insurers, Managed Care Organizations, and Purchasers*. Similar products will disseminate the recommendations of the updated guideline.

Organization of the Guideline Update

This updated guideline is divided into eight chapters that reflect the major components of tobacco dependence treatment (Fig. 2):

Chapter 1, Overview and Methods, provides an overview and rationale for the updated guideline, as well as a detailed description of the methodology used to review the scientific literature and develop the original and updated guidelines.

Chapter 2, Assessment of Tobacco Use, establishes the importance of determining the tobacco use status of every patient at every visit.

Chapter 3, Brief Clinical Interventions, is intended to provide clinicians with guidance as they use brief interventions to treat tobacco users willing to quit, tobacco users unwilling to make a quit attempt at this time, and tobacco users who have recently quit.

A. For the Patient Willing To Quit, provides brief clinical approaches to assist patients in quit attempts.

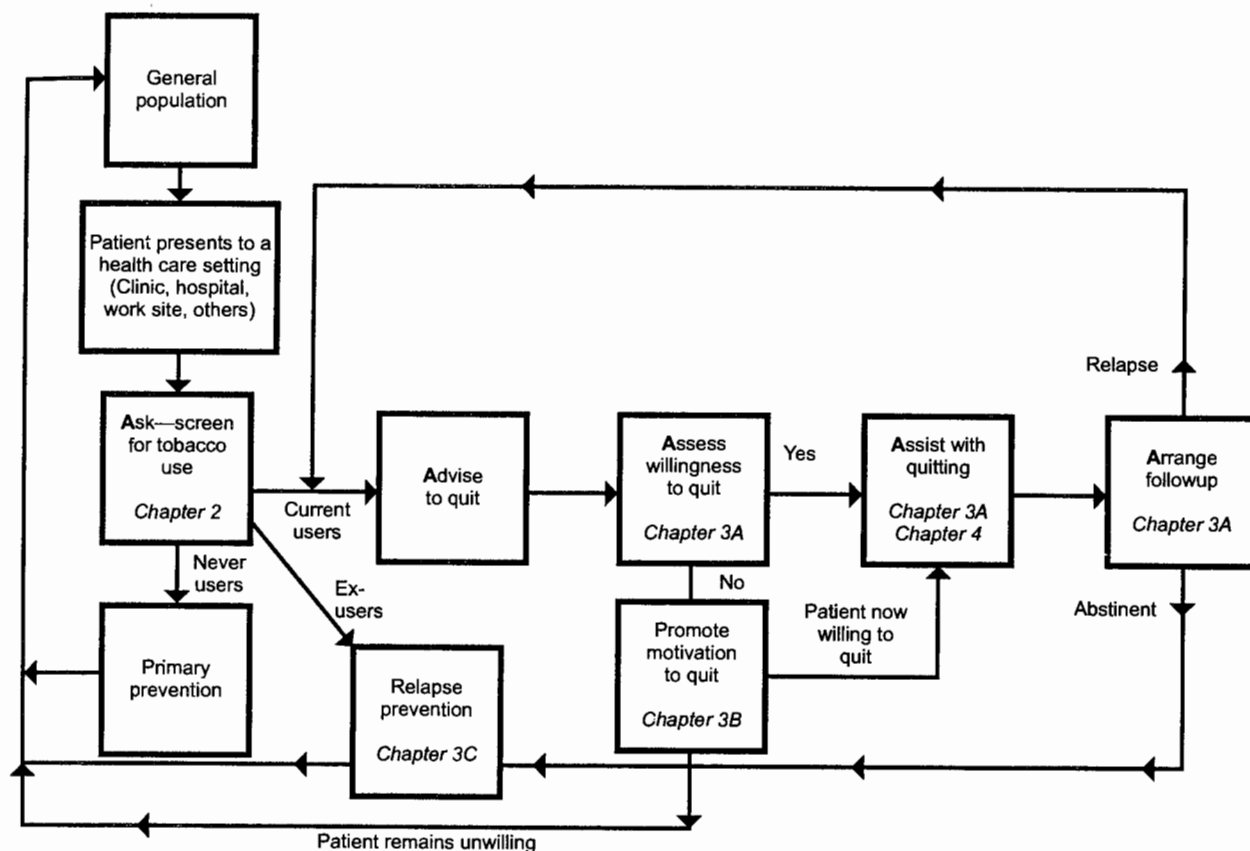


Fig. 2. Model for treatment of tobacco use and dependence.

B. For the Patient Unwilling To Quit, provides brief clinical approaches designed to motivate the patient to make a quit attempt at this time.

C. For the Patient Who Has Recently Quit, provides clinicians with brief strategies designed to reinforce an ex-tobacco user's commitment to stay tobacco-free.

Chapter 4, *Intensive Clinical Interventions*, provides clinicians with more intensive strategies to treat tobacco users.

Chapter 5, Systems Interventions: Relevance to Health Care Administrators, Insurers, and Purchasers, is directed at health care administrators, insurers, purchasers, and other decision-makers who can affect health care systems. This chapter provides these decision-makers with strategies to modify health care systems to improve the delivery of tobacco treatment services.

Chapter 6, Evidence, presents the evidentiary basis for the updated guideline recommendations.

A. Screening and Assessment, provides recommendations and analysis results regarding screening for tobacco use and specialized assessment.

B. Treatment Structure and Intensity, provides recommendations and analysis results regarding advice, intensity of clinical interventions, and type of clinician, format, and follow-up procedures.

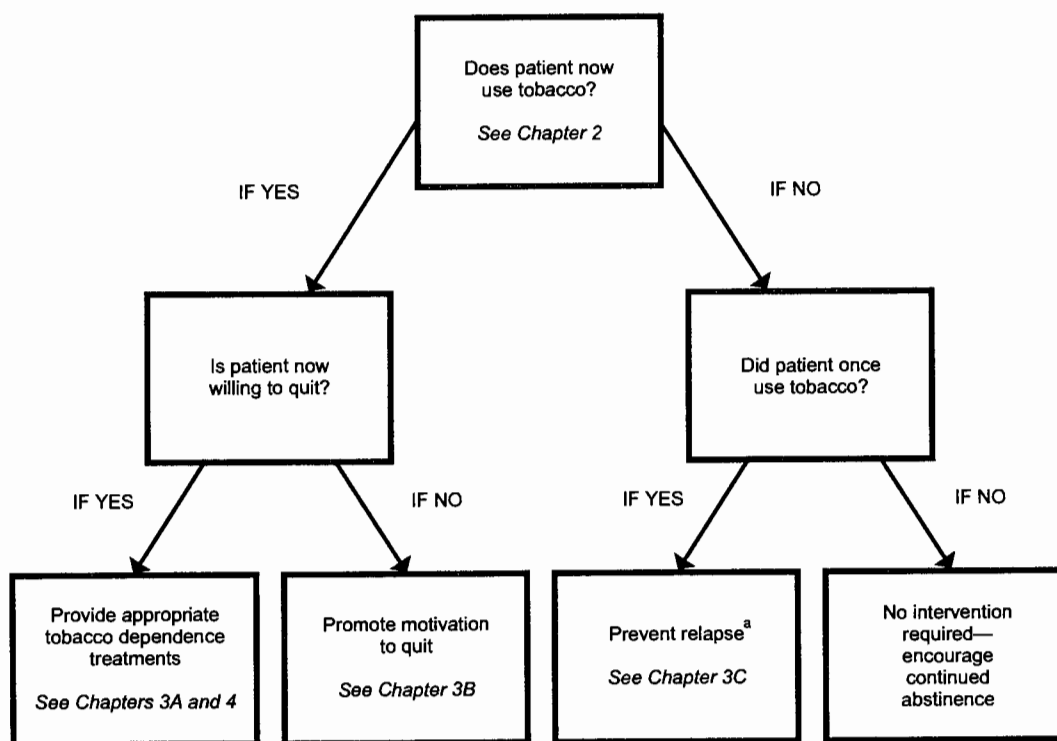
C. Treatment Elements, provides recommendations and analysis results regarding types of counseling and behavioral therapies and pharmacotherapy

Chapter 7, Special Populations, provides information on specific populations such as women, pregnant tobacco users, racial and ethnic minorities, hospitalized patients, older adults, tobacco users with other chemical dependencies, and children and adolescents.

Chapter 8, Special Topics, provides specific information on topics not otherwise addressed in the updated guideline such as weight gain associated with tobacco cessation, noncigarette tobacco products, clinician training, and reimbursement for tobacco cessation treatment.

2. Assessment of Tobacco Use

At least 70% of smokers see a physician each year, and more than 50% see a dentist.⁴¹⁻⁴³ Other smokers see physician assistants, nurse practitioners, nurses, physical and occupational therapists, pharmacists, and other clinicians. Therefore, all clinicians, particularly physicians and dentists, are uniquely poised to intervene with patients who use tobacco. Moreover, 70% of smokers report wanting to quit.³ Finally, smokers cite a physician's advice to quit as



^a Relapse prevention interventions are not necessary in the case of the adult who has not used tobacco for many years.

Fig. 3. Algorithm for treating tobacco use.

an important motivator for attempting to stop smoking.^{44–46} These data suggest that most smokers are interested in quitting, clinicians are frequently in contact with smokers, and clinicians have high credibility with smokers.

Unfortunately, clinicians are not capitalizing on this unique opportunity. More than one third of current smokers report never having been asked about their smoking status or urged to quit.^{11,47} Moreover, a population-based survey found that less than 15% of smokers who saw a physician in the past year were offered assistance, and only 3% had a follow-up appointment to address tobacco use.⁴⁸ Fewer still have received specific advice on how to quit smoking successfully. This guideline clearly identifies empirically validated tobacco treatment strategies to spur clinicians, tobacco treatment specialists, and administrators to intervene effectively with patients who use tobacco.

The first step in treating tobacco use and dependence is to identify tobacco users. As the data analysis in Chapter 6 shows, the identification of smokers itself increases rates of clinician intervention. Effective identification of tobacco use status not only opens the door for successful interventions (eg, physician advice), but also it guides clinicians to identify appropriate interventions based on patients' tobacco use status and willingness to quit.

Screening for current or past tobacco use will result in four possible responses: (1) the patient uses tobacco and is

now willing to make a quit attempt, (2) the patient uses tobacco but is not now willing to make a quit attempt, (3) the patient once used tobacco but has since quit, or (4) the patient never regularly used tobacco. This clinical practice guideline is organized to provide the clinician with simple but effective interventions for all of these patients (Fig. 3).

3. Brief Clinical Interventions

Background

This section of the guideline presents specific strategies to guide clinicians providing brief interventions. These brief interventions can be provided by any clinician but are most relevant to primary care clinicians (physicians, nurses, dentists, hygienists, respiratory therapists, pharmacists, etc) who see a wide variety of patients and who are bound by time constraints. These strategies are based on the evidence described in Chapters 6, 7, and 8, as well as on panel opinion. Guideline analysis suggests that a wide variety of clinicians can implement these brief strategies effectively. The goals of these strategies are clear: to change clinical culture and practice patterns to ensure that every patient who uses tobacco is identified and offered treatment. The strategies underscore a central theme: it is essential to

Table 3. The "5 A's" for Brief Intervention

<ul style="list-style-type: none"> • Ask about tobacco use. Identify and document tobacco use status for every patient at every visit. (Brief Strategy A1) • Advise to quit. In a clear, strong and personalized manner urge every tobacco user to quit. (Brief Strategy A2) • Assess willingness to make a quit attempt. Is the tobacco user willing to make a quit attempt at this time? (Brief Strategy A3) • Assist in quit attempt. For the patient willing to make a quit attempt, use counseling and pharmacotherapy to help him or her quit. (Brief Strategy A4) • Arrange follow-up. Schedule follow-up contact, preferably within the first week after the quit date. (Brief Strategy A5)
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provide at least a brief intervention to all tobacco users at each clinical visit. Several observations are relevant to this theme. First, institutional changes in clinical practice are necessary to ensure that all patients who use tobacco are identified for intervention (see Chapter 5, Systems Interventions: Relevance to Health Care Administrators, Insurers, and Purchasers). Second, the compelling time limits on primary care physicians in the United States today⁴⁹ (median visit = 12–16 min)⁵⁰ often require brief interventions, although more intensive interventions would produce greater success. Third, although many smokers are reluctant to seek intensive cessation programs,⁵¹ they nevertheless can receive a brief intervention every time they visit a clinician.²²

Table 4. Clinical Guidelines for Prescribing Pharmacotherapy for Smoking Cessation

Who should receive pharmacotherapy for smoking cessation?	All smokers trying to quit, except in the presence of special circumstances. Special consideration should be given before using pharmacotherapy with selected populations: those with medical contraindications, those smoking fewer than 10 cigarettes/day, pregnant/breastfeeding women, and adolescent smokers.
What are the first-line pharmacotherapies recommended in this guideline?	All five of the United States Food and Drug Administration (FDA)-approved pharmacotherapies for smoking cessation are recommended, including bupropion SR, nicotine gum, nicotine inhaler, nicotine nasal spray, and nicotine patch.
What factors should a clinician consider when choosing among the 5 first-line pharmacotherapies?	Because of the lack of sufficient data to rank-order these 5 medications, choice of a specific first-line pharmacotherapy must be guided by factors such as clinician familiarity with the medications, contraindications for selected patients, patient preference, previous patient experience with a specific pharmacotherapy (positive or negative), and patient characteristics (eg, history of depression, concerns about weight gain).
Are pharmacotherapeutic treatments appropriate for lighter smokers (eg, 10–15 cigarettes/day)?	If pharmacotherapy is used with lighter smokers, clinicians should consider reducing the dose of first-line nicotine replacement therapy pharmacotherapies. No adjustments are necessary when using bupropion SR.
What second-line pharmacotherapies are recommended in this guideline?	Clonidine and nortriptyline.
When should second-line agents be used for treating tobacco dependence?	Consider prescribing second-line agents for patients unable to use first-line medications because of contraindications or for patients for whom first-line medications are not helpful. Monitor patients for the known adverse effects of second-line agents.
Which pharmacotherapies should be considered with patients particularly concerned about weight gain?	Bupropion SR and nicotine replacement therapies, in particular nicotine gum, have been shown to delay, but not prevent, weight gain.
Are there pharmacotherapies that should be especially considered in patients with a history of depression?	Bupropion SR and nortriptyline appear to be effective with this population.
Should nicotine replacement therapies be avoided in patients with a history of cardiovascular disease?	No. The nicotine patch in particular is safe and has been shown not to cause adverse cardiovascular effects.
May tobacco dependence pharmacotherapies be used long-term (eg, 6 months or more)?	Yes. This approach may be helpful with smokers who report persistent withdrawal symptoms during the course of pharmacotherapy or who desire long-term therapy. A minority of individuals who successfully quit smoking use ad libitum nicotine replacement therapy medications (gum, nasal spray, inhaler) long-term. The use of these medications long-term does not present a known health risk. Additionally, the FDA has approved the use of bupropion SR for a long-term maintenance indication.
May pharmacotherapies ever be combined?	Yes. There is evidence that combining the nicotine patch with either nicotine gum or nicotine nasal spray increases long-term abstinence rates over those produced by a single form of nicotine replacement therapy.

Action	Strategies for Implementation
<p>Implement an office-wide system that ensures that for EVERY patient at EVERY clinic visit tobacco-use status is queried and documented.</p> <p>Repeated assessment is <i>not</i> necessary in the case of the adult who has never used tobacco or has not used tobacco for many years and for whom this information is clearly documented in the medical record.</p>	<p>Expand the vital signs to include tobacco use or use an alternative universal identification system.</p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p style="text-align: center;">Vital Signs</p> <p>Blood Pressure: _____</p> <p>Pulse: _____ Weight: _____</p> <p>Temperature: _____</p> <p>Respiratory Rate: _____</p> <p>Tobacco Use: Current Former Never (circle one)</p> </div> <p>Alternatives to expanding the vital signs are to place tobacco-use status stickers on all patient charts or to indicate tobacco use status using electronic medical records or computer reminder systems.</p>

Brief Strategy A1. Ask: Systemically identify all tobacco users at every visit.

Action	Strategies for Implementation
<p>In a <i>clear, strong, and personalized</i> manner, urge every tobacco user to quit.</p>	<p>Advice should be:</p> <ul style="list-style-type: none"> • <i>Clear</i>: "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." • <i>Strong</i>: "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." • <i>Personalized</i>: 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.

Brief Strategy A2. Advise: Strongly urge all tobacco users to quit.

This chapter is divided into three sections to guide brief clinician interventions with three types of patients: (A) current tobacco users now willing to make a quit attempt, (B) current tobacco users unwilling at this time to make a quit attempt, and (C) former tobacco users who have recently quit. Adults who have never used tobacco or who have been abstinent for an extended period do not require intervention. The clinician may congratulate them on their status and encourage them to maintain their tobacco-free lifestyle.

A. For the Patient Willing To Quit

Given that so many tobacco users visit a primary care clinician each year, it is important that these clinicians be

prepared to intervene with tobacco users who are willing to quit. The five major steps (the "5 A's") to intervention in the primary care setting are listed in Table 3. It is important for the clinician to *ask* the patient if he or she uses tobacco (Brief Strategy A1), *advise* him or her to quit (Brief Strategy A2), *assess* willingness to make a quit attempt (Brief Strategy A3), *assist* him or her in making a quit attempt (Brief Strategy A4), and *arrange* for follow-up contacts to prevent relapse (Brief Strategy A5). The strategies are designed to be brief, requiring 3 minutes or less of direct clinician time. Office systems that institutionalize tobacco use assessment and intervention will greatly foster the adoption of these strategies (see Chapter 5). Finally, these strategies are consistent with those produced by the NCI^{13,52} and the American Medical Association,²⁷ as well as others.^{26,53,54}

Action	Strategies for Implementation
Ask every tobacco user if he or she is willing to make a quit attempt at this time (eg, within the next 30 days).	<p>Assess patient's willingness to quit:</p> <ul style="list-style-type: none"> • If the patient is willing to make a quit attempt at this time, provide assistance (see Chapter 3A, Brief Strategy A4). • If the patient will participate in an intensive treatment, deliver such a treatment or refer to an intensive intervention (see Chapter 4). • If the patient clearly states he or she is unwilling to make a quit attempt at this time, provide a motivational intervention (see Chapter 3B). • If the patient is a member of a special population (eg, adolescent, pregnant smoker, racial/ethnic minority), consider providing additional information (see Chapter 7).

Brief Strategy A3. Assess: Determine willingness to make a quit attempt.

In addition to counseling, all smokers making a quit attempt should receive pharmacotherapy, except in the presence of special circumstances. Table 4 shows guidelines for prescribing pharmacotherapy for smoking cessation.

B. For the Patient Unwilling To Quit

Promoting the Motivation To Quit. All patients entering a health care setting should have their tobacco use status assessed routinely. Clinicians should advise all tobacco users to quit and then assess the patient's willingness to make a quit attempt. For patients not ready to make a quit attempt at this time, clinicians should use a brief intervention designed to promote the motivation to quit.

Patients unwilling to make a quit attempt during a visit may lack information about the harmful effects of tobacco, may lack the required financial resources, may have fears or concerns about quitting, or may be demoralized because of previous relapse.⁵⁵ Such patients may respond to a motivational intervention that provides the clinician an opportunity to educate, reassure, and motivate, such as the motivational intervention built around the "5 R's": *relevance, risks, rewards, roadblocks, and repetition*. Clinical components of the "5 R's" are shown in Brief Strategy B, Page 1218. Motivational interventions are most likely to be successful when the clinician is *empathic, promotes patient autonomy* (eg, choice among options), *avoids arguments*, and *supports the patient's self-efficacy* (eg, by identifying previous successes in behavior change efforts).⁵⁶⁻⁵⁸

C. For the Patient Who Has Recently Quit

Preventing Relapse. Because of the chronic relapsing nature of tobacco dependence, clinicians should provide brief effective relapse prevention treatment. When clinicians encounter a patient who has quit tobacco use re-

cently, they should reinforce the patient's decision to quit, review the benefits of quitting, and assist the patient in resolving any residual problems arising from quitting. Although most relapse occurs early in the quitting process,^{59,60} some relapse occurs months or even years after the quit date.^{31,61} Therefore, clinicians should engage in relapse prevention interventions even with former tobacco users who no longer consider themselves actively engaged in the quitting process. Relapse prevention interventions are especially important soon after quitting and can be delivered by means of either scheduled clinic visits, telephone calls, or any time the clinician encounters an ex-tobacco user. A systematic, institutionalized mechanism to identify recent quitters and contact them is essential to deliver relapse prevention messages effectively.

Relapse prevention interventions can be divided into two categories: minimal practice and prescriptive interventions.

Minimal Practice Interventions. Minimal practice relapse prevention interventions should be part of every encounter with a patient who has quit recently (Brief Strategy C1, Page 1219). These interventions are appropriate for most recent quitters and can be addressed briefly during a coincident clinic visit or a scheduled follow-up visit. Because most relapse occurs within the first 3 months after quitting, relapse prevention is especially appropriate during this period.^{62,63} In addition, strategies designed to reduce relapse should be included in the initial preparation for a quit attempt (see Chapter 3A, Brief Strategy A4. Assist: Aid the patient in quitting, and Chapter 3B, Brief Strategy B. Enhancing motivation to quit tobacco—the "5 R's"). Finally, encourage patients to report difficulties promptly (eg, lapses, depression, medication side-effects) while continuing efforts to quit.

Prescriptive Interventions. Prescriptive relapse prevention components are individualized based on information obtained about problems the patient has encountered in

Action	Strategies for Implementation
Help the patient with a quit plan.	<p>A patient's preparations for quitting:</p> <ul style="list-style-type: none"> • Set a quit date: Ideally, the quit date should be within 2 weeks. • Tell family, friends, and coworkers about quitting, and request understanding and support. • Anticipate challenges to planned quit attempt, particularly during the critical first few weeks. These include nicotine withdrawal symptoms. • Remove tobacco products from your environment. Prior to quitting, avoid smoking in places where you spend a lot of time (eg, work, home, car).
Provide practical counseling (problem-solving/skills training).	<p>Abstinence: Total abstinence is essential. "Not even a single puff after the quit date."</p> <p>Past quit experience: Identify what helped and what hurt in previous quit attempts.</p> <p>Anticipate triggers or challenges in upcoming attempt: Discuss challenges/triggers and how patient will successfully overcome them.</p> <p>Alcohol: Since alcohol can cause relapse, the patient should consider limiting/abstaining from alcohol while quitting.</p> <p>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.</p>
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 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 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 Table 4 for clinical guidelines and 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 materials.	<p>Sources: Federal agencies, nonprofit agencies, or local/state health departments</p> <p>Type: Culturally/racially/educationally/age appropriate for the patient.</p> <p>Location: Readily available at every clinician's workstation.</p>

Brief Strategy A4. Assist: Aid the patient in quitting.

maintaining abstinence (Brief Strategy C2, Page XX). These more intensive relapse prevention interventions may be delivered during a dedicated follow-up contact (in person or by telephone) or through a specialized clinic or program.

4. Intensive Clinical Interventions

Background

Intensive tobacco dependence treatment can be provided by any suitably trained clinician who has the resources

available to give intensive interventions. Based on the evidence in Chapter 6, it has been shown that more intensive tobacco dependence treatment is more effective than brief treatment. Also, it should be noted that intensive interventions are appropriate for any tobacco user willing to participate in them. There is no evidence that the efficacy or cost-effectiveness of intensive interventions is limited to a subpopulation of tobacco users (eg, heavily dependent smokers).⁶⁴

In many cases, intensive tobacco dependence interventions are provided by clinicians who specialize in the treatment of tobacco dependence. Such specialists are not de-

Action	Strategies for Implementation
Schedule follow-up contact, either in person or via telephone.	<i>Timing:</i> 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.
	<i>Actions during follow-up contact:</i> 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 Chapter 4).

Brief Strategy A5. Arrange: Schedule followup contact.

financed by their professional affiliation or by the field in which they trained. Rather, specialists view tobacco dependence treatment as a primary professional role. Specialists possess the skills, knowledge, and training to provide efficacious interventions across a range of intensities, and are often affiliated with programs offering intensive treatment interventions or services (programs with staff dedicated to tobacco interventions, where treatment involves multiple counseling sessions, and so on). In addition to offering intensive treatments, specialists often conduct research on tobacco dependence and its treatment.

As noted above, there is substantial evidence that intensive interventions produce higher success rates than do less intensive interventions (as indicated by several findings of this guideline). In addition, the tobacco dependence interventions offered by specialists represent an important treatment resource for patients who do not receive tobacco dependence treatment from their primary care clinician.

Although the specialist contributes greatly to tobacco treatment efforts, constraints limit the impact of the specialist's service delivery activities. For example, only a minority of smokers participate in the intensive programs typically offered by specialists.^{51,65} This suggests that, in the future, the specialist may contribute to tobacco treatment efforts through activities such as:

- Serving as a resource to nonspecialists who offer tobacco dependence services as part of general health care delivery. This might include training nonspecialists in counseling strategies, providing consultation on difficult cases and for inpatients, and providing specialized assessment services.
- Developing and evaluating changes in office/clinic procedures that increase the rates at which tobacco users are identified and treated.
- Conducting evaluation research to determine the effectiveness of ongoing tobacco dependence treatment activities in relevant institutional settings.
- Developing and evaluating innovative treatment strategies that may increase the effectiveness and utilization of tobacco dependence treatments.

Strategies for Intensive Tobacco Dependence Intervention

Table 5 highlights guideline findings based on analyses found in Chapter 6, as well as on panel opinion, that seem particularly relevant to the implementation of intensive treatment programs. The findings from Table 5 lead to the development of an intensive treatment strategy (see Intensive Strategy. Components of an intensive intervention, Page 1221). Of course, implementation of this strategy depends on factors such as resource availability and time constraints.

5. Systems Interventions. Relevance to Health Care Administrators, Insurers, and Purchasers

Background

Traditionally, efforts to increase tobacco intervention in the health care setting have targeted the individual clinician. Such a restricted focus is no longer appropriate. Two considerations argue for expanding the scope of tobacco intervention efforts. First, efforts directed at the individual clinician have yielded disappointing results. For instance, national data suggest that, in a given visit with a clinician, more than one-third of smokers are not advised and assisted with cessation.^{11,14,41} Second, an increasing number of Americans today receive their health care in managed care settings. As a consequence, agents such as health system administrators, insurers, and health care purchasers now play a significant role in the health care of most Americans. For example, managed care organizations and other insurers influence medical care through restrictive formularies, performance feedback to clinicians, and marketing approaches that prompt patient demand for particular services.

The influence of health care system administrators, insurers, and purchasers could, in theory, be used to encourage and support the consistent and effective identification and treatment of tobacco users. These agents could craft and implement supportive systems, policies, and environ-

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 (eg., having children in the home), health concerns, age, gender, and other important patient characteristics (eg., prior quitting experience, personal barriers to cessation).
Risks	<p>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 (eg., smokeless tobacco, cigars, and pipes) will not eliminate these risks. Examples of risks are:</p> <ul style="list-style-type: none"> • <i>Acute risks:</i> Shortness of breath, exacerbation of asthma, harm to pregnancy, impotence, infertility, increased serum carbon monoxide. • <i>Long-term risks:</i> Heart attacks and strokes, lung and other cancers (larynx, oral cavity, pharynx, esophagus, pancreas, bladder, cervix), chronic obstructive pulmonary diseases (chronic bronchitis and emphysema), long-term disability and need for extended care. • <i>Environmental risks:</i> Increased risk of lung cancer and heart disease in spouses; higher rates of smoking by children of tobacco users; increased risk for low birth weight, SIDS, asthma, middle ear disease, and respiratory infections in children of smokers.
Rewards	<p>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:</p> <ul style="list-style-type: none"> • Improved health. • Food will taste better. • Improved sense of smell. • Save money. • Feel better about yourself. • Home, car, clothing, breath will smell better. • Can stop worrying about quitting. • Set a good example for children. • Have healthier babies and children. • Not worry about exposing others to smoke. • Feel better physically. • Perform better in physical activities. • Reduced wrinkling/aging of skin.
Roadblocks	<p>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:</p> <ul style="list-style-type: none"> • 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.

Brief Strategy B. Enhancing motivation to quit tobacco: The "5 R's".

mental prompts that render tobacco use treatment an integral part of health care. Indeed, research clearly shows that systems-level change can reduce smoking prevalence among enrollees of managed health care plans.⁶⁶

Unfortunately, as a society we have not capitalized on the opportunity to use today's health care organizations, insurers, and purchasers to combat tobacco use. For ex-

ample, treatments for tobacco use (both pharmacotherapy and counseling) are not consistently provided as paid services for subscribers of health insurance packages.^{67,68} A recent survey found that only 22 states provided Medicaid coverage for tobacco dependence treatment.⁶⁹ Another survey demonstrated that only 39% of managed care organizations had partially implemented the recommendations

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 (eg, 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 (eg, depression, weight gain, alcohol, other tobacco users in the household).

Brief Strategy C1. Components of minimal practice 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:

Problem	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 (eg, bupropion SR, nicotine replacement therapies, 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.

Brief Strategy C2. Components of prescriptive relapse prevention.

within the original guideline, and only 9% had fully implemented the recommendations.⁷⁰ This lack of coverage is puzzling given that studies have shown that physician advice to quit is at least as cost-effective as several other preventive medical practices, including the treatment of mild or moderate hypertension or high cholesterol.^{71,72} These and other findings resulted in the addition of a new

objective to the national health promotion and disease prevention objectives for the year 2000 (*Healthy People 2000*):

- Increase to 100% the proportion of health plans that offer treatment of nicotine addiction (eg, tobacco use cessation counseling by health care providers, tobacco use cessation classes, prescriptions for nicotine replacement therapies, and/or other cessation services).⁷³

Table 5. Findings Relevant to Intensive Interventions

- There is a strong dose-response relation between counseling intensity and cessation success. In general, the more intense the treatment intervention, the greater the rate of smoking cessation. Treatments may be made more intense by increasing (A) the length of individual treatment sessions and (B) the number of treatment sessions.
- Many different types of providers (physicians, nurses, dentists, psychologists, pharmacists, etc) are effective in increasing rates of tobacco cessation, and involving multiple types of providers may enhance abstinence rates.
- Proactive telephone calls and individual and group counseling are effective tobacco cessation formats.
- Particular types of counseling and behavioral therapies are especially effective. Practical counseling (problem-solving/skills-training approaches), and the provision of intra-treatment and extra-treatment social support are associated with significant increases in abstinence rates, as are aversive smoking techniques (eg, rapid smoking).
- Pharmacotherapies such as bupropion SR or nicotine replacement therapies consistently increase abstinence rates. Therefore, their use should be encouraged for all quitters, but special consideration is required with some populations (eg, pregnant smokers, adolescents).
- Tobacco dependence treatments are effective across diverse populations (eg, populations varying on gender, age, and ethnicity).

This objective has been modified in *Healthy People 2010* to state:

- Increase insurance coverage of evidence-based treatment for nicotine dependence to 100%.⁷⁴

In sum, without supportive systems, policies, and environmental prompts, the individual clinician will likely not assess and treat tobacco use consistently. Therefore, just as clinicians must assume responsibility to treat their patients for tobacco use, so must health care administrators, insurers, and purchasers assume responsibility to craft policies, provide resources, and display leadership that results in consistent and effective tobacco use treatment.

Cost-Effectiveness of Smoking Cessation Interventions

Smoking cessation treatments are not only clinically effective, but they are economically defensible as well. It is vital that all three audiences targeted in this guideline recognize that smoking cessation treatments ranging from clinician advice to pharmacotherapy to specialist-delivered intensive programs are cost-effective in relation to other medical interventions.⁶⁴ Cost-effectiveness analyses have shown that smoking cessation treatments compare quite favorably with routine medical interventions such as the treatment of hypertension and hypercholesterolemia, and with other preventive interventions such as periodic mammography.^{71,75-77} In fact, smoking cessation treatment has been referred to as the "gold standard" of preventive

interventions.⁷⁸ Smoking cessation treatment remains highly cost-effective, even though a single application of any effective treatment for tobacco dependence may produce sustained abstinence in only a minority of smokers.

The cost-effectiveness of guideline recommendations for smoking cessation is addressed in detail in Chapter 8.

Recommendations for Health Care Administrators, Insurers, and Purchasers

Health care delivery administrators, insurers, and purchasers can promote the treatment of tobacco dependence through a systems approach. Purchasers (often corporations, companies, or other consortia that purchase health care benefits for a group of individuals) should make tobacco assessment and treatment a contractual obligation of the health care insurers and/or providers that sell services to them. In addition to improving the health of their employees or subscribers, mandating coverage for tobacco dependence treatment will result in lower rates of absenteeism⁷⁹ and lower utilization of health care resources.⁸⁰ Health care administrators and insurers must provide clinicians with assistance to ensure that institutional changes promoting tobacco dependence treatment are implemented universally and systematically. A number of institutional policies would facilitate these interventions such as:

- Implementing a tobacco-user identification system in every clinic (Systems Strategy 1).
- Providing education, resources, and feedback to promote provider intervention (Systems Strategy 2).
- Dedicating staff to provide tobacco dependence treatment and assessing the delivery of this treatment in staff performance evaluations (Systems Strategy 3).
- Promoting hospital policies that support and provide tobacco dependence services (Systems Strategy 4).
- Including tobacco dependence treatments (both counseling and pharmacotherapy) identified as effective in this guideline, as paid or covered services for all subscribers or members of health insurance packages (Systems Strategy 5).
- Reimbursing clinicians and specialists for delivery of effective tobacco dependence treatments and including these interventions among the defined duties of the clinicians (Systems Strategy 6).

These strategies are based on the evidence described in Chapters 6, 7, and 8, as well as on panel opinion.

6. Evidence

Background

The recommendations summarized in Chapters 2, 3, 4, and 5 are the result of a review and analysis of the extant tobacco cessation literature. The current chapter reports the results of this review and analysis, and describes the

Assessment	Assessments should ensure that tobacco users are willing to make a quit attempt using an intensive treatment program. Other assessments can provide information useful in counseling (eg, stress level, presence of comorbidity; see Chapter 6A, Specialized Assessment).
Program clinicians	Multiple types of clinicians are effective and should be used. One counseling strategy would be to have a medical/health care clinician deliver messages about health risks and benefits and deliver pharmacotherapy, and nonmedical clinicians deliver additional psychosocial or behavioral interventions.
Program intensity	Because of evidence of a strong dose-response relation, the intensity of the program should be: <i>Session length:</i> longer than 10 minutes. <i>Number of sessions:</i> 4 or more sessions. <i>Total contact time:</i> longer than 30 minutes.
Program format	Either individual or group counseling may be used. Proactive telephone counseling also is effective. Use of adjuvant self-help material is optional. Followup assessment intervention procedures should be used (see Chapter 6B).
Type of counseling and behavioral therapies	Counseling and behavioral therapies should involve practical counseling (problemsolving/skills-training) (see Table 21) and intra-treatment (see Table 22) and extra-treatment social support (see Table 23).
Pharmacotherapy	Every smoker should be encouraged to use pharmacotherapies endorsed in this guideline, except in the presence of special circumstances. Special consideration should be given before using pharmacotherapy with selected populations (eg, pregnancy, adolescents) (see Table 4 for clinical guidelines and Tables 33-39 for specific instructions and precautions). The clinician should explain how these medications increase smoking cessation success and reduce withdrawal symptoms. The first-line pharmacotherapy agents include: bupropion SR, nicotine gum, nicotine inhaler, nicotine nasal spray, and the nicotine patch.
Population	Intensive intervention programs may be used with all tobacco users willing to participate in such efforts.

Intensive Strategy. Components of an intensive intervention.

efficacy of various treatments, assessments, and strategies for their implementation. This chapter addresses such questions as: Does the professional discipline of the clinician make a difference in the efficacy of the intervention? Are different types of providers effective in delivering interventions? Are minimal interventions, such as clinician advice to quit smoking, effective or are more intensive interventions required? Does the duration of an intervention in number of treatment sessions or in total face-to-face contact time substantially influence efficacy? Are pharmacologic interventions effective, and if so, which ones? Which counseling strategies are particularly helpful? In short, which treatments or assessments are efficacious and how should they be used?

The panel examined the relation between outcomes and 10 major assessment or treatment characteristics or strategies. These 10 characteristic types, and the categories within each, are listed in Table 6. Type of outcome varied across the different characteristics being analyzed. In most analyses, long-term abstinence was the outcome measure, in others it was the rate of smoker identification. The analyses reported in this chapter almost exclusively addressed treatments for cigarette smoking, as opposed to the use of other forms of tobacco, as the small number of

studies on the use of noncigarette tobacco products precluded their separate analysis. Finally, the panel attempted to analyze treatment and assessment strategies that constitute distinct approaches that exist in current clinical practice.

The panel chose categories within each characteristic according to three major criteria. First, some categories reflected generally accepted dimensions or taxonomies. An example of this is the categorical nature of the clinician types (physician, psychologist, nurse, and so on). Second, information on the category had to be available in the published literature. Many questions of theoretical interest had to be abandoned simply because the requisite information was not available. Third, the category had to occur with sufficient frequency to permit meaningful statistical analysis. For example, the cut-points of some continuous variables (eg, total amount of contact time) were determined so there was a sufficient number of studies within each analytical category to permit meaningful analysis.

In ideal circumstances, the panel could evaluate each characteristic by consulting randomized controlled trials relevant to the specific categories in question. Unfortunately, with the exception of pharmacologic interventions, very few or no randomized controlled trials are specifically designed to address the effects of the various cate-

Action	Strategies for Implementation
Implement an office-wide system that ensures that, for EVERY patient at EVERY clinic visit, tobacco-use status is queried and documented.	<p>Office system change: Expanding the Vital Signs to include tobacco use or implement an alternative universal identification system.</p> <p>Responsible staff: Nurse, medical assistant, receptionist, or other individual already responsible for measuring the vital signs. These staff must be instructed regarding the importance of this activity and serve as non-smoking role models.</p> <p>Frequency of utilization: Every visit for every patient regardless of the reason for the visit. (Repeated assessment is <i>not</i> necessary in the case of the adult who has never used tobacco or not used tobacco for many years, and for whom this information is clearly documented in the medical record.)</p> <p>System implementation steps: Prepare progress notepaper or computer records to include tobacco use along with the traditional vital signs for every patient visit. A vital sign stamp also can be used. Alternatives to the vital sign stamp are to place tobacco-use status stickers on all patient charts or to indicate smoking status using computer reminder systems.</p> <div style="border: 1px solid black; padding: 10px; margin-top: 10px;"> <p style="text-align: center;">VITAL SIGNS</p> <p>Blood Pressure: _____</p> <p>Pulse: _____ Weight: _____</p> <p>Temperature: _____</p> <p>Respiratory Rate: _____</p> <p>Tobacco Use: Current Former Never (circle one)</p> </div>

Systems Strategy 1. Implement a tobacco-user identification system in every clinic.

Action	Strategies for Implementation
Health care systems should ensure that clinicians have sufficient training to treat tobacco dependence, clinicians and patients have cessation resources, and clinicians are given feedback about their tobacco dependence treatment practices.	<p>Educate: On a regular basis, offer lectures/seminars/ in-services with continuing medical education and/or other credit for tobacco dependence treatment.</p> <p>Provide resources: Have patient self-help materials as well as bupropion SR and nicotine replacement "starter kits" readily available in every examination room.</p> <p>Report: Include the provision of tobacco dependence treatment on "report cards" for managed care organizations and other insurers (eg, National Committee for Quality Assurance's Health Plan Employer Data and Information Set [NCQA HEDIS]).</p> <p>Provide feedback: Drawing on data from chart audits, electronic medical records, and computerized patient databases, evaluate the degree to which clinicians are identifying, documenting, and treating patients who use tobacco, and provide feedback to clinicians about their performance.</p>

Systems Strategy 2. Provide education, resources, and feedback to promote provider intervention.

gories related to these treatment or assessment characteristics. Moreover, treatment characteristics are frequently confounded with one another. For example, comparisons among clinicians are almost always confounded with the type of counseling and behavioral therapy, format, and

intensity of the interventions. Psychologists tend to deliver relatively intensive interventions, whereas physicians tend to deliver brief advice to individuals. Therefore, direct, unconfounded comparisons of categories within a particular characteristic were often impossible. These character-

Action	Strategies for Implementation
Clinical sites should communicate to all staff the importance of intervening with tobacco users and should designate a staff person (eg, nurse, medical assistant, or other clinician) to coordinate tobacco dependence treatments. Nonphysician personnel may serve as effective but lower cost providers of tobacco dependence interventions.	<p><i>Designate</i> a tobacco dependence treatment coordinator for every clinical site.</p> <p><i>Delineate</i> the responsibilities of the tobacco dependence treatment coordinator, including instructing patients on the effective use of treatments (eg, pharmacotherapy, telephone calls to and from prospective quitters, and scheduled followup visits, especially in the immediate post-quit period).</p> <p><i>Communicate</i> to each staff member (eg, nurse, physician, medical assistant, pharmacist, or other clinician) his or her responsibilities in the delivery of tobacco cessation services. Incorporate a discussion of these staff responsibilities into training of new and temporary staff.</p>

Systems Strategy 3. Dedicate staff to provide tobacco dependence treatment and assess the delivery of this treatment in staff performance evaluations.

Action	Strategies for Implementation
Provide tobacco dependence treatment to all tobacco users admitted to a hospital.	<p><i>Implement</i> a system to identify and document the tobacco-use status of all hospitalized patients.</p> <p><i>Identify</i> a clinician(s) to deliver tobacco dependence inpatient consultation services for every hospital.</p> <p><i>Offer</i> tobacco dependence treatment to all hospitalized patients who use tobacco.</p> <p><i>Reimburse</i> providers for tobacco dependence inpatient consultation services.</p> <p><i>Expand</i> hospital formularies to include FDA-approved tobacco dependence pharmacotherapies.</p> <p><i>Ensure</i> compliance with Joint Commission on Accreditation of Health Care Organizations regulations mandating that all sections of the hospital be entirely smoke-free.</p> <p><i>Educate</i> hospital staff that first-line medications may be used to reduce nicotine withdrawal symptoms, even if the patient is not intending to quit.</p>

Systems Strategy 4. Promote hospital policies that support and provide inpatient tobacco dependence services.

Action	Strategies for Implementation
Provide all insurance subscribers, including members of managed care organizations, with coverage for effective tobacco dependence treatments, including pharmacotherapy and counseling.	<p><i>Cover:</i> Include effective tobacco dependence treatments (both counseling and pharmacotherapy) as part of the basic benefits package for all health insurance packages.</p> <p><i>Educate:</i> Inform subscribers, including members of managed care organizations, of the availability of covered tobacco dependence treatments (both counseling and pharmacotherapy) and encourage patients to use these services.</p>

Systems Strategy 5. Include tobacco dependence treatments (both counseling and pharmacotherapy) identified as effective in this guideline as paid or covered services for all subscribers or members of health insurance packages.

istics were nevertheless analyzed because of their clinical importance, and because it was possible to reduce confounding by careful selection of studies and by statistical control of some confounding factors.

Additional topics, which did not lend themselves to analysis because of a lack of published long-term abstinence data, yet were important and clinically relevant, were nevertheless considered by the panel through a review of the

existing literature. The strength of evidence associated with these recommendations clearly indicate that they are not based on meta-analyzed randomized controlled trials.

The present chapter addresses the 10 treatment and assessment characteristics outlined in Table 6 and is divided into three sections: (A) screening and assessment, (B) treatment structure and intensity, and (C) treatment elements. For each topic, background information, clinical recom-

Action	Strategies for Implementation
Reimburse fee-for-service clinicians and specialists for delivery of effective tobacco dependence treatments; include tobacco dependence treatments in the defined duties of salaried clinicians and those working in capitated environments.	<p><i>Include</i> tobacco dependence treatment as a reimbursable activity for fee-for-service providers.</p> <p><i>Inform</i> fee-for-service clinicians and specialists that they will be reimbursed for using effective tobacco dependence treatments.</p> <p><i>Include</i> tobacco dependence intervention in the job descriptions and performance evaluations of salaried clinicians and specialists.</p>

Systems Strategy 6. Reimburse clinicians and specialists for delivery of effective tobacco dependence treatments and include these interventions among the defined duties of clinicians.

recommendations, and the basis for those recommendations are provided. As described in Chapter 1, each recommendation was given a strength of evidence classification based on the criteria shown in Table 7. Finally, for some topics, recommendations for further research are provided.

A. Screening and Assessment.

Screen for Tobacco Use. Recommendation: All patients should be asked if they use tobacco and should have their tobacco-use status documented on a regular basis. Evidence has shown that this significantly increases rates of clinician intervention. (Strength of Evidence = A) **Recommendation:** Clinic screening systems such as expanding the vital signs to include tobacco-use status, or the use of other reminder systems such as chart stickers or computer prompts are essential for the consistent assessment, documentation, and intervention with tobacco use. (Strength of Evidence = B)

A thorough review of articles published since the end-date of the original guideline literature review (December 31, 1994), revealed no studies that met criteria for the screening meta-analyses. Therefore, the panel decided to rely on the meta-analyses from the original guideline to determine the impact of tobacco screening systems. Such screening systems were evaluated in terms of their impact on two outcomes: the rate of tobacco cessation intervention by clinicians, and the rate of cessation by patients who smoke.

Identifying Tobacco Users: Impact on Clinical Intervention. Nine studies met the selection criteria from the original guideline and were analyzed using a random-effects meta-analysis to assess the impact of screening systems on the rate of smoking cessation intervention by clinicians. The results of this meta-analysis are shown in Table 8. Implementing clinic systems designed to increase the assessment and documentation of tobacco use status markedly increases the rate at which clinicians intervene with their patients who smoke.

Identifying Tobacco Users: Impact on Tobacco Cessation. Three studies met the selection criteria from the original guideline and were analyzed using a random-effects meta-analysis to assess the impact of identifying smokers on actual rates of smoking cessation. The results of this meta-analysis are shown in Table 9. These results suggest that having a clinic system in place that identifies smokers results in higher rates of smoking cessation, although this finding was not statistically significant and was based on a small number of studies.

Brief Strategy A1 (see Chapter 3A) and Systems Strategy A1 (see Chapter 5) detail an approach for including tobacco-use status as a vital sign with systematic prompts and reminders. Although the data assessing this intervention were exclusively gathered from cigarette smokers, the panel felt that these results were generalizable to all tobacco users. This approach is designed to produce consistent assessment and documentation of tobacco use. Evidence from controlled trials shows that this approach increases the probability that tobacco use is consistently assessed and documented.^{12,81-85}

Future Research. The following topic regarding screening for tobacco use requires additional research:

- Additional evidence regarding the impact of screening systems on tobacco abstinence rates.

Specialized Assessment. Recommendation: Once a tobacco user is identified and advised to quit, the clinician should assess the patient's willingness to quit at this time. (Strength of Evidence = C)

- If the patient is willing to make a quit attempt at this time, interventions identified as effective in this guideline should be initiated. (see Chapter 3A and 4)

- If the patient is unwilling to quit at this time, a motivational intervention should be provided. (see Chapter 3B)

Recommendation: Tobacco dependence treatment is effective and should be delivered even if specialized

Table 6. Treatment and Assessment Characteristics Analyzed for Their Relation to Abstinence Outcomes

Characteristics Analyzed	Categories of Those Characteristics
Screen for Tobacco Use	No screening system in place Screening system in place
Advice to Quit	No advice to quit Physician advice to quit
Intensity of Person-to-Person Clinical Contact	No person-to-person intervention Minimal counseling (longest session ≤ 3 min in duration) Low intensity counseling (longest session > 3 min and ≤ 10 min in duration) Higher intensity counseling (longest session > 10 min) Total amount of contact time Number of person-to-person treatment sessions
Type of Clinician	No clinician Self-help materials only Nonphysician health care clinician (eg, psychologist, counselor, social worker, nurse, dentist, graduate student, pharmacist) Physician Number of types of clinicians
Formats of Psychosocial Intervention	No contact Self-help/self-administered (eg, pamphlet, audiotape, videotape, mailed information, computer program) Individual counseling/contact Group counseling/contact Proactive telephone counseling/contact Number of types of formats
Self-Help Interventions	Number of self-help interventions Self-help interventions
Types of Counseling and Behavioral Therapies	No person-to-person intervention or minimal counseling General—problem-solving/coping skills/relapse prevention/stress management approach Negative affect/depression intervention Weight/diet/nutrition intervention Extra-treatment social support intervention Intra-treatment social support intervention Contingency contracting/instrumental contingencies Rapid smoking Other aversive smoking techniques Cigarette fading/smoking reduction prequit Acupuncture
Pharmacologic Interventions	Placebo pharmacotherapy Bupropion SR Clonidine Nicotine gum Nicotine inhaler Nicotine nasal spray Nicotine patch Nortriptyline
Combination Nicotine Replacement Therapy	One nicotine replacement therapy Two nicotine replacement therapies
Over-the-Counter Pharmacotherapy	Placebo over-the-counter nicotine patch therapy Over-the-counter nicotine patch therapy

Table 7. Summary of Strength of Evidence for Recommendations

Strength of Evidence Classification	Criteria
Strength of Evidence = A	Multiple well-designed randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings.
Strength of Evidence = B	Some evidence from randomized clinical trials supported the recommendation, but the scientific support was not optimal. For instance, few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation.
Strength of Evidence = C	Reserved for important clinical situations where the panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.

Table 8. Meta-Analysis: Impact of Having a Tobacco Use Status Identification System in Place on Rates of Clinician Intervention with Their Patients Who Smoke ($n = 9$ studies)

Screening System	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Intervention Rate (95% CI)
No screening system in place to identify smoking status (reference group)	9	1.0	38.5
Screening system in place to identify smoking status	9	3.1 (2.2–4.2)	65.6 (58.3–72.6)

CI = confidence interval

Table 9. Meta-Analysis: Impact of Having a Tobacco Use Status Identification System in Place on Abstinence Rates Among Patients Who Smoke ($n = 3$ studies)

Screening System	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
No screening system in place to identify smoking status (reference group)	3	1.0	3.1
Screening system in place to identify smoking status	3	2.0 (0.8–4.8)	6.4 (1.3–11.6)

CI = confidence interval

assessments are not used or available. (Strength of Evidence = A)

Every individual entering a health care setting should receive an assessment that determines his or her tobacco use status and interest in quitting. The patient should be asked, "Are you willing to make a quit attempt at this time?" Such an assessment (willing or unwilling) is a necessary first step in treatment. In addition, every patient should be assessed for physical or medical conditions that

Table 10. Variables Associated with Higher or Lower Abstinence Rates

Variables Associated with Higher Abstinence Rates	Examples
High motivation Ready to change	Tobacco user reports motivation to quit. Tobacco user is ready to quit within a 1-month period.
Moderate to high self-efficacy	Tobacco user is confident in his or her ability to quit.
Supportive social network	A smoke-free workplace and home; friends who do not smoke in the quitter's presence.
Variables Associated with Lower Abstinence Rates	Examples
High nicotine dependence	Tobacco user has had severe withdrawal during previous quit attempts, smokes heavily (> 20 cigarettes/d), and/or has first cigarette of the day within 30 minutes after waking in the morning.
History of psychiatric comorbidity	Tobacco user has a history of depression, schizophrenia, alcoholism, or other chemical dependency.
High stress level	Stressful life circumstances and/or recent or anticipated major life changes (eg, divorce, job change, and marriage).

may affect the use of planned treatments (eg, pharmacotherapy).

The clinician also may want to perform specialized assessments of individual and environmental attributes that provide information for tailoring treatment and that predict quitting success. Specialized assessments refer to the use of formal instruments (eg, questionnaires, clinical interviews, or physiologic indices such as carbon monoxide, serum nicotine/cotinine levels, and/or pulmonary function) that may be associated with cessation outcome. Some of the variables targeted by specialized assessments that predict quitting success are listed in Table 10.

Several considerations should be kept in mind regarding the use of specialized assessments. First, there is little consistent evidence that a smoker's status on a specialized

assessment is useful for treatment matching. The one exception is that persons highly nicotine dependent may benefit more from 4 mg as opposed to 2 mg nicotine gum (see Chapter 6C, Pharmacotherapy). More importantly, the panel found that, regardless of their standing on specialized assessments, all smokers have the potential to benefit from cessation interventions. Therefore, delivery of tobacco dependence treatments should not depend on the use of specialized assessments. Finally, tailored interventions based on specialized assessments (eg, stages of change) do not consistently produce higher long-term quit rates than do nontailored interventions of equal intensity. There do exist, however, some promising studies that suggest that individualizing self-help materials may be beneficial.^{86,87} However, more studies are needed that contrast individualized self-help interventions with nonindividualized interventions of equivalent intensity. In addition, the panel recognizes that some effective interventions, such as general problem-solving (see Chapter 6C, Types of Counseling and Behavioral Therapies), entail treatment tailoring based on a systematic assessment of individual patient characteristics.

The existing evidence suggests that treatment can be effective despite the presence of risk factors for relapse (eg, severe previous withdrawal, depression, other smokers in the home), but abstinence rates in smokers with these characteristics tend to be lower than rates in those without these characteristics.⁸⁸⁻⁹²

Future Research. The following topic regarding specialized assessment requires additional research:

- Whether treatment adjustment based on specialized assessments can improve long-term abstinence rates.

B. Treatment Structure and Intensity

Advice To Quit Smoking. Recommendation: All physicians should strongly advise every patient who smokes to quit because evidence shows that physician advice to quit smoking increases abstinence rates. (Strength of Evidence = A)

Recommendation: All clinicians should strongly advise their patients who use tobacco to quit. Although studies have not independently addressed the impact of advice to quit by all types of nonphysician clinicians, it is reasonable to believe that such advice is effective in increasing their patients' long-term quit rates. (Strength of Evidence = B)

A thorough literature review identified no new studies since 1994 that examined the efficacy of advice to quit and that met the inclusion criteria for analysis. Therefore, the panel decided to rely on the analysis from the original guideline. Seven studies were included in the meta-analysis of the efficacy of physician advice to quit smoking. In

Table 11. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Advice to Quit by a Physician ($n = 7$ studies)

Advice	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
No advice to quit (reference group)	9	1.0	7.9
Physician advice to quit	10	1.3 (1.1-1.6)	10.2 (8.5-12.0)

CI = confidence interval

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 Table 11. This analysis shows that brief physician advice significantly increases long-term smoking abstinence rates.

Physician advice only was examined in the Table 11 meta-analysis because there were too few studies to examine advice delivered by any other types of clinicians. The analysis for total amount of contact time (see Table 13 provided in the following subsection) indicates that minimal counseling (advice) delivered by a variety of clinician types increase 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 (see Chapter 8). Given the large number of smokers who visit a clinician each year, the potential public health impact of universal advice to quit is substantial.

Future Research. The following topics regarding advice to quit require additional research:

- The efficacy of advice to quit smoking given by specific nonphysician clinicians such as nurses, psychologists, pharmacists, dentists, and dental hygienists.
- The cumulative efficacy of combined advice from physicians and nonphysician providers.

Intensity of Clinical Interventions. Recommendation: Minimal interventions lasting less than 3 minutes increase overall tobacco abstinence rates. Every tobacco user should be offered at least a minimal intervention whether or not he or she is referred to an intensive intervention. (Strength of Evidence = A)

Recommendation: There is a strong dose-response relation between the session length of person-to-person contact and successful treatment outcomes. Intensive interventions are more effective than less intensive interventions and should be used whenever possible. (Strength of Evidence = A)

Table 12. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Various Intensity Levels of Person-to-Person Contact ($n = 43$ studies)

Level of Contact	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
No contact	30	1.0	10.9
Minimal counseling (< 3 min)	19	1.3 (1.01, 1.6)	13.4 (10.9, 16.1)
Low intensity counseling (3–10 min)	16	1.6 (1.2, 2.0)	16.0 (12.8, 19.2)
Higher intensity counseling (> 10 min)	55	2.3 (2.0, 2.7)	22.1 (19.4, 24.7)

CI = confidence interval

Recommendation: Person-to-person treatment delivered for four or more sessions appears especially effective in increasing abstinence rates. Therefore, if feasible, clinicians should strive to meet four or more times with individuals quitting tobacco use. (Strength of Evidence = A)

These recommendations are supported by three separate analyses, one involving session length, one involving total amount of contact time, and one involving the number of sessions.

Session Length. Forty-three studies met selection criteria for comparisons among various session lengths. Whenever possible, session length was categorized based on the maximum amount of time the clinician spent with a smoker addressing tobacco dependence in a single contact. Minimal counseling interventions were defined as 3 minutes or less, low intensity counseling was defined as greater than 3 minutes to 10 minutes, and higher intensity counseling interventions were defined as greater than 10 minutes. Interventions could involve multiple patient-clinician contacts with the session length determined for coding purposes as the length of time of the longest session. These levels of person-to-person contact were compared with a no-contact reference group involving study conditions where subjects received no person-to-person contact (eg, self-help-only conditions). There is a dose-response relation between session length and abstinence rates. As Table 12 shows, all three session lengths (minimal counseling, low intensity counseling, and higher intensity counseling) significantly increased abstinence rates over those produced by no-contact conditions. However, there was a clear trend for abstinence rates to increase across these session lengths, with higher intensity counseling producing abstinence rates that were significantly higher than the rates produced by minimal or low intensity counseling.

Table 13. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Total Amount of Contact Time ($n = 35$ studies)

Total Contact Time	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
No min	16	1.0	11.0
1–3 min	12	1.4 (1.1, 1.8)	14.4 (11.3, 17.5)
4–30 min	20	1.9 (1.5, 2.3)	18.8 (15.6, 22.0)
31–90 min	16	3.0 (2.3, 3.8)	26.5 (21.5, 31.4)
91–300 min	16	3.2 (2.3, 4.6)	28.4 (21.3, 35.5)
> 300 min	15	2.8 (2.0, 3.9)	25.5 (19.2, 31.7)

CI = confidence interval

Total Amount of Contact Time. Thirty-five studies met the selection criteria for the analysis assessing the impact of total contact time. The amount of contact time was calculated from the text as the total time accumulated (the number of sessions multiplied by the session length). When the exact time was not known for minimal and low intensity interventions, they were assigned median lengths of 2 and 6.5 minutes, respectively. The total amount of contact time was then categorized as no-contact, 1–3 minutes, 4–30 minutes, 31–90 minutes, 91–300 minutes, and greater than 300 minutes. There is a dose-response relation between total amount of contact time and abstinence rates. As Table 13 shows, any contact time significantly increased abstinence rates over those produced by no-contact. However, there was a clear trend for abstinence rates to increase across contact time, with 31–90 minutes producing abstinence rates that were significantly higher than the rates produced by 1–3 minutes of total contact time. There was no evidence that more than 90 minutes of contact time increases abstinence rates further.

Number of Sessions. Forty-five studies involving at least some person-to-person contact met selection criteria for the analysis addressing the impact of number of treatment sessions. The number of treatment sessions was categorized as zero or one session, two to three sessions, four to eight sessions, and greater than eight sessions. Zero or one session was used as the reference group. As shown in Table 14, multiple treatment sessions increase smoking abstinence rates over those produced by zero or one session. The evidence suggests a dose-response relation between number of sessions and treatment efficacy, with treatments lasting more than eight sessions significantly more effective than interventions lasting either zero to one or two to three sessions.

Future Research. The following topics regarding intensity of person-to-person contact require additional research:

Table 14. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Number of Person-to-Person Treatment Sessions ($n = 45$ studies)

Number of Sessions	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
0-1 session	43	1.0	12.4
2-3 sessions	17	1.4 (1.1, 1.7)	16.3 (13.7, 19.0)
4-8 sessions	23	1.9 (1.6, 2.2)	20.9 (18.1, 23.6)
> 8 sessions	51	2.3 (2.1, 3.0)	24.7 (21.0, 28.4)

CI = confidence interval

• The effects of treatment duration and spacing of sessions (ie, the number of days or weeks over which treatment is spread). For instance, does front-loading sessions (having the majority of the sessions during the first few weeks of a quit attempt), or spacing sessions throughout the quit attempt yield better long-term abstinence rates?

• Methods to increase the patient utilization and completion of intensive treatments.

• Efficacy of intensive inpatient treatment programs.

Type of Clinician. Recommendation: Treatment delivered by a variety of clinician types increases abstinence rates. Therefore, all clinicians should provide smoking cessation interventions. (Strength of Evidence = A)

Recommendation: Treatments delivered by multiple types of clinicians are more effective than interventions delivered by a single type of clinician. Therefore, if feasible, the delivery of interventions by more than one type of clinician is encouraged. (Strength of Evidence = C)

Clinician Types. Twenty-nine studies met selection criteria for the analysis examining the effectiveness of various types of clinicians providing smoking cessation interventions. These analyses compared the efficacy of interventions delivered by specific types of clinicians with interventions where there were no clinicians (eg, where there was no intervention or the intervention consisted of self-help materials only). Smoking cessation interventions delivered by any single type of health care provider, such as a physician or nonphysician clinician (eg, psychologist, nurse, dentist, or counselor), or by multiple clinicians, increase abstinence rates relative to interventions where there is no clinician (eg, self-help interventions). None of the studies in these analyses involved pharmacotherapy, but they did involve psychosocial intervention of varying intensities. Results are shown in Table 15. Results are consistent across diverse clinician groups, with no clear advantage to any single clinician type.

Table 15. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Interventions Delivered by Various Types of Clinicians ($n = 29$ studies)

Type of Clinician	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
No clinician	16	1.0	10.2
Self-help	47	1.1 (0.9, 1.3)	10.9 (9.1, 12.7)
Nonphysician clinician	39	1.7 (1.3, 2.1)	15.8 (12.8, 18.8)
Physician clinician	11	2.2 (1.5, 3.2)	19.9 (13.7, 26.2)

CI = confidence interval

Table 16. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Interventions Delivered by Various Numbers of Clinician Types ($n = 37$ studies)

Number of Clinician Types	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
No clinician	30	1.0	10.8
One clinician type	50	1.8 (1.5, 2.2)	18.3 (15.4, 21.1)
Two clinician types	16	2.5 (1.9, 3.4)	23.6 (18.4, 28.7)
Three or more clinician types	7	2.4 (2.1, 2.9)	23.0 (20.0, 25.9)

CI = confidence interval

Number of Clinician Types. Thirty-seven studies met selection criteria for the analysis examining the effectiveness of multiple clinicians used in smoking cessation interventions. Please note that "multiple clinicians" refers to the number of different types of clinicians, not the number of total clinicians regardless of type. The latter information was rarely available from the study reports. Smoking cessation interventions delivered by multiple types of clinicians increase abstinence rates relative to those produced by interventions where there is no clinician. Results are shown in Table 16. The data displayed in Table 16 also show a nonsignificant trend for multiple types of clinicians to be more efficacious than a single clinician type. This suggests that a variety of clinicians, including physician clinicians, and nonphysician clinicians, such as nurses, dentists, dental hygienists, psychologists, pharmacists, and health educators, can play an important role in promoting smoking cessation.

Future Research. The following topics regarding type of clinician require additional research:

• The effectiveness of specific types of clinicians, such as nurses, physician assistants, pharmacists, social workers, etc.

Table 17. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Various Types of Format ($n = 58$ studies)

Format	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
No format	20	1.0	10.8
Self-help	93	1.2 (1.02, 1.3)	12.3 (10.9, 13.6)
Proactive telephone counseling	26	1.2 (1.1, 1.4)	13.1 (11.4, 14.8)
Group counseling	52	1.3 (1.1, 1.6)	13.9 (11.6, 16.1)
Individual counseling	67	1.7 (1.4, 2.0)	16.8 (14.7, 19.1)

CI = confidence interval

- The relative effectiveness of various numbers and types of clinicians, with the intensity of the intervention held constant.

- Strategies to integrate tobacco dependence treatment across diverse disciplines and settings.

Formats of Psychosocial Treatments. Recommendation: Proactive telephone counseling, and group and individual counseling formats are effective and should be used in smoking cessation interventions. (Strength of Evidence = A)

Recommendation: Smoking cessation interventions that are delivered in multiple formats increase abstinence rates and should be encouraged. (Strength of Evidence = A)

Format Types. Fifty-eight studies met selection criteria and were included in the analysis comparing different types of formats. Smoking cessation interventions delivered by means of proactive telephone counseling/contact, individual counseling, and group counseling/contact all increase abstinence rates relative to no intervention.

This format meta-analysis also evaluated the efficacy of self-help interventions (eg, pamphlets/booklets/mailings/manuals, videotapes, audiotapes, referrals to 12-step programs, mass media community level interventions, reactive telephone hotlines/help lines, computer programs/Internet, and lists of community programs). Interventions delivered by means of widely varied self-help materials (whether as stand-alone treatments or as adjuvants) appear to increase abstinence rates relative to no intervention in this particular analysis. However, the effect of self-help is weak and inconsistent across analyses conducted for this guideline. The impact of self-help is certainly smaller and less certain than that of proactive telephone, individual, or group counseling. Results of this analysis are shown in Table 17.

Table 18. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Number of Formats ($n = 54$ studies)

Number of Formats*	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
No format	20	1.0	10.8
One format	51	1.5 (1.2, 1.8)	15.1 (12.8, 17.4)
Two formats	55	1.9 (1.6, 2.2)	18.5 (15.8, 21.1)
Three or four formats	19	2.5 (2.1, 3.0)	23.2 (19.9, 26.6)

*Formats included self-help, proactive telephone counseling, group, or individual counseling. CI = confidence interval

Number of Formats. Fifty-four studies met selection criteria and were included in the analysis comparing the number of format types used for smoking cessation interventions. The self-help treatments included in this analysis occurred either by themselves or as adjuvants to other treatments. Smoking cessation interventions that used more than two format types were more effective than interventions that used a single format type. Results of this analysis are shown in Table 18.

Self-help: focused analyses. Because the format analysis revealed self-help to be of marginal efficacy, another analysis was undertaken to provide additional, focused information on self-help. Studies were accepted for this analysis if the presence of self-help materials constituted the sole difference in treatment arms. In the main format analysis, some treatment arms differed on factors other than self-help per se (eg, intensity of adjuvant counseling). The treatments that accompanied self-help material in the focused analysis ranged from no advice or counseling to intensive counseling. The results of this analysis were comparable to those in the larger format analysis (ie, self-help was of marginal efficacy).

Twenty-one studies met selection criteria to evaluate the efficacy of providing multiple types of self-help interventions (eg, pamphlets, videotapes, audiotapes, and reactive hotlines/help lines). The results provide little evidence that the provision of multiple types of self-help, when offered without any person-to-person intervention, significantly enhances treatment outcomes (Table 19).

There are two limitations to interpreting these results. First, self-help materials vary greatly in nature and intensity. It is possible that some sub-types of self-help are, in fact, efficacious (eg, those that are individualized). Second, a large number of smokers report that they quit on their own without clinical support or contact.⁹³ The extent to which use of self-help materials aids self-quitters was not addressed in guideline analyses.

The previous analyses failed to show a consistent, beneficial effect because of self-help. Two final meta-analyses addressed the impact of self-help brochures per se. In one

Table 19. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Number of Types of Self-Help ($n = 21$ studies)

Factor	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
No self-help	17	1.0	14.3
One type of self-help	27	1.0 (0.9, 1.1)	14.4 (12.9, 15.9)
Two or more types	10	1.1 (0.9, 1.5)	15.7 (12.3, 19.2)

CI = confidence interval

analysis, brochures were used as the only intervention. In the other analysis, self-help brochures were used as adjuncts to counseling. In neither analysis did self-help significantly boost abstinence rates.

Future Research. The following topics regarding formats require additional research:

- Identify which combinations of formats are effective.
- The efficacy of innovative approaches to self-help such as individualized computerized interventions.^{87,94,95}
- The efficacy of reactive telephone hotlines/help lines.^{60,96-99}
- The relative efficacy of different types of self-help interventions.
- The efficacy of self-help materials as adjuvant treatments. Do they add significantly to the effectiveness of other proven tobacco dependence treatments such as individual counseling, group counseling, proactive telephone counseling, and pharmacotherapy?

Follow-up Assessment and Procedures. Recommendation: All patients who receive a tobacco dependence intervention should be assessed for abstinence at the completion of treatment and during subsequent clinic contacts.¹ Abstinent patients should receive relapse prevention treatment (see Chapter 3C, For the Patient Who Has Quit).² Patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt. (Strength of Evidence = C):

- If the patient is willing to make another quit attempt, provide or arrange additional treatment (see Chapter 3A, For the Patient Willing To Quit).
- If the patient is not willing to try to quit, provide an intervention to promote motivation to quit (see Chapter 3B, For the Patient Unwilling To Quit).

All patients should be assessed with respect to their smoking status during all follow-up tobacco dependence contacts. In particular, assessments within the first week after quitting also should be encouraged.¹⁰⁰ Abstinent patients should receive relapse prevention treatment (see Chapter 3C, Brief Strategy C1 and Brief Strategy C2) including reinforcement for their decision to quit, congrat-

ulations on their success at quitting, and encouragement to remain abstinent.⁶² Clinicians also should inquire about current and future threats to abstinence and provide appropriate suggestions for coping with these threats.

Patients who have relapsed should again be assessed for their willingness to quit. Patients who are currently motivated to make another quit attempt should be provided with a tobacco dependence intervention (see Chapter 3A, For the Patient Willing To Quit). Clinicians may wish to increase the intensity of psychosocial treatment at this time or refer the patient to a tobacco dependence specialist/program for a more intensive treatment if the patient is willing. In addition, pharmacotherapy should be again offered to the patient. If the previous cessation attempt included pharmacotherapy, the clinician should review whether the patient used these medications in an effective manner and determine whether the medication was helpful. Based on this assessment, recommend retreatment with the same pharmacotherapy, another pharmacotherapy, or combination nicotine replacement therapies (see Tables 33-39).

Patients who are unwilling to quit at the current time should receive a brief intervention designed to promote the motivation to quit (see Chapter 3B, Brief Strategy B. Enhancing motivation to quit tobacco—the “5 R’s”).

Future Research. The following topics regarding follow-up assessment require additional research:

- The optimal timing and types of relapse prevention interventions.
- The efficacy of various formats for relapse prevention treatments. For instance, are telephone contacts effective in reducing the likelihood of relapse after a minimal intervention?

C. Treatment Elements

Types of Counseling and Behavioral Therapies. Recommendation: Three types of counseling and behavioral therapies result in higher abstinence rates: (1) providing smokers with practical counseling (problem-solving skills/skills training), (2) providing social support as part of treatment, and (3) helping smokers obtain social support outside of treatment. These types of counseling and behavioral therapies should be included in smoking cessation interventions. (Strength of Evidence = B)

Recommendation: 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. (Strength of Evidence = B)

Sixty-two studies met selection criteria for analyses examining the effectiveness of interventions using various

Table 20. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Various Types of Counseling and Behavioral Therapies ($n = 62$ studies)

Type of Counseling and Behavioral Therapy	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
No counseling	35	1.0	11.2
behavioral therapy			
Relaxation/breathing	31	1.0 (0.7, 1.3)	10.8 (7.9, 13.8)
Contingency contracting	22	1.0 (0.7, 1.4)	11.2 (7.8, 14.6)
Weight/diet	19	1.0 (0.8, 1.3)	11.2 (8.5, 14.0)
Cigarette fading	25	1.1 (0.8, 1.5)	11.8 (8.4, 15.3)
Negative affect	8	1.2 (0.8, 1.9)	13.6 (8.7, 18.5)
Intra-treatment social support	50	1.3 (1.1, 1.6)	14.4 (12.3, 16.5)
Extra-treatment social support	19	1.5 (1.1, 2.1)	16.2 (11.8, 20.6)
General—problem-solving	104	1.5 (1.3, 1.8)	16.2 (14.0, 18.5)
Other aversive smoking	19	1.7 (1.04, 2.8)	17.7 (11.2, 24.9)
Rapid smoking	19	2.0 (1.1, 3.5)	19.9 (11.2, 29.0)

CI = confidence interval

types of counseling and behavioral therapies. The results, shown in Table 20 reveal that four specific types of counseling and behavioral therapy categories yield statistically significant increases in abstinence rates relative to no-contact (eg, untreated control conditions). These categories are: (1) providing practical counseling such as problem-solving/skills training/relapse prevention/stress management, (2) providing support during a smoker's direct contact with a clinician (intra-treatment social support), (3) intervening to increase social support in the smoker's environment (extra-treatment social support), and (4) using aversive smoking procedures (rapid smoking, rapid puffing, other smoking exposure). A separate analysis was conducted eliminating studies that included the use of United States Food and Drug Administration (FDA)-approved pharmacotherapies. The results of this analysis were substantially similar to the main analysis.

The strength of evidence for the recommendations regarding types of counseling and behavioral therapy categories did not warrant an "A" rating for several reasons. First, smoking cessation interventions rarely used a particular type of counseling or behavioral therapy in isolation. Second, various types of counseling and behavioral therapies tended to be correlated with other treatment characteristics. For instance, some types of counseling and behavioral therapies were more likely to be delivered using a greater number of sessions across longer time periods. Third, it must be noted that all of these types of counseling and behavioral therapies were compared with no-contact/control conditions. Therefore, the control con-

Table 21. Common Elements of Practical Counseling (Problem-Solving/Skills Training) Treatment Component

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	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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 (eg, distracting attention)
Provide basic information about smoking and successful quitting.	<ul style="list-style-type: none"> • 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

ditions in this meta-analysis did not control for nonspecific or placebo effects of treatment. This further restricted the ability to attribute efficacy to particular types of counseling and behavioral therapies per se. Fourth, the studies used in this analysis often tailored the types of counseling and behavioral therapies to the needs of special populations being studied, thereby affecting the generalizability of the study results. Fifth, there was considerable heterogeneity within each type of counseling and behavioral therapy.

In the types of counseling and behavioral therapies meta-analysis, six studies examined the effect of dieting and physical activity interventions on smoking cessation. Although dieting and physical activity did not significantly increase abstinence rates based on that analysis, a single recent study published after the date for inclusion in meta-analysis found that vigorous exercise did boost quit rates.¹⁰¹

The treatments targeting negative affect were administered both to general populations as well as to special populations (eg, smokers with a history of depression).^{102,103} It is possible that different results would have been found if the study arms were restricted to smokers at risk for negative affect.

Tables 21, 22, and 23 outline elements of practical counseling (problem-solving/skills training), intra-treatment social support, and extra-treatment social support respec-

Table 22. Common Elements of Intra-Treatment Supportive Interventions

Supportive Treatment Component	Examples
Encourage the patient in the quit attempt	<ul style="list-style-type: none"> Note that effective tobacco dependence treatments are now available. Note that half of all people who have ever smoked have now quit. Communicate belief in patient's ability to quit.
Communicate caring and concern	<ul style="list-style-type: none"> 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	<p>Ask about:</p> <ul style="list-style-type: none"> Reasons the patient wants to quit. Concerns or worries about quitting. Success the patient has achieved. Difficulties encountered while quitting.

tively. These tables are designed to help clinicians using these counseling and behavioral therapies. It must be noted, however, that these treatment labels are nonspecific and include heterogeneous treatment elements.

Another type of behavioral therapy associated with superior outcomes is aversive smoking. This involves sessions of guided smoking where the patient smokes intensively, often to the point of discomfort, malaise, nausea, and/or vomiting. Some aversive smoking techniques, such as rapid smoking, may constitute a health risk and should

Table 23. Common Elements of Extra-Treatment Supportive Interventions

Supportive Treatment Component	Examples
Train patient in support solicitation skills	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> Mail letters to supportive others. Call supportive others. Invite others to cessation sessions. Assign patients to be "buddies" for one another.

Table 24. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Acupuncture ($n = 5$ studies)

Treatment	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
Placebo	7	1.0	8.3
Acupuncture	8	1.1 (0.7, 1.6)	8.9 (5.5, 12.3)

CI = confidence interval

be conducted only with appropriate medical screening and supervision. Aversive smoking interventions are infrequently used today.

Acupuncture. A separate meta-analysis was conducted for acupuncture. This analysis was conducted to achieve a sensitive test on the small body of studies that use this technique. Evidence, as shown in Table 24, did not support the efficacy of acupuncture as a smoking cessation treatment. 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.

Hypnosis. 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.¹⁰⁴

Other Interventions. There were insufficient studies to address the efficacy of other types of counseling and behavioral therapies such as physiologic feedback and restricted environmental stimulation therapy.

Future Research. The following topics regarding types of counseling and behavioral therapies require additional research:

- Motivational interventions, cigarette fading, hypnosis, physiologic feedback of smoking impacts, 12-step models, and restricted environmental stimulation therapy.
- Mechanisms through which counseling interventions exert their effects.

- Efficacy of specific counseling interventions among various patient populations (eg, those with cancers, COPD, and atherosclerosis).

Alternative Treatment Models for the Treatment of Tobacco Dependence—Stepped Care and Individual Tailoring. The panel concluded that there is not enough evidence to propose a recommendation regarding: (1) a stepped-care model for delivery of tobacco dependence treatment, and (2) individually tailored interventions (eg, using the transtheoretical model). Both of these intervention strategies hold promise, and enjoy some empirical support. Tailored self-help approaches especially enjoy some support.^{105–107} Unfortunately, there is insufficient data to indicate that either approach yields a significant incremental impact on long-term abstinence rates over the impact of nontailored counseling approaches of similar intensity. As a result, there needs to be additional research to test the efficacy of these strategies. Some of the needed research includes:

- Whether the use of stepped-care intervention strategies improves long-term abstinence rates.
- Whether the use of treatment matching strategies improves long-term abstinence rates.
- Whether the use of tailored intervention strategies improves long-term abstinence rates.
- Whether targeted reductions in the number of cigarettes smoked per day increases long-term rates of abstinence.¹⁰⁸
- Whether staged-based treatments developed in keeping with the transtheoretical model significantly improve long-term abstinence rates relative to comparably intense, alternative counseling strategies (eg, where patients receive only a standard motivational treatment or cessation treatment depending on their willingness to quit).

Pharmacotherapy. Recommendation: All patients attempting to quit should be encouraged to use effective pharmacotherapies for smoking cessation except in the presence of special circumstances. (Strength of Evidence = A)

Recommendation: Long-term smoking cessation pharmacotherapy should be considered as a strategy to reduce the likelihood of relapse (Strength of Evidence = C)

As with other chronic diseases, the most effective treatment of tobacco dependence requires the use of multiple modalities. Pharmacotherapy is a vital element of a multicomponent approach. The clinician should encourage all patients initiating a quit attempt to use one or a combination of efficacious pharmacotherapies, although pharmacotherapy use requires special consideration with some patient groups (eg, those with medical contraindications, those smoking fewer than 10 cigarettes a day, pregnant/

breast-feeding women, and adolescent smokers). The guideline panel identified five first-line medications (bupropion SR, nicotine gum, nicotine inhaler, nicotine nasal spray, and the nicotine patch) and two second-line medications (clonidine and nortriptyline) for smoking cessation. Each has been documented to significantly increase rates of long-term smoking abstinence. No other pharmacotherapeutic treatments were supported by a consistent body of scientific evidence.

The pharmacotherapy meta-analyses were designed to compare particular pharmacotherapies with the placebo controls in each study. Because of substantial differences across the studies evaluating the different types of pharmacotherapies, it is inappropriate to compare the results for one medication with those for another in the tables that follow.

Pharmacotherapy meta-analyses included predominately studies with “self-selected” populations. In addition, in pharmacotherapy studies both experimental and control subjects typically received substantial counseling. Both of these factors tend to produce higher abstinence rates in reference or placebo subjects than are typically observed among self-quitters.

Recommendations Regarding Specific Pharmacotherapies: First-Line Medications

First-line pharmacotherapies have been found to be safe and effective for tobacco dependence treatment and have been approved by the FDA for this use. First-line medications have established empirical record of efficacy, and should be considered first as part of tobacco dependence treatment except in cases of contraindications.

The listing of the first-line medications is provided alphabetically. Meta-analyses did not contrast the relative efficacy of these medications.

Bupropion SR (Sustained Release Bupropion). Recommendation: Bupropion SR is an efficacious smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

Two large multicenter studies met selection criteria and were included in the analysis comparing bupropion sustained release (SR) to placebo. Results of this analysis are shown in Table 25. As can be seen from this analysis, the use of bupropion SR approximately doubles long-term abstinence rates, compared to a placebo.

Bupropion SR is the first non-nicotine medication shown to be effective for smoking cessation and approved by the FDA for that use. Its mechanism of action is presumed to be mediated by its capacity to block neural re-uptake of dopamine and/or norepinephrine. It is contraindicated in patients with a seizure disorder, a current or prior diagnosis of bulimia or anorexia nervosa, use of a monoamine

Table 25. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Bupropion SR ($n = 2$ studies)

Pharmacotherapy	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
Placebo	2	1.0	17.3
Bupropion SR	4	2.1 (1.5, 3.0)	30.5 (23.2, 37.8)

CI = confidence interval

Table 26. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for 2 mg Nicotine Gum ($n = 13$ studies)

Pharmacotherapy	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
Placebo	16	1.0	17.1
Nicotine gum	18	1.5 (1.3, 1.8)	23.7 (20.6, 26.7)

CI = confidence interval

oxidase inhibitor within the previous 14 days, or in patients on another medication that contains bupropion. Bupropion SR can be used in combination with nicotine replacement therapies. Bupropion SR is available exclusively as a prescription medication both with an indication for smoking cessation (Zyban) and an indication for depression (Wellbutrin). Suggestions regarding the clinical use of bupropion SR are provided in Table 33.

Nicotine Gum. Recommendation: Nicotine gum is an efficacious smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

Recommendation: Clinicians should offer 4 mg rather than 2 mg nicotine gum to highly dependent smokers. (Strength of Evidence = B)

Thirteen studies met selection criteria and were included in the analysis comparing nicotine gum to placebo. Results of this analysis are shown in Table 26. As can be seen by the estimated odds ratio from this analysis, 2 mg nicotine gum improves long-term abstinence rates by approximately 30–80%, compared with placebo. Furthermore, a close review of the literature suggests that the 4 mg gum is more efficacious than the 2 mg gum as an aid to smoking cessation in highly dependent smokers (see Table 10, Variables associated with higher or lower abstinence rates).^{109,110}

Nicotine gum is currently available exclusively as an over-the-counter medication and is packaged with important instructions on correct usage, including chewing instructions. Suggestions regarding the clinical use of nicotine gum are provided in Table 34.

Table 27. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Nicotine Inhaler ($n = 4$ studies)

Pharmacotherapy	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
Placebo	4	1.0	10.5
Nicotine inhaler	4	2.5 (1.7, 3.6)	22.8 (16.4, 29.2)

CI = confidence interval

Table 28. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Nicotine Nasal Spray ($n = 3$ studies)

Pharmacotherapy	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
Placebo	3	1.0	13.9
Nicotine nasal spray	3	2.7 (1.8, 4.1)	30.5 (21.8, 39.2)

CI = confidence interval

Nicotine Inhaler. Recommendation: The nicotine inhaler is an efficacious smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

Four studies met selection criteria and were included in the analysis comparing the nicotine inhaler to placebo. Results of this analysis are shown in Table 27. As can be seen from this analysis, the nicotine inhaler more than doubles long-term abstinence rates, compared to a placebo inhaler.

The nicotine inhaler is available exclusively as a prescription medication. Suggestions regarding the clinical use of the nicotine inhaler are provided in Table 35.

Nicotine Nasal Spray. Recommendation: Nicotine nasal spray is an efficacious smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

Three studies met selection criteria and were included in the analysis comparing nicotine nasal spray to placebo. Results of this analysis are shown in Table 28. As can be seen from this analysis, nicotine nasal spray more than doubles long-term abstinence rates, compared to a placebo spray.

Nicotine nasal spray is available exclusively as a prescription medication. Suggestions regarding the clinical use of the nicotine nasal spray are provided in Table 36.

Nicotine Patch. Recommendation: The nicotine patch is an efficacious smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

Table 29. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for the Nicotine Patch ($n = 27$ studies)

Pharmacotherapy	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
Placebo	28	1.0	10.0
Nicotine patch	32	1.9 (1.7, 2.2)	17.7 (16.0, 19.5)

CI = confidence interval

Twenty-seven studies met selection criteria and were included in the analysis comparing the nicotine patch to placebo. Results of this analysis are shown in Table 29. As can be seen from this analysis, the nicotine patch approximately doubles long-term abstinence rates over those produced by placebo interventions.

The nicotine patch is available both as an over-the-counter medication and as a prescription medication. Suggestions regarding clinical use of the nicotine patch are provided in Table 37.

Recommendations Regarding Specific Pharmacotherapies: Second-Line Medications

Second-line medications are pharmacotherapies for which there is evidence of efficacy for treating tobacco dependence, but they have a more limited role than first-line medications because: (1) the FDA has not approved them for a tobacco dependence treatment indication, and (2) there are more concerns about potential adverse effects than exist with first-line medications. Second-line treatments should be considered for use on a case-by-case basis after first-line treatments have been used or considered.

The listing of the second-line medications is provided alphabetically. Meta-analyses did not contrast the relative efficacy of these medications.

Clonidine. Recommendation: Clonidine is an efficacious smoking cessation treatment. It may be used under a physician's supervision as a second-line agent to treat tobacco dependence. (Strength of Evidence = A)

Five studies met selection criteria and were included in the analysis comparing clonidine to placebo. Results of this analysis are shown in Table 30. As can be seen from this analysis, the use of clonidine approximately doubles abstinence rates, compared to placebo. These studies varied the clonidine dose from 0.1 mg/d to 0.75 mg/d. The drug was delivered either transdermally or orally. It should be noted that abrupt discontinuation of clonidine can result in symptoms such as nervousness, agitation, headache, and tremor, accompanied or followed by a rapid rise in blood pressure and elevated catecholamine levels.

Table 30. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Clonidine ($n = 5$ studies)

Pharmacotherapy	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
Placebo	6	1.0	13.9
Clonidine	8	2.1 (1.4, 3.2)	25.6 (17.7, 33.6)

CI = confidence interval

Table 31. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Nortriptyline ($n = 2$ studies)

Pharmacotherapy	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
Placebo	3	1.0	11.7
Nortriptyline	3	3.2 (1.8, 5.7)	30.1 (18.1, 41.6)

CI = confidence interval

Clonidine is used primarily as an antihypertensive medication and has not been approved by the FDA as a smoking cessation medication. Therefore, clinicians need to be aware of the specific warnings regarding this medication, as well as its adverse effect profile.

Additionally, a specific dosing regimen for the use of clonidine has not been established. Because of the warnings associated with clonidine discontinuation, the variability in dosages used to test this medication, and a lack of FDA approval, the guideline panel chose to recommend clonidine as a second-line agent. As such, clonidine should be considered for smoking cessation under a physician's direction with patients unable to use first-line medications because of contraindications or with patients who were unable to quit using first-line medications. Suggestions regarding clinical use of clonidine are provided in Table 38.

Nortriptyline. Recommendation: Nortriptyline is an efficacious smoking cessation treatment. It may be used under a physician's supervision as a second-line agent to treat tobacco dependence. (Strength of Evidence = B)

Two studies met selection criteria and were included in the analysis comparing nortriptyline to placebo. Results of this analysis are shown in Table 31. As can be seen from this analysis, the use of nortriptyline increases abstinence rates, compared to a placebo.

Nortriptyline is used primarily as an antidepressant and has not been evaluated or approved by the FDA as a smoking cessation medication. Clinicians need to be aware of the specific warnings regarding this medication as well as its side effect profile. Because of the limited number of studies examining nortriptyline and the small sample sizes

Table 32. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Combination Nicotine Replacement Therapy ($n = 3$ studies)

Factor	Number of Arms	Odds Ratio	Estimated Abstinence Rate (95% CI)
One NRT	3	1.0	17.4
Two NRTs	3	1.9 (1.3, 2.6)	28.6 (21.7, 35.4)

NRT = nicotine replacement therapy
CI = confidence interval

within those studies, the guideline panel determined that the recommendation warranted a strength of evidence equal to B. Because of this strength of evidence, the side effect profile, and the lack of FDA approval for tobacco dependence treatment, nortriptyline is recommended as a second-line agent. As such, nortriptyline should be considered for smoking cessation under a physician's direction with patients unable to use first-line medications because of contraindications or with patients who were unable to quit using first-line medications. Suggestions regarding clinical use of nortriptyline are provided in Table 39.

Combination Nicotine Replacement Therapy. Recommendation: Combining the nicotine patch with a self-administered form of nicotine replacement therapy (either the nicotine gum or nicotine nasal spray) is more efficacious than a single form of nicotine replacement, and patients should be encouraged to use such combined treatments if they are unable to quit using a single type of first-line pharmacotherapy. (Strength of Evidence = B)

Three studies met selection criteria for the combination nicotine replacement therapy (NRT) meta-analysis. This analysis was intended to address the hypothesis that combination pharmacotherapy is more effective than monotherapy (the use of a single pharmacotherapy) if the combination therapy comprises two different types of pharmacotherapy. Specifically, the hypothesis holds that one type of pharmacotherapy should involve passive dosing that produces relatively steady levels of drug in the body, while the second type of pharmacotherapy should permit *ad libitum* dosing that allows the user to adjust dosing on an acute basis.^{111,112} All three studies used the nicotine patch (15 mg) as one of the medications; in two studies the patch was supplemented with nicotine gum (2 mg),^{113,114} and in the remaining study the patch was supplemented with nicotine nasal spray.¹¹⁵ Comparison subjects receiving monotherapy were given the nicotine patch in two of these studies and nicotine gum in the third.

The results of the combination NRT meta-analysis are displayed in Table 32. The results show that the combi-

nation NRT treatment produced higher long-term abstinence rates than did NRT monotherapy. The recommendation to use combination NRT carries a strength of evidence rating of B. This is because the small number of studies in this analysis contained heterogeneous combination treatments as well as heterogeneous comparison conditions. It is important to note that the FDA has not approved a combination NRT strategy for treatment of smoking cessation. Because there is relatively little safety data on the conjoint use of NRTs, and because combination NRT could increase the risk of nicotine overdose, the panel recommends that this treatment strategy be used only with those patients unable to quit using a single type of pharmacotherapy. Combination NRT also is more expensive than is the use of a single NRT. This extra cost should be considered in making recommendations about NRT use.

Two studies have examined the impact of the combination of the nicotine patch plus nicotine gum on the suppression of the nicotine withdrawal syndrome.^{111,116} These studies show that combination NRT is more effective than a single NRT.

It is unknown whether the superiority of combination therapy is due to the use of two types of delivery systems or instead due to the fact that two delivery systems tend to produce higher blood nicotine levels than does the use of a single type of NRT. However, there is only modest evidence that using two forms of passive pharmacotherapies or increasing the dose of a single NRT increases long-term abstinence rates.¹¹⁷⁻¹²⁰ This suggests that the increment in success produced by combination NRTs may depend on the use of two distinct delivery systems: one passive and one *ad libitum*. This conclusion must remain tentative until more research is conducted on this topic. Finally, there is not yet sufficient data to determine whether combination NRTs are particularly efficacious with subpopulations of smokers (eg, those high in nicotine dependence).

Pharmacotherapies Not Recommended by the Guideline Panel

Antidepressants Other Than Bupropion SR and Nortriptyline. Smoking is significantly more prevalent among individuals with a history of depression, and these individuals have more difficulty quitting smoking than do smokers without a history of depression.¹²¹⁻¹²³ One antidepressant, bupropion SR, has been documented as effective for smoking cessation and approved by the FDA for this use (see above). Nortriptyline also appears to be effective (see above), although the FDA has not approved this medication for treatment of tobacco dependence. Trials have investigated the use of other antidepressants for smoking cessation, including other tricyclics and selective serotonin reuptake inhibitors, but no published articles met

selection criteria for review. Because of a paucity of data, the panel drew no conclusions about antidepressant therapy for smoking cessation except to recommend bupropion SR as a first-line agent and nortriptyline as a second-line agent.

Anxiolytics/Benzodiazepines/Beta-Blockers. A few trials have evaluated anxiolytics as a treatment for smoking cessation. Individual trials of propranolol¹²⁴ (a beta-blocker) and diazepam¹²⁵ (an anxiolytic) did not reveal a beneficial effect for these drugs compared with control interventions. Of the two studies assessing the anxiolytic buspirone that met inclusion criteria, only one revealed evidence of efficacy relative to placebo.^{126,127} Because of a lack of data, no meta-analyses were conducted, and no conclusions were drawn regarding the efficacy of anxiolytics in smoking cessation.

Silver Acetate. The two randomized clinical trials^{128,129} of silver acetate that met selection criteria revealed no beneficial effects for smoking cessation; therefore, the use of silver acetate as either a primary or an adjunctive treatment for smoking cessation was not supported.

Mecamylamine. Two studies meeting selection criteria evaluated the efficacy of mecamylamine for smoking cessation. In the single study that compared mecamylamine alone to placebo, no efficacy was noted.¹³⁰ In both studies, one combination of mecamylamine plus the nicotine patch was compared to placebo; in only one of these studies was the difference significant.¹³¹ Because of these findings, the panel drew no conclusions regarding mecamylamine as a sole medication.

Pharmacotherapy for Treating Tobacco Dependence: Issues Relevant to Use

Overcoming Clinician Reluctance to Use Pharmacotherapy. Some clinicians are reluctant to recommend and prescribe pharmacotherapy for their patients who smoke. Several reasons have been cited for this reluctance, including clinician beliefs that are prevalent but not supported by evidence. Examples of such beliefs are: smoking is a lifestyle choice and not a true dependence disorder; pharmacotherapy should be reserved for heavily dependent smokers or used only in conjunction with an intensive cessation treatment; and smokers will be most successful if they first try to quit on their own. Clinical and epidemiological data strongly counter these beliefs. A variety of findings show that tobacco dependence meets all accepted criteria for a drug dependence disorder. In most users, tobacco use produces tolerance, a well-characterized withdrawal syndrome, and an inability to control future use.²⁵ Thus, tobacco dependence warrants medical treatment just

as do other drug dependence disorders and other chronic diseases.

The panel concluded that, in the vast majority of cases, it is inappropriate to reserve pharmacotherapy until patients have tried to quit on their own. Although many smokers have quit on their own, the vast majority of unaided quit attempts, between 90–95%, end in failure.^{2,65} By using the pharmacotherapies found to be effective in this guideline, clinicians can double or triple their patients' chances of abstinence. Pharmacotherapies recommended in this guideline have been used effectively with psychosocial treatments that have varied greatly in intensity. When intensity of adjuvant treatments has been examined, data reveal that the pharmacotherapies are effective at low as well as high levels of psychosocial treatment intensity.^{132,133} Therefore, clinicians should recommend effective psychosocial treatments such as counseling, in addition to pharmacotherapy, to all patients for whom it is appropriate. Finally, pharmacotherapies are effective for a broad range of smokers, not just "hard core" smokers.

Extended Use of Pharmacotherapy. For some patients, it may be appropriate to continue pharmacotherapeutic treatment (bupropion SR or NRT) for periods longer than usually recommended. The Lung Health Study, which studied almost 4,000 smokers with early evidence COPD, reported that of the sustained quitters, 38% of the women and 30% of the men were still using nicotine gum at 12 months.¹³⁴ Other studies also have found that, among patients given free access to nicotine gum, 15–20% of successful abstainers continue to use the gum for a year or longer.^{135,136} Although weaning should be encouraged for all smoking cessation pharmacotherapies, continued use of such medication is clearly preferable to a return to smoking with respect to health consequences. This is because, unlike smoking, these medications do not (A) contain non-nicotine toxic substances (eg, "tar" and carbon monoxide), (B) produce dramatic surges in blood nicotine levels, and/or (C) produce strong dependence.¹³⁷

Recommending Specific Pharmacotherapy for Specific Patient Subgroups

There are five FDA-approved medications for treating tobacco dependence. Clinicians are interested in which medications to use with which patients. Unfortunately, this guideline provides little guidance on this topic, because of a lack of relevant research. Some studies have directly compared the efficacies of FDA-approved pharmacotherapies;¹¹⁸ however, there are too few studies to yield definitive conclusions.

More research is needed before evidence-based pharmacotherapy algorithms can be formulated; however, several factors may guide the clinician in choosing medica-

Table 33. Suggestions for the Clinical Use of Bupropion SR (FDA approved)

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation.
Precautions	<p><i>Pregnancy:</i> Pregnant smokers should be encouraged to quit first without pharmacologic treatment. Bupropion SR should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of bupropion SR treatment and potential concomitant smoking. Similar factors should be considered in lactating women. (FDA Class B)</p> <p><i>Cardiovascular diseases:</i> Generally well tolerated; infrequent reports of hypertension.</p> <p><i>Adverse effects:</i> The most common adverse effects reported by bupropion SR users were insomnia (35–40%) and dry mouth (10%).</p> <p><i>Contraindications:</i> Bupropion SR is contraindicated in individuals with a history of seizure disorder, a history of an eating disorder, who are using another form of bupropion (Wellbutrin or Wellbutrin SR), or who have used a monoamine oxidase inhibitor in the past 14 days.</p>
Dosage	Patients should begin with a dose of 150 mg q AM for 3 days, then increase to 150 mg bid. Dosing at 150 mg bid should continue for 7–12 weeks following the quit date. Unlike nicotine replacement products, patients should begin bupropion SR treatment 1–2 weeks <i>before</i> they quit smoking. For maintenance therapy, consider bupropion SR 150 mg bid for up to 6 months.
Availability	Zyban: Prescription only.
Prescribing instructions	<p><i>Cessation prior to quit date:</i> Recognize that some patients will lose their desire to smoke prior to their quit date, or will spontaneously reduce the amount they smoke.</p> <p><i>Scheduling of dose:</i> If insomnia is marked, taking the PM dose earlier (in the afternoon, at least 8 hours after the first dose) may provide some relief.</p> <p><i>Alcohol:</i> Use alcohol only in moderation.</p>
Cost/day*	\$3.33

*Cost data is based on the retail price of the medication purchased at a national chain pharmacy located in Madison, Wisconsin, April 2000.

FDA = United States Food and Drug Administration

tions for specific patient subpopulations. For example, highly dependent smokers who use nicotine gum should be urged to use 4 mg, as opposed to 2 mg, gum.^{109,110} Also, bupropion SR and nortriptyline have been demonstrated to be efficacious in patients trying to quit who have a history of depression.^{138,139} Additionally, for patients concerned about weight gain, some pharmacotherapies (eg, bupropion SR, NRT, in particular nicotine gum) have been shown to delay but not prevent weight gain during their use. Moreover, research suggests that some treatments (eg, NRTs) are less efficacious in women than in men.^{140,141} Finally, patient preferences and patient expectations regarding outcome also are important in guiding the choice of a specific pharmacotherapy.¹⁴² A series of clinical recommendations for pharmacotherapy selection is shown in Table 4 in Chapter 3. For a description of some of the issues related to the use of pharmacotherapy with pregnant women, please refer to the Pregnancy section in Chapter 7.

Currently, there is insufficient evidence to suggest that the use of tobacco dependence pharmacotherapies increases long-term abstinence rates among users of smokeless tobacco. Specifically, studies conducted with nicotine gum and the nicotine patch have shown that these two medications have not increased abstinence rates in this population.¹⁴³

Use of Nicotine Replacement Therapy in Cardiovascular Patients. Soon after the nicotine patch was released,

the media reported a possible link between the use of this medication and cardiovascular risk. This question has been systematically studied since that time. Separate analyses have now documented the lack of an association between the nicotine patch and acute cardiovascular events^{144–146} even in patients who continued to smoke intermittently while on the nicotine patch.¹⁴⁷ Because of inaccurate media coverage in the past, 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. Note that package inserts recommend caution with acute cardiovascular diseases (see Tables 33–37).

Future Research. The following pharmacotherapeutic topics require additional research:

- The effectiveness of a nicotine sublingual tablet as a tobacco dependence medication.
- The effectiveness of bupirone as a tobacco dependence medication.
- The effectiveness of mecamylamine as a tobacco dependence medication, both used alone and in combination with other medications.
- The use of sustained or long-term pharmacotherapy for treating tobacco dependence.
- The use of other antidepressants or anxiolytics as tobacco dependence medications.
- The relative efficacy and safety of the five FDA-approved pharmacotherapies both, in general, and for spe-

Table 34. Suggestions for the Clinical Use of Nicotine Gum (FDA approved)

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation.
Precautions	<p><i>Pregnancy:</i> Pregnant smokers should be encouraged to quit first without pharmacologic treatment. Nicotine gum should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of nicotine replacement and potential concomitant smoking. Similar factors should be considered in lactating women. (FDA Class D)</p> <p><i>Cardiovascular diseases:</i> NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) postmyocardial infarction period, those with serious arrhythmias, and those with serious or worsening angina pectoris.</p> <p><i>Adverse effects:</i> Common adverse effects of nicotine chewing gum include mouth soreness, hiccups, dyspepsia, and jaw ache. These effects are generally mild and transient, and often can be alleviated by correcting the patient's chewing technique (see prescribing instructions below).</p>
Dosage	Nicotine gum is available in 2 mg and 4 mg (per piece) doses. The 2 mg gum is recommended for patients smoking less than 25 cigarettes per day, while the 4 mg gum is recommended for patients smoking 25 or more cigarettes per day. Generally, the gum should be used for up to 12 weeks with no more than 24 pieces/d. Clinicians should tailor the dosage and duration of therapy to fit the needs of each patient.
Availability	Nicorette, Nicorette Mint: over-the-counter only.
Prescribing instructions	<p><i>Chewing technique:</i> Gum should be chewed slowly until a "peppery" or "minty" taste emerges, then "parked" between cheek and gum to facilitate nicotine absorption through the oral mucosa. Gum should be slowly and intermittently "chewed and parked" for about 30 minutes or until the taste dissipates.</p> <p><i>Absorption:</i> Acidic beverages (eg, coffee, juices, soft drinks) interfere with the buccal absorption of nicotine, so eating and drinking anything except water should be avoided for 15 minutes before and during chewing.</p> <p><i>Scheduling of dose:</i> Patients often do not use enough gum to get the maximum benefit: they chew too few pieces per day and they do not use the gum for a sufficient number of weeks. Instructions to chew the gum on a fixed schedule (at least one piece every 1–2 hours) for at least 1–3 months may be more beneficial than ad libitum use.</p>
Cost/day*	<p>\$6.25 for ten 2 mg pieces.</p> <p>\$6.87 for ten 4 mg pieces.</p>

*Cost data is based on the retail price of the medication purchased at a national chain pharmacy located in Madison, Wisconsin, April 2000.

FDA = United States Food and Drug Administration. NRT = nicotine replacement therapy

Table 35. Suggestions for Clinical Use of the Nicotine Inhaler (FDA approved)

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation.
Precautions	<p><i>Pregnancy:</i> Pregnant smokers should be encouraged to quit first without pharmacologic treatment. The nicotine inhaler should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of nicotine replacement and potential concomitant smoking. Similar factors should be considered in lactating women. (FDA Class D)</p> <p><i>Cardiovascular diseases:</i> NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) postmyocardial infarction period, those with serious arrhythmias, and those with serious or worsening angina pectoris.</p> <p><i>Local irritation reactions:</i> Local irritation in the mouth and throat was observed in 40% of patients using the nicotine inhaler. Coughing (32%) and rhinitis (23%) also were common. Severity was generally rated as mild and the frequency of such symptoms declined with continued use.</p>
Dosage	A dose from the nicotine inhaler consists of a puff or inhalation. Each cartridge delivers 4 mg of nicotine over 80 inhalations. Recommended dosage is 6–16 cartridges/day. Recommended duration of therapy is up to 6 months. Instruct patient to taper dosage during the final 3 months of treatment.
Availability	Nicotrol Inhaler: prescription only.
Prescribing instructions	<p><i>Ambient temperature:</i> Delivery of nicotine from the inhaler declines significantly at temperatures below 40°F. In cold weather the inhaler and cartridges should be kept in an inside pocket or warm area.</p> <p><i>Duration:</i> Use is recommended for up to 6 months, with gradual reduction in frequency of use over the last 6–12 weeks of treatment.</p> <p><i>Absorption:</i> Acidic beverages (eg, coffee, juices, soft drinks) interfere with the buccal absorption of nicotine, so eating and drinking anything except water should be avoided for 15 minutes before and during inhalation.</p> <p><i>Best effects:</i> Best effects are achieved by frequent puffing.</p>
Cost/day*	\$10.94 for 10 cartridges.

*Cost data is based on the retail price of the medication purchased at a national chain pharmacy located in Madison, Wisconsin, April 2000.

FDA = United States Food and Drug Administration. NRT = nicotine replacement therapy

Table 36. Suggestions for Clinical Use of Nicotine Nasal Spray (FDA approved)

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation.
Precautions	<p><i>Pregnancy:</i> Pregnant smokers should be encouraged to quit first without pharmacologic treatment. Nicotine nasal spray should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of nicotine replacement and potential concomitant smoking. Similar factors should be considered in lactating women. (FDA Class D)</p> <p><i>Cardiovascular diseases:</i> NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) postmyocardial infarction period, those with serious arrhythmias, and those with serious or worsening angina pectoris.</p> <p><i>Nasal/airway reactions:</i> Some 94% of users report moderate to severe nasal irritation in the first 2 days of use; 81% still reported nasal irritation after 3 weeks, although rated severity was mild to moderate. Nasal congestion and transient changes in sense of smell and taste also were reported. Nicotine nasal spray should not be used in persons with severe reactive airway disease.</p> <p><i>Dependency:</i> Nicotine nasal spray has a dependence potential intermediate between other nicotine-based therapies and cigarettes. About 15–20% of patients report using the active spray for longer periods than recommended (6–12 months), and 5% used the spray at a higher dose than recommended.</p>
Dosage	A dose of nicotine nasal spray consists of one 0.5 mg delivery to each nostril (1 mg total). Initial dosing should be 1–2 doses per hour, increasing as needed for symptom relief. Minimum recommended treatment is 8 doses/d, with a maximum limit of 40 doses/d (5 doses/h). Each bottle contains approximately 100 doses. Recommended duration of therapy is 3–6 months.
Availability	Nicotrol NS: Prescription only.
Prescribing instructions	<i>Dose delivery:</i> Patients should not sniff, swallow, or inhale through the nose while administering doses because this increases irritating effects. The spray is best delivered with the head tilted slightly back.
Cost/day*	\$5.40 for 12 doses.

*Cost data is based on the retail price of the medication purchased at a national chain pharmacy located in Madison, Wisconsin, April 2000.

FDA = United States Food and Drug Administration. NRT = nicotine replacement therapy.

cific subpopulations (eg, women, adolescents, smokeless users, depressed patient, post-myocardial infarction patients).

- The use of combined tobacco dependence pharmacotherapies in general and for specific subpopulations (eg, highly dependent smokers).
- The efficacy of combining active and passive NRTs versus combining two active or two passive NRTs.
- When clonidine and nortriptyline should be used in lieu of or in combination with other tobacco dependence pharmacotherapies.
- The optimal combination of counseling and pharmacotherapy intensities (see Tables 38 and 39).

Over-the-Counter Pharmacotherapeutic Interventions. Recommendation: Over-the-counter nicotine patch therapy is more efficacious than placebo and its use should be encouraged. (Strength of evidence = B)

There were three placebo-controlled studies with six arms that met selection criteria for the analysis of pharmacotherapeutic interventions in over-the-counter (OTC) settings. These three studies specifically examined the effect of patch versus placebo. The only adjuvant treatments in these studies were a self-help manual, instructions contained in the package, or written directions for using the patch. As shown in Table 40, the use of the nicotine patch in OTC settings nearly doubles abstinence rates, compared

with placebo. There were too few studies done in the OTC setting to permit meta-analysis of the OTC effect of any other pharmacotherapy.

The FDA has approved nicotine gum and the nicotine patch for OTC use. These products are identical to the patches and gum previously available only via prescription. Although the OTC status of these medications has increased their availability and use, this does not reduce the clinician's responsibility to intervene with smokers or insurers/managed care organizations to cover the costs of such treatment. Moreover, OTC availability may enhance the capacity of nonphysician clinicians to intervene comprehensively when treating tobacco dependence.

All clinicians have specific responsibilities regarding these products, such as encouraging their use when appropriate, providing counseling and follow-up, encouraging total abstinence, and offering instruction on appropriate use. Additionally, patients should be urged to read the package insert and consult with their pharmacist. Finally, the clinician may advise patients regarding the selection and use of an OTC product versus a non-OTC product such as bupropion SR or a prescription nicotine replacement treatment (nasal spray or inhaler). Clinicians also may provide or recommend counseling for patients quitting with an OTC product. It should be noted that a single recent study not included within the meta-analysis reported low abstinence rates with OTC patch use.¹⁴⁸

Table 37. Suggestions for Clinical Use of the Nicotine Patch (FDA approved)

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation.	
Precautions	<p><i>Pregnancy:</i> Pregnant smokers should be encouraged to quit first without pharmacologic treatment. The nicotine patch should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of nicotine replacement and potential concomitant smoking. Similar factors should be considered in lactating women. (FDA Class C)</p> <p><i>Cardiovascular diseases:</i> NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) postmyocardial infarction period, those with serious arrhythmias, and those with serious or worsening angina pectoris.</p> <p><i>Skin reactions:</i> Up to 50% of patients using the nicotine patch will have a local skin reaction. Skin reactions are usually mild and self-limiting, but may worsen over the course of therapy. Local treatment with hydrocortisone cream (1%) or triamcinolone cream (0.5%) and rotating patch sites may ameliorate such local reactions. In less than 5% of patients such reactions require the discontinuation of nicotine patch treatment.</p> <p><i>Other adverse effects:</i> insomnia.</p>	
Dosage	Treatment of 8 weeks or less has been shown to be as efficacious as longer treatment periods. 16-hour and 24-hour patches are of comparable efficacy. Clinicians should consider individualizing treatment based on specific patient characteristics such as previous experience with the patch, amount smoked, degree of addictiveness, etc. Finally, clinicians should consider starting treatment on a lower patch dose in patients smoking 10 or fewer cigarettes per day.	
Availability	<p>Nicoderm CQ, Nicotrol, generic: over-the-counter.</p> <p>Nicotine patches, generic (various doses): prescription.</p>	
Brand	Duration	Dosage
Nicoderm CQ	4 weeks	21 mg/24 hours
	then 2 weeks	14 mg/24 hours
	then 2 weeks	7 mg/24 hours
Nicotrol	8 weeks	15 mg/16 hours
Prescribing instructions	<p><i>Location:</i> At the start of each day the patient should place a new patch on a relatively hairless location, typically between the neck and waist.</p> <p><i>Activities:</i> No restrictions while using the patch.</p> <p><i>Time:</i> Patches should be applied as soon as the patient wakes on their quit day. With patients who experience sleep disruption, have the patient remove the 24-hour patch prior to bedtime or use the 16-hour patch.</p>	
Cost/day*	<p>Brand name patches (Nicoderm CQ, Nicotrol): \$4.00–\$4.50.</p> <p>Generic patches recently became available and may be less expensive.</p>	

*Cost data is based on the retail price of the medication purchased at a national chain pharmacy located in Madison, Wisconsin, April 2000.
 FDA = United States Food and Drug Administration. NRT = nicotine replacement therapy.

Future Research Important topics for future research are:

- The efficacy of nicotine patch and nicotine gum when access is OTC.

- The extent to which individuals use pharmacotherapies optimally when access is OTC.

- The extent to which the efficacy of OTC pharmacotherapy is enhanced by adjuvant treatments (eg, pharmacist counseling, telephone counseling, computer self-help resources, clinician interventions).

- The extent to which OTC status increases or reduces the use of pharmacotherapies by poor or minority populations.

7. Special Populations

Background

Many factors could potentially affect the choice, delivery, and efficacy of tobacco dependence treatments. For

instance, should interventions be tailored or modified on the basis of gender, race/ethnicity, age, comorbidity, or hospitalization status? Should pregnant smokers receive pharmacotherapy? Do tobacco dependence interventions interfere with other chemical dependence treatments? These and other special issues and populations are considered in this chapter.

A variety of health care specialties can play a key role in addressing issues related to special populations (eg, obstetricians and family practitioners for pregnant smokers; gynecologists and family practitioners for preconception counseling and general health maintenance; pediatricians, family practitioners, and dentists for children and adolescents; internists, including cardiologists, pulmonologists, oncologists, and general internists, and family practitioners for hospitalized patients; geriatricians for older smokers; and dentists and dental hygienists for smokeless tobacco users).

Table 38. Suggestions for Clinical Use of Clonidine (not FDA approved for smoking cessation)

Patient selection	Appropriate as a second-line pharmacotherapy for smoking cessation.
Precautions	<p><i>Pregnancy:</i> Pregnant smokers should be encouraged to quit first without pharmacologic treatment. Clonidine should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of clonidine and potential concomitant smoking and first-line pharmacotherapies have not been successful. Similar factors should be considered in lactating women. (FDA Class C)</p> <p><i>Adverse effects:</i> Most commonly reported adverse effects include dry mouth (40%), drowsiness (33%), dizziness (16%), sedation (10%), and constipation (10%). As an antihypertensive medication, clonidine can be expected to lower blood pressure in most patients. Therefore, clinicians may need to monitor blood pressure when using this medication.</p> <p><i>Rebound hypertension:</i> Failure to gradually reduce the dose over a period of 2–4 days may result in a rapid increase in blood pressure, agitation, confusion, and/or tremor.</p>
Dosage	Doses used in various clinical cessation trials have varied significantly, from 0.15–0.75 mg/d PO to 0.10–0.20 mg/d transdermal (TTS), without a clear dose-response relation to cessation. Initial dosing is typically 0.10 mg bid PO or 0.10 mg/d TTS, increasing by 0.10 mg/d per week if needed. The dose duration also varied across the clinical trials, ranging from 3 weeks to 10 weeks.
Availability	<p><i>Oral:</i> Clonidine (generic), Catapres: prescription only.</p> <p><i>Transdermal:</i> Catapres: prescription only.</p>
Prescribing instructions	<p><i>Initiate:</i> Initiate clonidine shortly before (up to 3 days) or on the quit date.</p> <p><i>Location (TTS Only):</i> At the start of each week, the patient should place a new patch on a relatively hairless location between the neck and waist.</p> <p><i>Activities:</i> Use of either form may produce sedation, a hazard while driving or operating machinery. Users should not discontinue clonidine therapy abruptly.</p>
Cost/day*	<p>Clonidine: \$0.24 for 0.2 mg.</p> <p>Catapres (transdermal): \$3.50.</p>

*Cost data is based on the retail price of the medication purchased at a national chain pharmacy located in Madison, Wisconsin, April 2000.

FDA = United States Food and Drug Administration.

Table 39. Suggestions for Clinical Use of Nortriptyline (FDA approved)

Patient selection	Appropriate as a second-line pharmacotherapy for smoking cessation.
Precautions	<p><i>Pregnancy:</i> Pregnant smokers should be encouraged to quit first without pharmacologic treatment. Nortriptyline should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of nortriptyline, potential concomitant smoking, and first-line pharmacotherapies have not been successful. Nortriptyline has been associated with limb reduction anomalies.</p> <p><i>Adverse effects:</i> Most commonly reported adverse effects include sedation, dry mouth (64–78%), blurred vision (16%), urinary retention, lightheadedness (49%), and shaky hands (23%).</p> <p><i>Cardiovascular effects:</i> Because of risk of arrhythmias, changes in contractility, and blood flow, use with extreme caution in patients with cardiovascular disease.</p>
Dosage	Doses used in smoking cessation trials have initiated treatment at a dose of 25 mg/d, increasing gradually to a target dose of 75–100 mg/d. Duration of treatment used in smoking cessation trials has been approximately 12 weeks.
Availability	Nortriptyline HCl (generic): prescription only.
Prescribing instructions	<p>Therapy is initiated 10–28 days before the quit date to allow nortriptyline to reach steady state at the target dose.</p> <p><i>Activities:</i> Use may produce sedation, a hazard while driving or operating machinery.</p> <p>Overdose may produce marked cardiotoxic effects. Risk of overdose should be considered carefully in using nortriptyline.</p>
Cost/day*	\$0.74 for 75 mg

*Cost data is based on the retail price of the medication purchased at a national chain pharmacy located in Madison, Wisconsin, April 2000.

FDA = United States Food and Drug Administration. NRT = nicotine replacement therapy.

One overriding issue relevant to all tobacco users considering a quit attempt is to ensure that all textual materials used (eg, self-help brochures) are at an appropriate reading level. This is particularly important given epidemiological data showing that tobacco use rates are markedly higher among individuals of lower educational attainment.¹⁴⁹

Gender

Recommendation: The same smoking cessation treatments are effective for both men and women. Therefore, except in the case of the pregnant smoker, the

Table 40. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Over-the-Counter Nicotine Patch Therapy ($n = 3$ studies)

OTC Therapy	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
Placebo	3	1.0	6.7
Over-the-counter nicotine patch therapy	3	1.8 (1.2, 2.8)	11.8 (7.5, 16.0)

OTC = over-the-counter. CI = confidence interval.

Table 41. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Augmented Interventions with Pregnant Smokers ($n = 7$ studies)

Pregnant Smokers	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
Usual care	7	1.0	6.6
Augmented intervention	8	2.8 (2.2, 3.7)	16.8 (13.1, 20.5)

CI = confidence interval

same interventions can be used with both men and women. (Strength of Evidence = B)

One important question regarding quitting smoking is whether men and women should receive different cessation interventions. Smoking cessation clinical trials reveal that the same treatments benefit both men and women;^{140,150} however, research suggests that some treatments are less efficacious in women than in men (eg, NRTs).^{151,152}

Although research suggests that women benefit from the same interventions as do men, women may face different stressors and barriers to quitting that may be addressed in treatment. These include greater likelihood of depression, greater weight control concerns, hormonal cycles, and others.¹⁵³ This suggests that women may benefit from tobacco dependence treatments that address these topics, although few studies have examined programs targeted to one gender. Finally, women who are considering becoming pregnant may be especially receptive to tobacco dependence treatment.

Future Research. The following topics regarding gender require additional research:

- The efficacy of interventions that are targeted to specific genders.
- The impact of gender-specific motives that may increase quit attempts and success (eg, quitting to improve fertility and reproductive health, erectile dysfunction, pregnancy outcomes, physical appearance, and osteoporosis).
- Gender differences in efficacy of tobacco dependence treatments found to be effective in this guideline.

Pregnancy

Recommendation: Because of the serious risks of smoking to the pregnant smoker and the fetus, whenever possible pregnant smokers should be offered extended or augmented psychosocial interventions that exceed minimal advice to quit. (Strength of Evidence = A)

Recommendation: Although abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in preg-

nancy can yield benefits. Therefore, clinicians should offer effective smoking cessation interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy. (Strength of Evidence = B)

Recommendation: Pharmacotherapy should be considered when a pregnant woman is otherwise unable to quit, and when the likelihood of quitting, with its potential benefits, outweighs the risks of the pharmacotherapy and potential continued smoking. (Strength of Evidence = C)

The selection criteria for the pregnancy meta-analysis were adjusted to reflect this unique population. Abstinence data were included only if they were biochemically confirmed, because of reports of high levels of deception regarding smoking status among pregnant women.^{154–156} Studies that had follow-up time points of less than 5 months were included because of the desire for preparturition data. For the meta-analysis, either minimal interventions (< 3 min) or interventions labeled as “usual care” constituted the reference condition. Seven studies met the criteria and were included in the analysis comparing augmented smoking cessation interventions with usual care in pregnant women. A “usual care” intervention with pregnant smokers typically consists of a recommendation to stop smoking, often supplemented by provision of self-help material or referral to a stop-smoking program. Extended or augmented psychosocial interventions typically involve these treatment components as well as more intensive counseling than minimal advice. As can be seen from the data in Table 41, extended or augmented interventions are significantly more efficacious than usual care in pregnant women.

Components of some extended or augmented psychosocial interventions are listed in Table 42. These interventions were selected from articles included in the Table 41 meta-analysis and should guide the clinician treating the pregnant smoker.

Smoking in pregnancy imparts risks to both the woman and the fetus. Cigarette smoking by pregnant women has been shown to cause adverse fetal outcomes, including stillbirth, spontaneous abortion, decreased fetal growth, premature birth, low birthweight, placental abruption, sud-

Table 42. Examples of Effective Interventions with Pregnant Patients

Ershoff et al (1989) ¹⁵⁴	Brief health educator discussion of risks (3–5 min); advised of a free smoking cessation class; and pregnancy-specific self-help materials mailed weekly for 7 weeks.
Walsh et al (1997) ¹⁵⁵	Physician advice regarding risks (2–3 min); videotape with information on risks, barriers, and tips for quitting; midwife counseling in one 10-minute session; self-help manual; and follow-up letters.
Windsor et al (1985) ¹⁵⁶	Pregnancy-specific self-help materials (Pregnant Woman's Self-Help Guide To Quit Smoking) and one 10-minute counseling session with a health educator.
Windsor et al (1993) ³⁷	Cessation skills and risk counseling in one 15-minute session by a health counselor; education on how to use pregnancy-specific self-help materials (same materials as in Windsor et al, 1985 ¹⁵⁶); a follow-up medical letter; and social support with a buddy letter, a buddy contract, and a buddy tip sheet.

den infant death syndrome, cleft palate and cleft lip, and childhood cancer. 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.¹⁵⁷

The first step in intervention is assessment of tobacco use status. This is especially important in a population with reported high rates of deception. Research has shown that the use of multiple choice questions (see Table 43), as opposed to a simple yes/no question can increase disclosure among pregnant women by as much as 40%.¹⁵⁸

Quitting smoking prior to conception or early in the pregnancy is most beneficial, but health benefits result from abstinence at any time. Therefore, a pregnant smoker should receive encouragement and assistance in quitting throughout her pregnancy.

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.^{159,160} Postpartum relapse may be decreased by continued emphasis on the relationship between maternal smoking and poor health outcomes in infants and children (sudden infant death syndrome, respiratory infections, asthma, and middle ear disease).^{159–162} Preventing postpartum relapse is, however, an area that would benefit from future research. Table 43 outlines clinical factors to address when counseling pregnant women about smoking.

For pregnant smokers who are unable to quit with the help of an augmented intervention (see Table 42), clini-

cians may consider additional or alternative psychosocial treatments such as those described in Chapter 4. The exception to this would be the use of rapid smoking, which can result in extremely high blood nicotine levels.

Clinicians may choose to consider pharmacotherapy for pregnant smokers who have been unable to quit using psychosocial interventions. In such cases, the clinician and pregnant smoker must contrast the risks and unknown efficacy of pharmacotherapy in pregnant women with the substantial risks of continued smoking. Although smoking during pregnancy clearly leads to substantial risks for both the pregnant smoker and the fetus, the clinician and patient also must be aware of potential risks of different pharmacotherapies. For example, a number of studies have shown that nicotine itself presents risks to the fetus, including neurotoxicity,¹⁶³ and bupropion SR has been shown to cause seizures in 1 out of 1,000 patients.¹⁶⁴

If the clinician and pregnant or lactating patient decide to use NRT pharmacotherapy, the clinician should consider monitoring blood nicotine levels to assess level of drug delivery. In addition, the clinician should consider using medication doses that are at the low end of the effective dose range, and consider choosing delivery systems that yield intermittent, rather than continuous, drug exposure (eg, nicotine gum rather than the nicotine patch). Because none of these medications has been tested in pregnant women for efficacy in treating tobacco dependence, the relative ratio of risks to benefits is unclear. Additionally, since small amounts of these medications are passed through breast milk, they may pose some risks for nursing infants.

Future Research. The following topics regarding smoking and pregnancy require additional research:

- Relapse prevention with pregnant women and women who have recently given birth.
- The efficacy of relapse prevention programs for spontaneous “self-quitters.”
- The most efficacious amount of contact time, number of sessions, and duration for smoking cessation interventions with pregnant women.
- The efficacy of various counseling and behavioral therapies and motivational interventions (eg, physiologic feedback of adverse impacts, quitting benefits).
- Efficacious treatments for highly dependent smokers.
- The safety and efficacy of tobacco dependence pharmacotherapy during pregnancy to the woman and the fetus, including the relative risks and benefits of pharmacotherapy use as a function of dependence and the appropriate formulation and timing of pharmacotherapy
- The safety and efficacy of tobacco dependence pharmacotherapy to the woman and child during nursing.
- The efficacy of targeted or individualized interventions in pregnancy.

Table 43. Clinical Practice When Assisting a Pregnant Patient in Smoking Cessation

Clinical Practice	Rationale
Assess pregnant woman's tobacco use status using a multiple-choice question to improve disclosure.	Many pregnant women deny smoking, and the multiple-choice question format improves disclosure. For example: Which of the following statements best describes your cigarette smoking? <ul style="list-style-type: none"> • I smoke regularly now—about the same as before finding out I was pregnant. • I smoke regularly now, but I've cut down since I found out I was pregnant. • I smoke every once in a while. • I have quit smoking since finding out I was pregnant. • I wasn't smoking around the time I found out I was pregnant, and I don't currently smoke cigarettes.
Congratulate those smokers who have quit on their own.	To encourage continued abstinence.
Motivate quit attempts by providing educational messages about the impact of smoking on both the woman's and the fetus' health.	These are associated with higher quit rates.
Give clear, strong advice to quit as soon as possible.	Quitting early in pregnancy provides the greatest benefit to the fetus.
Suggest the use of problem-solving methods and provide social support and pregnancy-specific self-help materials.	Reinforces pregnancy-specific benefits and ways to achieve cessation.
Arrange for follow-up assessments throughout pregnancy, including further encouragement of cessation.	The woman and her fetus will benefit even when quitting occurs late in pregnancy.
In the early postpartum period, assess for relapse and use relapse prevention strategies recognizing that patients may minimize or deny tobacco use.	Postpartum relapse rates are high even if a woman maintains abstinence throughout pregnancy. Relapse prevention may start during pregnancy (see Chapter 3C, Brief Strategies C1 and C2).

- Strategies for linking preconception, pregnancy, and postpartum (including pediatric) interventions.

Racial and Ethnic Minorities

Recommendation: Smoking cessation treatments have been shown to be effective across different racial and ethnic minorities. Therefore, members of racial and ethnic minorities should be provided treatments shown to be effective in this guideline. (Strength of Evidence = A)

Recommendation: Whenever possible, tobacco dependence treatments should be modified or tailored to be appropriate for the ethnic or racial populations with which they are used. (Strength of Evidence = C)

Ethnic and racial minority groups in the United States—African Americans, American Indians/Alaska Natives, Asians and Pacific Islanders, Hispanics—experience higher mortality in a number of disease categories, compared with others. For example, African Americans experience substantial excess mortality from cancer, cardiovascular disease, and infant death, all of which are directly affected by tobacco use.^{165,166} American Indian/Alaska Native subgroups have some of the highest documented rates of infant mortality caused by sudden infant death syndrome,¹⁶⁷ which also is affected by tobacco use. Therefore, there is a critical need to deliver effective tobacco

dependence interventions to ethnic and racial minorities. Unfortunately, there is evidence that large proportions of some racial/ethnic groups lack adequate access to primary care providers.¹⁶⁶ This suggests that special efforts and resources should be provided to meet the treatment needs of these populations.

There are well-documented differences between racial and ethnic minorities and whites in smoking prevalence, smoking patterns, and quitting behavior in the United States.^{166,168,169} In addition, smoking prevalence and patterns vary substantially among minority subgroups.^{166,167} Racial and ethnic minority groups also differ from whites in awareness of the health effects of smoking¹⁷⁰ and report a sense of fatalism that may affect disease prevention efforts. On the other hand, both tobacco dependence and desire to quit appear to be prevalent across all racial and ethnic groups.^{166,168,169,171}

Studies have demonstrated the efficacy of a variety of smoking cessation interventions in minority populations. Nicotine patch,¹⁷² clinician advice,^{173,174} counseling,¹⁷⁵ tailored self-help manuals and materials, and telephone counseling^{173,176} have been shown to be effective with African Americans. Nicotine patch¹⁷⁷ and self-help materials, including a mood management component,¹⁷⁸ have been shown to be effective with Hispanic smokers. Screening for tobacco use, clinician advice, clinic staff reinforce-

ment, and follow-up materials have been shown to be effective for American Indian populations.¹⁷⁹

Few studies have examined interventions specifically designed for particular ethnic or racial groups, and there is no consistent evidence that targeted cessation programs result in higher quit rates in these groups than do generic interventions of comparable intensity.¹⁷⁶ Moreover, smoking cessation interventions developed for the general population have been effective with racial and ethnic minority participants. Therefore, clinicians should offer treatments identified as effective in this guideline to their patients from all racial and ethnic groups. It is essential, however, that cessation counseling or self-help materials be conveyed in a language understood by the smoker. Additionally, culturally appropriate models or examples may increase the smoker's acceptance of treatment. Clinicians should remain sensitive to individual differences and health beliefs that may affect treatment acceptance and success in all populations (see section in Chapter 6A, Specialized Assessment).

Future Research. The following topics regarding racial and ethnic minorities require additional research:

- The efficacy of targeted versus generic interventions for different racial and ethnic minority populations.
- The identification of the specific barriers or impediments to treatment or treatment success (eg, socioeconomic status, inadequate access to medical care), and the differential health effects related to smoking patterns for racial and ethnic minorities.
- Motivators of cessation that are especially effective with members of racial and ethnic minorities (eg, fear of illness requiring long-term care and disability).

Hospitalized Smokers

Recommendation: Smoking cessation treatments have been shown to be effective for hospitalized patients. Therefore, hospitalized patients should be provided smoking cessation treatments shown to be effective in this guideline. (Strength of Evidence = B)

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 postdischarge counseling telephone calls. As can be seen from the data in Table 44,

Table 44. Meta-Analysis: Efficacy of and Estimated Abstinence Rates for Augmented Interventions with Hospitalized Smokers (*n* = 4 studies)

Hospitalized Smokers	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
Usual care	4	1.0	19.2
Augmented intervention	6	1.3 (1.04, 1.6)	23.3 (19.5, 27.1)

CI = confidence interval

Table 45. Suggested Interventions for Hospitalized Patients

For every hospitalized patient, the following steps should be taken:

- Ask each patient on admission if he or she uses tobacco and document tobacco use status.
- For current tobacco users, list tobacco use status on the admission problem list and as a discharge diagnosis.
- Use counseling and pharmacotherapy to assist all tobacco users to maintain abstinence and to treat withdrawal symptoms.
- Provide advice and assistance on how to quit during hospitalization and remain abstinent after discharge.

augmented smoking cessation interventions among hospitalized patients increase rates of smoking abstinence

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.^{16,180} Lung, head, and neck cancer patients who are successfully treated, but who continue to smoke, are at elevated risk for a second cancer.¹⁸¹⁻¹⁸⁵ Additionally, smoking negatively affects bone and wound healing.¹⁸⁶⁻¹⁸⁸

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 smoking, highlighting the patient's personal vulnerability to the health risks of smoking. 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. As a result, every hospitalized smoker is temporarily housed in a smoke-free environment. For these reasons, clinicians should use hospitalization as an opportunity to promote smoking cessation in their patients who smoke.^{189,190} 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 Table 45.

Future Research. The following topics regarding hospitalized patients require additional research:

- The efficacy of interventions provided by different hospital personnel, including nurses.
- The efficacy of pharmacotherapy with hospitalized patients.
- Relapse prevention once the patient leaves the hospital.

Smokers With Psychiatric Comorbidity and/or Chemical Dependence

Recommendation: Smokers with comorbid psychiatric conditions should be provided smoking cessation treatments identified as effective in this guideline. (Strength of Evidence = C)

Recommendation: Bupropion SR and nortriptyline, efficacious treatments for smoking cessation in the general population, also are effective in treating depression. Therefore, bupropion SR and nortriptyline should be especially considered for the treatment of tobacco dependence in smokers with current or past history of depression. (Strength of Evidence = C)

Recommendation: Evidence indicates that smoking cessation interventions do not interfere with recovery from chemical dependence. Therefore, smokers receiving treatment for chemical dependence should be provided smoking cessation treatments shown to be effective in this guideline, including both counseling and pharmacotherapy (Strength of Evidence = C)

The term "psychiatric comorbidity" refers to the co-occurrence of smoking with another 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 smokers for several reasons:

- Psychiatric disorders are more common among smokers than in the general population. For instance, as many as 30% of patients seeking smoking cessation services may have a history of depression,¹²¹ and 20% or more may have a history of alcohol abuse or dependence.¹⁹¹⁻¹⁹⁵ Among abusers of alcohol and drugs, smoking occurs at rates well above population average (eg, greater than 70%).¹⁹⁶⁻¹⁹⁸ 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.¹⁹⁹⁻²⁰²
- As noted in the Specialized Assessment section in Chapter 6A, smokers with psychiatric comorbidities have heightened risk for relapse to smoking after a cessation attempt.^{88,191,195,202}

Although psychiatric comorbidity places smokers at increased risk for relapse, such smokers can be helped by smoking cessation treatments.^{195,203-207} Currently, there is insufficient evidence to determine whether smokers with psychiatric comorbidity benefit more from specialized or tailored cessation treatments than from standard treatments.^{102,208} 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 (eg, little increase in aggression).²⁰⁹⁻²¹¹ Finally, stopping smoking may affect the pharmacokinetics of certain psychiatric medications.²¹² Therefore, clinicians may wish to monitor closely the actions or side effects of psychiatric medications in smokers making a quit attempt.

Evidence shows that bupropion SR is efficacious for both depression and smoking cessation. Therefore, it appears to be an appropriate medication to use with depressed smokers trying to quit. Nortriptyline is also efficacious for both depression and smoking cessation, but its adverse effect profile renders it a second-line medication.

The treatment of tobacco dependence can be provided concurrent to treating patients for other chemical dependencies (alcohol and other drugs). With patients in treatment for chemical dependence, there is little evidence that patients with other chemical dependencies relapse to other drug use when they stop smoking.^{209,213,214} However, such patients should be followed closely after they stop smoking.

Future Research. The following topics regarding psychiatric comorbidity and/or chemical dependence require additional research:

- The relative efficacy of bupropion SR and nortriptyline versus NRT in patients with psychiatric comorbidity, including depression.
- The efficacy and impact of tobacco dependence treatments within the context of other chemical dependence treatments.
- The importance and efficacy of specialized assessment and tailored interventions in these populations.

Children and Adolescents

Recommendations: Clinicians should screen pediatric and adolescent patients, and their parents, for tobacco use and provide a strong message regarding the importance of totally abstaining from tobacco use. (Strength of Evidence = C)

Recommendation: Counseling and behavioral interventions shown to be effective with adults should be considered for use with children and adolescents. The content of these interventions should be modified to be developmentally appropriate. (Strength of Evidence = C)

Recommendation: When treating adolescents, clinicians may consider prescriptions for bupropion SR or NRT when there is evidence of nicotine dependence and desire to quit tobacco use. (Strength of Evidence = C)

Recommendation: Clinicians in a pediatric setting should offer smoking cessation advice and interventions to parents to limit children's exposure to second-hand smoke. (Strength of Evidence = B)

Tobacco use is a pediatric concern. In the United States, more than 6,000 children and adolescents try their first cigarette each day.⁷ More than 3,000 children and adolescents become daily smokers every day,⁸ resulting in approximately 1.23 million new smokers under the age of 18 each year.⁷ Among adults who had ever smoked daily, 89% tried their first cigarette and 71% were daily users at or before age 18.⁶³ Among high school seniors who had used smokeless tobacco, 79% had first done so by the ninth grade.^{63,215} By the time they are high school seniors, 22% of adolescents smoke daily.^{216–218} Young people experiment with or begin regular use of tobacco for a variety of reasons related to social and parental norms, advertising, peer influence, parental smoking, weight control, and curiosity.^{63,219} Nicotine dependence, however, is established rapidly even among adolescents.²²⁰ Because of the importance of primary prevention in this population, clinicians should pay particular attention to delivering these messages to their patients. Specifically, because tobacco use often begins during preadolescence²²¹ clinicians should routinely assess and intervene with this population. Prevention strategies useful in more general settings can be found in the Institute of Medicine report *Growing Up Tobacco Free*.²²²

Young people vastly underestimate the addictiveness of nicotine. Of daily adolescent smokers who think that they will not smoke in 5 years, nearly 75% are still smoking 5–6 years later.⁶³ Of the nearly three fourths of adolescents (70.2%) who have ever tried smoking, more than one third (35.8%) became daily smokers during high school. Seventy percent of adolescent smokers wish they had never started smoking in the first place.²²³ About three out of every four adolescent smokers have made at least one serious attempt to quit smoking and have failed.²²⁴

Tobacco Use Treatments in Children and Adolescents.

A recent study has shown that adolescents' smoking status was identified in 72.4% of office visits, but smoking cessation counseling was provided at only 16.9% of clinic visits of adolescent smokers.²⁰ Therefore, clinicians both need to assess adolescent tobacco use and offer cessation counseling. Clinicians also should make an effort to prepare adolescents to quit smoking. For instance, clinicians may use motivational interventions such as those listed in Chapter 3B or consider techniques adapted for use with children.⁵⁶ Also, children and adolescents may benefit from

community- and school-based intervention activities. The messages delivered by these programs should be reinforced by the clinician.⁶³

A recent comprehensive review of adolescent cessation programs in a variety of settings has concluded that such programs produce quit rates that exceed naturally occurring quit rates, but that more and higher quality research needs to be done.²²⁵

Children and adolescents also benefit from the delivery to parents of information regarding second-hand smoke exposure. A review of the studies conducted by the expert panel showed that the delivery of information to parents regarding the harms of exposing children to second-hand smoke reduces childhood exposure to second-hand smoke and may reduce parental smoking rates.^{162,226,227}

Because there is no evidence that bupropion SR or nicotine replacement is harmful for children and adolescents, clinicians may consider their use when tobacco dependence is obvious. However, because of the psychosocial and behavioral aspects of smoking in adolescents, clinicians should be confident of the patient's tobacco dependence and intention to quit before instituting pharmacotherapy. Factors such as degree of dependence, number of cigarettes per day, and body weight should be considered (see Table 4 for adult clinical recommendations).²²⁸

Future Research. The following topics regarding adolescents and children require additional research:

- The efficacy of advice and counseling.
- The efficacy of pharmacotherapy.
- The efficacy of interventions designed specifically to motivate youth to stop using tobacco.
- The efficacy of interventions designed to treat tobacco dependence in youth.
- The efficacy of child-focused versus family-focused interventions.
- The efficacy of treating parents' tobacco use in the context of pediatric visits.

Older Smokers

Recommendation: Smoking cessation treatments have been shown to be effective for older adults. Therefore, older smokers should be provided smoking cessation treatments shown to be effective in this guideline. (Strength of Evidence = A)

It is estimated that 13 million Americans ages 50 and older and 4.5 million adults over age 65 smoke cigarettes.²²⁹ Smokers over the age of 65 can both quit smoking and benefit from abstinence.^{16,230} Smoking cessation in older smokers can reduce the risk of myocardial infarction, death from coronary heart disease, and lung cancer. Moreover, abstinence can promote more rapid recovery from illnesses that are exacerbated by smoking and can improve cerebral

circulation.^{231,232} In fact, age does not appear to diminish the benefits of quitting smoking.²³¹

The smoking cessation interventions that have been shown to be effective in the general population also have been shown to be effective with older smokers. Research has demonstrated the efficacy of the "4 A's" (ask, advise, assist, and arrange follow-up) in patients ages 50 and older.²³³ Counseling interventions,^{234–236} physician advice,²³⁵ buddy support programs,²³⁷ age-tailored self-help materials,^{229,235,238} telephone counseling,^{229,238} and the nicotine patch²³⁹ have all been shown to be effective in treating tobacco use in adults ages 50 and older.

Because of particular concerns of this population (eg, mobility issues) the use of proactive telephone counseling appears particularly promising with older smokers.

Future Research. The following topics regarding older smokers require additional research:

- The efficacy of general tobacco use and dependence interventions, as well as those designed particularly for older smokers in promoting tobacco abstinence
- The efficacy of pharmacotherapy.
- Effective methods to motivate older smokers to make a quit attempt.

8. Special Topics

Background

Many additional factors that influence the efficacy of tobacco dependence interventions were considered by the panel. These include weight gain after cessation, the treatment of tobacco users other than cigarette smokers, and institutional barriers that may interfere with tobacco users receiving treatment. This chapter provides the panel's recommendations and supporting evidence on these disparate topics.

Weight Gain After Smoking Cessation

Recommendation: The clinician should acknowledge that quitting smoking is often followed by weight gain. Additionally, the clinician should: (1) note that the health risks of weight gain are small when compared to the risks of continued smoking, (2) recommend physical activities and a healthy diet to control weight, and (3) recommend that patients concentrate primarily on smoking cessation, not weight control, until ex-smokers are confident that they will not return to smoking. (Strength of Evidence = C)

Recommendation: For smokers who are greatly concerned about weight gain, it may be most appropriate to prescribe or recommend bupropion SR or NRT, in

particular nicotine gum, which have been shown to delay weight gain after quitting. (Strength of Evidence = B)

The majority of smokers who quit smoking gain weight. Most will gain fewer than 10 pounds, but there is a broad range of weight gain, with as many as 10% of quitters gaining as much as 30 pounds.^{240–242} However, weight gain that follows smoking cessation is a negligible health threat compared with the risks of continued smoking.^{242,243}

Women tend to gain slightly more weight than men do.²⁴² For both sexes, African Americans, people under age 55, and heavy smokers (those smoking more than 25 cigarettes/d) are at elevated risk for major weight gain.^{240,242,244–248}

For some smokers, especially women, concerns about weight or fears about weight gain are motivators to start smoking or continue smoking.^{249–252} Adolescents, even as young as junior high age, who are concerned about their weight initiate smoking more often than do other adolescents.^{253–256}

Concern about weight varies substantially by ethnicity. For example, adolescent African American females are much less likely to report that they smoke to control weight than are European Americans.²⁵⁷ This is an important area for further study, as little tobacco research focuses on women of minority ethnicities.²⁵⁷

Some evidence suggests that attempts to prevent weight gain (eg, strict dieting) may undermine the attempt to quit smoking.^{258–260} Other evidence suggests that weight gain is reduced if smoking cessation is accompanied by a moderate increase in physical activity.²⁶¹ 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.¹⁰¹

Nicotine replacement—in particular, nicotine gum—appears to be effective in delaying postcessation weight gain. Moreover, there appears to be a dose-response relation between gum use and weight suppression (ie, 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.^{246,262–265}

Bupropion SR also appears to be effective in delaying post-cessation weight gain.^{118,266,267} 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 or he had not used bupropion SR.^{118,266}

Postcessation weight gain appears to be caused both by increased intake (eg, eating and alcohol consumption) and by metabolic adjustments. The involvement of metabolic mechanisms suggests that even if smokers do not increase their caloric intake upon quitting, they will, on average, gain some weight.^{268–273} Once an individual relapses and

Table 46. Clinician Statements to Help a Patient Prepare For and Cope With Postcessation Weight Gain

Clinician statements

- "The great majority of smokers gain weight once they quit smoking. However, even without special attempts at dieting or exercise, weight gain is usually limited to 10 pounds."
- "There is evidence that smokers will gain weight once they quit smoking, even if they do not eat more. However, there are medications that will help you quit smoking and limit or delay weight gain. I can recommend one for you."
- "The amount of weight you will likely gain from quitting will be a minor health risk compared with the risks of continued smoking."
- "Try to put your concerns about weight on the back burner. You are most likely to be successful if you first try to quit smoking, and then later take steps to reduce your weight. Tackle one problem at a time! After you have quit smoking successfully, we can talk about how to reduce your weight."
- "I know weight is important to you, and that you don't want to gain a lot of weight. However, temporarily—just until you are confident that you have quit smoking for good—let's focus on strategies to get you healthy rather than on weight. Think about eating plenty of fruit and vegetables, getting regular exercise, getting enough sleep, and not eating a lot of fats. Right now, this is probably the best thing you can do for both your weight and your effort to quit smoking."
- "Although you may gain some weight after quitting smoking, compare the importance of this with the added years of healthy living you will gain, your better appearance (less wrinkled skin, whiter teeth, fresher breath), and good feelings about quitting."

begins smoking at precessation levels, he or she will usually lose some or all of the weight gained during the quit attempt.^{272,274,275}

The research evidence reviewed above illustrates why concerns about weight gain are barriers to smoking abstinence. Many smokers (especially women) are concerned about their weight and fear that quitting will produce weight gain. Many also believe that they can do little to prevent postcessation weight except to return to smoking. These beliefs are especially difficult to address clinically because they are congruent with research findings; that is, the beliefs have some basis in fact.

Recommendations to Clinicians When Addressing Weight Gain. How should the clinician deal with concerns about weight gain? First, the clinician should neither deny the likelihood of weight gain nor minimize its significance to the patient. Rather, the clinician should inform the patient about the likelihood of weight gain and prepare the patient for its occurrence. However, the clinician should counter exaggerated fears about weight gain given the relatively moderate weight gain that typically occurs. Certain types of information may help prepare the patient for postcessation weight gain (see Table 46). Clinicians also should inform the patient that smoking presents a much greater

health risk than the negligible health risk involved in the modest weight gain associated with smoking abstinence. Second, before and during the quit attempt the clinician should stress that quitting smoking is the patient's primary, immediate priority, and that the patient will be most successful in the long run if he or she does not take strong measures (eg, strict dieting) to counteract weight gain during a quit attempt (see Table 46).

Third, during the quit attempt, the clinician should offer to help the patient address weight gain (either personally or via referral) once the patient has successfully quit smoking. Specifically, the clinician should recommend that intensive weight control strategies be avoided until the patient is no longer experiencing withdrawal symptoms and is confident that he or she will not return to smoking. The patient should, however, be encouraged to maintain or adopt a healthy lifestyle, including engaging in moderate exercise, eating plenty of fruits and vegetables, and limiting alcohol consumption.¹⁰¹

Future Research. The following topics regarding weight gain during tobacco dependence treatment require additional research:

- The impact of weight gain concerns on women of minority ethnicities.
- The efficacy of weight control measures during quit attempts and their effect on tobacco abstinence and weight.
- The efficacy of pharmacotherapy to control weight gain during quit attempts.
- The efficacy of the use of exercise to control weight gain during a quit attempt.
- The impact of weight gain concerns on adolescent smoking.

Noncigarette Tobacco Products

Recommendation: Smokeless/spit tobacco users should be identified, strongly urged to quit, and treated with the same counseling cessation interventions recommended for smokers. (Strength of Evidence = B)

Recommendation: Clinicians delivering dental health services should provide brief interventions to all smokeless/spit (chewing tobacco and snuff) tobacco users. (Strength of Evidence = A)

Recommendation: Users of cigars, pipes, and other noncigarette combustible forms of tobacco should be identified, strongly urged to quit, and offered the same counseling interventions recommended for smokers. (Strength of Evidence = C)

Like cigarette smoking, the use of smokeless or spit tobacco, such as chewing tobacco and snuff, produces addiction to nicotine and has serious health consequences. Consumption of such smokeless tobacco products has increased in recent years,^{276–278} especially among young

males. Health risks from these products include abrasion of teeth, gingival recession, periodontal bone loss, leukoplakia, and oral cancer and cardiovascular disease.²⁷⁹⁻²⁸¹ Thus, the use of smokeless tobacco is not a safe alternative to smoking.

Cigar smoking also poses serious health risks. Cigar smokers are at higher risk for coronary heart disease, COPD, lung and other cancers, with evidence of dose-response effects.^{282,283} Cigar use is particularly concerning because cigar sales in the United States also have increased nearly 50% between 1993 and 1997.²⁸² In 1997, an estimated 6 million United States teenagers ages 14-19 (37% of males, 16% of females) smoked at least one cigar within the past year. Clinicians also should be aware of and address the use of other noncigarette tobacco products, including pipes, cigarillos, loose tobacco, bidis, and betel quid.

A close review of the literature showed that there is evidence that dental health clinicians (eg, dental hygienists) delivering brief advice to quit using smokeless/spit tobacco can increase abstinence rates.^{284,285} Although somewhat limited, there is evidence that nonpharmacologic treatments used for smoking cessation also are effective in smokeless tobacco cessation. Therefore, clinicians should offer quitting advice and assistance to their patients who use tobacco regardless of the formulation of the tobacco product. Some information may be particularly relevant in the treatment of smokeless tobacco use. For instance, a large majority of moist snuff users have identifiable oral lesions, and this information may be useful in motivating a quit attempt.

Currently, there is insufficient evidence to suggest that the use of tobacco dependence pharmacotherapies increases long-term abstinence among users of smokeless tobacco. Specifically, studies conducted with nicotine gum and the nicotine patch have shown that these two medications have not increased abstinence rates in this population.¹⁴³

Future Research. The following topics regarding noncigarette tobacco products require additional research:

- The efficacy of advice and counseling treatments to promote abstinence among users of noncigarette tobacco products.
- The efficacy of pharmacotherapy treatments to promote abstinence among users of noncigarette tobacco products.
- The efficacy of combined pharmacotherapy and counseling and behavioral therapies with users of noncigarette tobacco products.

Clinician Training

Recommendation: All clinicians and clinicians-in-training should be trained in effective strategies to assist

tobacco users willing to make a quit attempt and to motivate those unwilling to quit at this time. (Strength of Evidence = B)

The above recommendation is based on panel review of the published literature rather than a formal meta-analysis. Relevant studies focused primarily on physician training. Many of these studies examined the impact of training as it co-occurred with other systems changes such as reminder systems or staff education.^{286,287} Training appears to be more effective when coupled with these systems changes.

Clinicians must be trained in effective tobacco use treatments if guideline recommendations are to be implemented. The importance of training is clear in that clinicians report lack of relevant knowledge as a significant barrier to intervening with their patients who use tobacco.²⁸⁸⁻²⁹¹

Training should be directed at both clinicians-in-training as well as practicing clinicians. Training should be reinforced throughout the clinicians' education and practice.²⁹² For clinicians-in-training, most disciplines neither provide training nor require competency in tobacco use interventions. For example, an NCI expert panel found that medical schools do not consistently train students in effective smoking cessation interventions.²⁹³ That panel recommended that a specific curriculum devoted to tobacco dependence treatment be included as part of each medical student's education. This curriculum may be taught as part of a preventive medicine or substance abuse course or as a class by itself. Similar recommendations would be relevant to virtually all other clinical disciplines. More recently, a survey of United States medical schools found that most medical schools (69%) did not require clinical training in tobacco dependence treatment.²⁸⁹ Training in tobacco use interventions should not only transmit essential treatment skills but also inculcate the belief that cessation treatment is a standard of good practice.²⁹⁴

Practicing clinicians also would benefit from continuing education that addresses tobacco dependence treatment. This guideline recommends that clinicians be reimbursed for treating tobacco dependence and that their intervention activities be tracked. Either of these policies should foster increased interest in establishing expertise in treating tobacco use among practicing clinicians.

Several factors would promote the training of clinicians in tobacco intervention activities:²⁹³

- Inclusion of education and training in tobacco dependence treatments in the required curricula of all clinical disciplines.
- Inclusion of questions on effective tobacco dependence treatment in licensing and certification exams for all clinical disciplines.
- Adoption by specialty societies of a uniform standard of competence in tobacco dependence treatment for all members.

Finally, clinicians who currently use any tobacco product should participate in treatment programs to stop their own tobacco use permanently. Clinicians have an important role as models for their patients. Therefore, it is heartening that many types of clinicians have dramatically decreased their tobacco use over the past 20 years. In a report on tobacco-use prevalence by occupation, the rate of smoking was noted to be 5.5% among physicians, 7.4% among dentists, 8.7% among physical therapists, and 22.0% among registered nurses.²⁹⁵ All of these prevalence rates are lower than tobacco-use rates in the general population.

Future Research. The following topics regarding clinician training require additional research:

- The efficacy of training programs for other health disciplines such as nursing, psychology, dentistry (including hygienists), social work, and pharmacy.
- The effective elements in successful training programs (eg, continuing medical education, interactive components).
- The efficacy of systems changes, such as reminder systems (and performance feedback), when implemented with training programs.

Economic Aspects of Tobacco Dependence Treatments and Health Systems Interventions

Recommendation: The smoking cessation treatments shown to be efficacious in this guideline (both pharmacotherapy and counseling) are highly cost-effective relative to other reimbursed treatments (eg, treatment of hyperlipidemia and mammography screening) and should be provided to all smokers. (Strength of Evidence = A)

Recommendation: Intensive smoking cessation interventions are especially efficacious and cost-effective, and smokers should have ready access to these services as well as to less intensive interventions. (Strength of Evidence = B)

Recommendation: Smoking cessation treatments (both pharmacotherapy and counseling) should be included as a paid or covered benefit by health benefits plans because doing so improves utilization and overall abstinence rates. (Strength of Evidence = B)

Recommendation: Sufficient resources should be allocated for clinician reimbursement and systems support to ensure the delivery of efficacious tobacco use treatments. (Strength of Evidence = C)

Recommendation: Provision of guideline-based interventions to treat tobacco use and addiction should be included in standard ratings and measures of over-

all health care quality (eg, National Committee for Quality Assurance's Health Plan Employer Data and Information Set [NCQA HEDIS], the Foundation for Accountability [FACCT]). (Strength of Evidence = C)

Smoking cessation treatments ranging from brief clinician advice to specialist-delivered intensive programs, including pharmacotherapy, are not only clinically effective, but also they are extremely cost-effective relative to other commonly used disease prevention interventions and medical treatments. Cost-effectiveness analyses have shown that smoking cessation treatment compares quite favorably with routinely reimbursed medical interventions such as the treatment of hypertension and hypercholesterolemia, as well as with preventive screening interventions such as periodic mammography or Papanicolaou smears.^{28,71,75-77,296-298} Treating tobacco dependence is particularly important economically in that it can prevent a variety of costly chronic diseases, including heart disease, cancer, and pulmonary disease. In fact, smoking cessation treatment has been referred to as the "gold standard" of preventive interventions.⁷⁸

It is important to note that smoking cessation is also cost-effective in special populations such as hospitalized patients and pregnant women. For hospitalized patients, successful tobacco abstinence not only reduces general medical costs in the short-term, but also reduces the number of future hospitalizations.¹⁶ Smoking cessation interventions for pregnant women are especially cost-effective because they result in fewer low-birthweight babies and perinatal deaths, fewer physical, cognitive, and behavioral problems during infancy and childhood, and also yield important health benefits for the mother.^{299,300}

Although data suggest that, among clinical interventions, intensive interventions are more cost-effective than low-intensity interventions,⁶⁴ widely disseminated public health interventions may have even greater cost-effectiveness.³⁰¹

The failure of a health plan to cover tobacco dependence treatment as an insured benefit could reduce access to these services and reduce the number of people seeking these services. It has been found that when smoking cessation services are provided as a fully covered benefit by a health plan in contrast to a health plan that required a significant co-pay, the overall utilization of cessation treatment increases and smoking prevalence within the health plan will decrease.⁶⁶ Moreover, the presence of prepaid or discounted prescription drug benefits increases patients' receipt of pharmacotherapy and smoking abstinence rates.^{136,302,303}

Primary care clinicians frequently cite insufficient insurance reimbursement as a barrier to the provision of preventive services such as smoking cessation treatment.³⁰⁴ An 8-year insurance industry study found that reimbursing

physicians for provision of preventive care resulted in reported increases in exercise, seat belt use, and weight loss, as well as decreased alcohol use and a trend toward decreased smoking.³⁰⁵

It may be in the best interests of insurance companies, managed care organizations, and governmental bodies within a specific geographic area to work collectively to ensure that tobacco dependence interventions are a covered benefit. This also would allow the financial benefits of these services to be realized by all the health plans within a community.

The provision of tobacco dependence treatment should be increased by: (1) attention to health plan "report cards" (eg, NCQA HEDIS),^{306,307} which support smoker identification and treatment, and (2) accreditation criteria used by the Joint Commission on Accreditation of Health Care Organizations and other accrediting bodies, which include the presence of effective tobacco assessment and intervention policies.

Future Research. The following topics regarding cost-effectiveness and health systems require additional research:

- To what extent are the various tobacco dependence treatments cost-effective, both short and long term?
- What is the best way to remove systemic barriers that prevent clinicians from effectively delivering tobacco dependence treatments?
- What are the best systemic interventions to encourage provider and patient utilization of effective tobacco dependence treatments?
- Whether reimbursement for tobacco dependence treatment is recovered later in reduced health care costs.
- Evaluation of the relative costs and economic impacts of different formats of efficacious treatments (eg, proactive telephone counseling, face-to-face contact, pharmacotherapy).

Alternative Treatment Goals: Harm Reduction

There is insufficient evidence to support a recommendation regarding harm reduction interventions. In harm reduction strategies, tobacco users alter, rather than eliminate, their use of nicotine or tobacco to reduce or avoid its harmful consequences. Many harm reduction strategies have been proposed such as reduced use of tobacco (perhaps with the conjoint use of pharmacotherapy), use of less hazardous tobacco/nicotine products, or use of less addictive tobacco/nicotine products.³⁰⁸ It is difficult to evaluate the potential benefits of harm reduction strategies because of a lack of published data. For instance, it is unknown whether public health would ultimately be better served by smokers' attempting to reduce or shift their tobacco use (eg, smoke fewer cigarettes) rather than by

making repeated quit attempts. It must be borne in mind that all types of tobacco use (eg, smokeless, pipe, cigar) carry significant health risks. Specifically, the use of smokeless/spit tobacco is not a safe alternative to smoking. Moreover, increased health risks have been documented even in "light" smokers (less than five cigarettes per day).³⁰⁹ Finally, evidence suggests that when smokers are forced to reduce their nicotine intake, they frequently engage in compensatory smoking (eg, taking more puffs per cigarette, taking deeper puffs).³¹⁰

In sum, it is not known whether harm reduction strategies would reduce tobacco exposure over the long-term, whether they would reduce negative health outcomes, whether their encouragement would yield greater benefits than an exclusive reliance on abstinence, and whether they might increase tobacco use prevalence by suggesting the availability of a "safe" tobacco strategy. As a result, prior to embracing any harm reduction strategy, extensive research will need to be performed on the feasibility, efficacy, and costs and benefits of these strategies. Some of the needed research includes:

- Are a significant number of smokers able to maintain smoking reduction behaviors (eg, reduced quantity) for long periods of time? What techniques promote such reductions, and what are the characteristics of those who are able to reduce and those who are unable to do so?
- What degree of compensatory smoking occurs when smokers reduce the number of cigarettes smoked or smoke low tar cigarettes when:
 - Aided by medications (eg, bupropion SR or NRT)
 - Unaided by medications
- What are the physiologic and health impacts of smoking reduction strategies (ie, reduced smoking rate or use of low tar and/or low nicotine cigarettes) when:
 - Aided by medications (eg, bupropion SR or NRT)
 - Unaided by medications
- Will a significant number of smokers use nontobacco medicines (eg, bupropion SR and/or NRT) in lieu of smoking over the long term, and will this benefit health?
- What are the public health and clinical implications of recommending a harm reduction strategy in addition to abstinence strategies (eg, a message such as "You should quit. If you can't quit, you should try to reduce.")?
- Would the forced reduction of the nicotine content of cigarettes by the tobacco companies constitute an effective societal intervention?³¹¹
- What medications are most effective in promoting reduced smoking (short and long term) without compensatory smoking?
- How effective are behavioral interventions in promoting reduced smoking (short and long term) without compensatory smoking?

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