

administrators are (1) consider making tobacco assessment, counseling, and treatment a contractual obligation of the insurers and providers that sell services; and (2) ensure that institutional changes to promote smoking cessation interventions are universally implemented.

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# Executive Summary

Smoking cessation interventions offer clinicians and health care providers their greatest opportunity to improve the current and future health of all Americans (U.S. Department of Health and Human Services [DHHS], 1989). It is essential, therefore, that clinicians, smoking cessation specialists, health care administrators, and health care purchasers take an active role in reducing the prevalence of tobacco use. One way to do this is through the support and delivery of effective smoking cessation interventions.

This guideline is a product of the Smoking Cessation Guideline Panel (the "panel"), which was charged by AHCPR to identify effective, experimentally validated smoking cessation treatments and practices. Through a systematic and exhaustive review and analysis of the available scientific research literature, the panel developed practice recommendations that address three principal audiences: the broad range of primary care clinicians, for whom smoking cessation is just one of many clinical activities; smoking cessation specialists, for whom smoking cessation treatment is a major professional activity; and health care administrators/insurers/purchasers. The last group can influence smoking cessation by supporting the implementation and reimbursement of effective cessation activities.

Major findings and recommendations of this guideline can be summarized in six points:

1. Effective smoking cessation treatments are available, and every patient who smokes should be offered one or more of these treatments.
2. It is essential that clinicians determine and document the tobacco-use status of every patient treated in a health care setting.
3. Brief cessation treatments are effective, and at least a minimal intervention should be provided to every patient who uses tobacco.
4. A dose-response relation exists between the intensity and duration of a treatment and its effectiveness. In general, the more intense the treatment, the more effective it is in producing long-term abstinence from tobacco.
5. Three treatment elements, in particular, are effective, and one or more of these elements should be included in smoking cessation treatment:
  - Nicotine replacement therapy (nicotine patches or gum)
  - Social support (clinician-provided encouragement and assistance)

- Skills training/problem solving (techniques on achieving and maintaining abstinence)
6. Effective reduction of tobacco use requires that health care systems make institutional changes that result in systematic identification of, and intervention with, all tobacco users at every visit.

The vast majority of data available to the panel came from studies of interventions with smokers. Therefore, in most sections of the guideline, the panel specifically refers to “smoking” or “smoking cessation.” However, panel consensus is that many, if not all, recommendations in this guideline pertain to assessment and treatment of all tobacco users. Therefore, the panel encourages clinicians and other individuals providing cessation services to use these recommendations to guide their treatment of smokeless tobacco users as well as cigar and pipe users.

The six major findings listed above should be important for all three professional target audiences. However, some findings have special relevance to certain audiences, and Chapter 2 of this guideline distills findings for the three audiences. For instance, the smoking cessation specialist is directed to the section entitled Tobacco Cessation Specialists and Programs, where findings regarding the effective constituents of intensive cessation treatments are summarized.

Many guideline findings are highly relevant to primary care and other clinicians. One important finding for this audience is that virtually all types of clinicians—physicians, nurses, nurse practitioners, dentists, psychologists, pharmacists, respiratory and physical therapists, physician assistants, and many others—can effectively deliver tobacco cessation treatments (Cohen, Stookey, Katz, et al., 1989; Dix Smith, McGhan, Lauger, 1995; Hall, Tunstall, Rugg, et al., 1985; Hollis, Lichtenstein, Vogt, et al., 1993; National Heart, Lung, and Blood Institute, 1991; Ockene, Kristeller, Goldberg, et al., 1991; Wewers, Bowen, Stanislaw, et al., 1994). Also emphasized is the fact that very brief treatments, such as firm advice to quit smoking, can effectively boost long-term cessation. In addition, clinicians are offered a series of specific steps to follow to intervene effectively with their patients who use tobacco (see the first section in Chapter 2, Primary Care Clinicians).

The attention of health care administrators/insurers/purchasers is directed to the third section of Chapter 2, which highlights the importance of institutional changes that ensure that health care systems identify and intervene with every patient who uses tobacco. This unique emphasis reflects panel recognition of the increasing role of managed care in health care delivery. This recognition requires the guideline to move beyond a traditional focus on the clinician and to address the potential of health care delivery organizations to ensure that tobacco users are reliably identified and treated.

The most significant message of this guideline has great relevance to anyone concerned with health care. This guideline challenges clinicians and others to change the nature of clinical practice to address universally and systematically the leading preventable cause of illness and death in our society (DHHS, 1988; 1989).

Tobacco use has an enormous impact on health in the United States. Approximately 25 percent of adult Americans smoke cigarettes, yet smokers enter and exit the health care system each day without receiving treatment for this important health risk. Clinicians have unique access to individuals who use tobacco—more than 70 percent of smoking Americans visit a clinician each year. Yet half of these individuals report having never been urged to quit by a clinician, and more than 70 percent now say they want to quit and have made at least one unsuccessful prior quit attempt. American clinicians are missing a unique opportunity to help their patients who use tobacco. This guideline offers a simple and flexible set of strategies that ensure that all patients who use tobacco are offered motivational interventions and effective treatments to overcome this powerful addiction.



# 1 Overview

## Rationale for Guideline Development

The Agency for Health Care Policy and Research (AHCPR) convenes expert panels to develop clinical guidelines for health care practitioners. AHCPR determines the need for guidelines for a given condition based on several factors, including prevalence, related morbidity and mortality, economic burden imposed by the condition, variation in clinical practice related to the condition, availability of methods for improvement of care, and availability of data on which to base recommendations for care.

Tobacco use has been cited as the chief avoidable cause of illness and death in our society, responsible for more than 400,000 deaths in the United States each year. Smoking is a known cause of cancer, heart disease, stroke, and chronic obstructive pulmonary disease (Centers for Disease Control [CDC], 1993a). Tobacco use is surprisingly prevalent, given the health dangers it presents and the public's awareness of those dangers (DHHS, 1989). Recent estimates are that 25 percent of Americans smoke (CDC, 1994). Moreover, smoking prevalence among adolescents appears to be rising, with more than 3,000 children and adolescents becoming regular users of tobacco each day. This ensures that a new generation of Americans will be addicted to nicotine and at risk for the host of harmful consequences of tobacco use. Tobacco use is not only dangerous to individuals, it yields staggering societal costs as well. The estimated smoking-attributable cost for medical care in 1993 is \$50 billion, and the cost of lost productivity and forfeited earnings due to smoking-related disability is estimated at \$47 billion per year (Herdman, Hewitt, and Laschober, 1993).

Despite the tragic health consequences of smoking, physicians and other health care clinicians often fail to assess and treat tobacco use consistently and effectively. For instance, only half of smokers seeing a primary care physician in the past year report being asked about their smoking (Robinson, Laurent, and Little, 1995), and only a minority of smokers report being advised to quit (CDC, 1993b). This failure to assess and intervene exists in the face of substantial evidence that even brief smoking cessation treatments can be effective (e.g., Fiore, Smith, Jorenby, et al., 1994, Glynn and Manley, 1990; Russell, Wilson, Taylor, et al., 1979).

The evidence reviewed above suggests 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, preventive interventions. The last point is buttressed by overwhelming evidence that smoking cessation interventions, if delivered in a timely and effective manner, greatly reduce the smoker's risk of suffering from smoking-related disease (DHHS, 1990). Indeed, it is difficult to

identify a condition in developed countries that presents such a mix of lethality, prevalence, and neglect, despite effective and readily available interventions.

Clinicians know that tobacco use is a serious health problem. But 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. Clinicians may fail to intervene because they are unaware of the availability of efficacious, brief treatments that are ideal for clinical settings. Or, clinicians may fail to intervene because of inadequate clinic or institutional support for routine assessment and treatment of tobacco use.

This guideline addresses these barriers on the basis of a careful evaluation and synthesis of relevant existing scientific literatures. The guideline comprises specific evidence-based recommendations to guide clinicians and smoking cessation specialists in their tobacco intervention efforts. Additional specific recommendations guide insurers, managed care providers, and other health care administrators in their efforts to develop and implement institutional supports for reliable assessment and treatment of tobacco use. The National Cancer Institute (NCI) projects that if 100,000 physicians were to help 10 percent of their patients who smoke to stop each year, the number of smokers in the United States would drop by an additional 2 million people annually (Fiore, Pierce, Remington, et al., 1990). Even greater cessation would occur if other types of health care clinicians (e.g., nurses) would also intervene with their patients who smoke. This guideline, therefore, is a potentially powerful tool in the mission to curtail the greatest preventable cause of death and disability in the United States today.

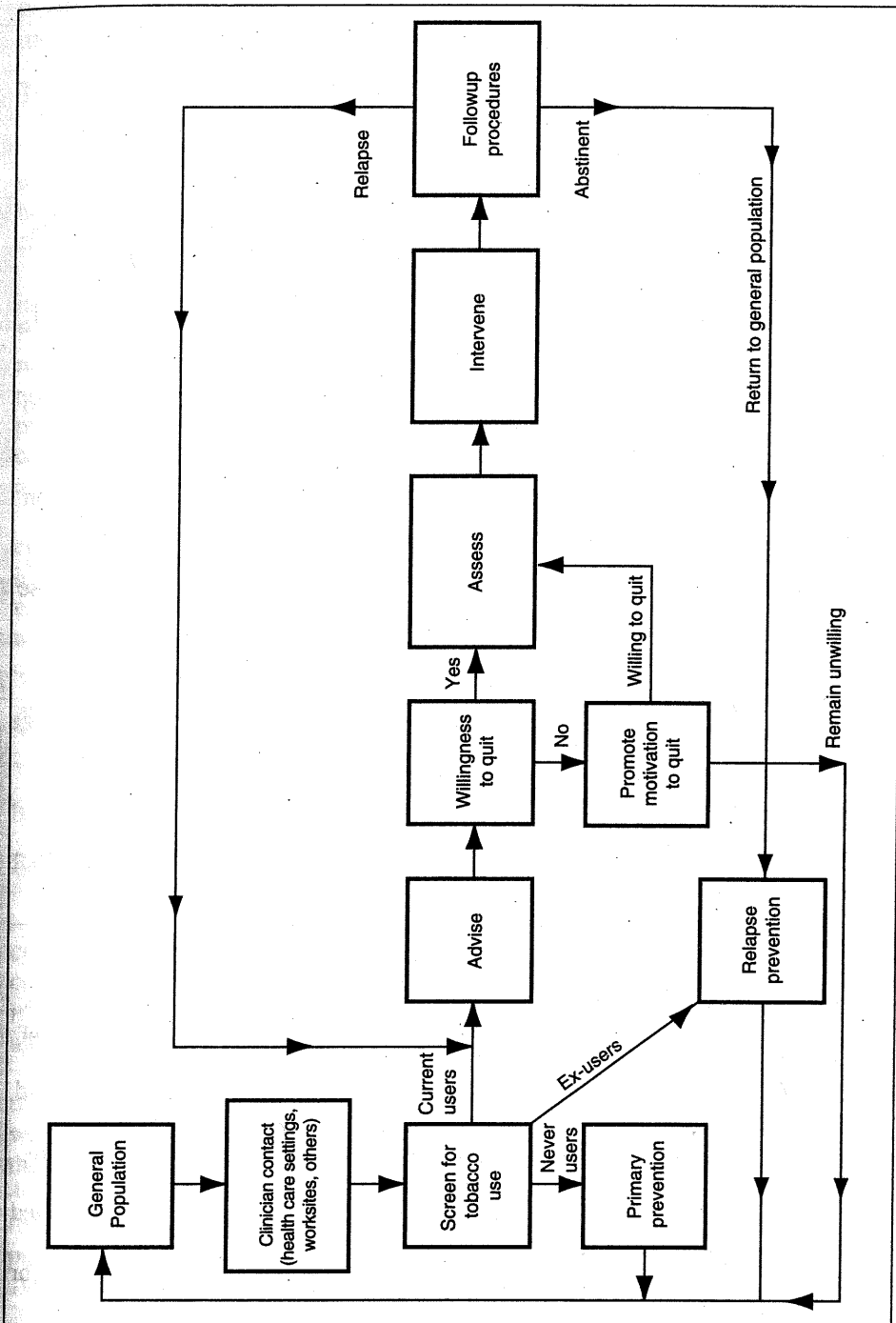
### **Organization of the Guideline and Other Products**

This guideline is divided into five chapters. Chapter 1, Overview, provides an overview and rationale for the guideline, as well as a detailed description of the methodology used to review the scientific literature and develop the guideline.

Chapter 2, Recommendations for Three Target Audiences, is directed at the three key audiences for this guideline—primary care clinicians, smoking cessation specialists, and health care delivery administrators, insurers, and purchasers. These sections are designed as stand-alone guides for implementing the relevant components of the guideline.

Chapter 3, Evidence, presents the evidentiary basis for the guideline recommendations. The sections within this chapter are organized around the Model for Tobacco Cessation Evidence (Figure 1); each section describes the scientific data that support the components of the evidence model. The section on Screen for Tobacco Use provides the scientific evidence that forms the basis for recommendations regarding the identification of tobacco users. This section corresponds to the "Screen for Tobacco Use" box in Figure 1.

Figure 1. Model for tobacco cessation evidence



The section on Advice to Quit Smoking characterizes the evidence that supports the importance of clinicians advising every tobacco user to quit. This section corresponds to the "Advise" box in Figure 1. For those smokers who are willing to make a quit attempt, the section on Specialized Assessment addresses the formal assessment of smokers prior to a cessation attempt. This section corresponds to the "Assess" box of Figure 1. The section on Interventions, the longest section of the chapter, provides the scientific evidence evaluating various characteristics and types of tobacco cessation interventions. This corresponds to the "Intervene" box of Figure 1. Finally, the evidence supporting the importance of followup interventions after a smoker has quit is described in the section on Followup Assessment and Procedures. This corresponds to the "Followup Procedures" box in Figure 1.

Chapter 4 of the guideline, Promoting the Motivation to Quit and Preventing Relapse, addresses two issues not covered in the previous chapters. The first section addresses strategies to motivate smokers not willing to make a quit attempt at this time. The second section provides recommendations to prevent relapse among individuals trying to quit.

Chapter 5, Special Populations and Topics, provides specific information on specific populations (women, racial and ethnic minorities, hospitalized patients, children and adolescents) and special topics (weight gain upon quitting, smokeless tobacco use) not otherwise addressed in the guideline. These special populations and topics are not identified in Figure 1.

In addition to this *Clinical Practice Guideline*, a larger document, the *Smoking Cessation Guideline Technical Report* (the "technical report"), contains more detailed information on the methodology employed in developing this guideline. This technical report may be obtained by contacting the National Technical Information Service. Additionally, two quick reference guides are available, as well as a consumer guide.

## **Guideline Development Methodology**

### **Introduction**

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The panel attempted, through the recommendations in the guideline, to provide clinicians with effective strategies to assist patients who use tobacco. Recommendations were influenced by two goals. The first was to be as clear as possible in identifying those treatment strategies found to be efficacious. The second was that recommendations be made in such a way that they could be implemented across diverse clinical settings and patient populations.

The guideline is based on systematic reviews of the available scientific literature. The reviews involved a comprehensive examination of literature published from 1976 through 1994. The panel identified randomized 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 almost all recommendations contained in this guideline. However, the panel occasionally made recommendations in the absence of randomized controlled

trials. It did so when faced with an important clinical practice issue for which considerable suggestive evidence existed. The panel clearly identified the level or strength of evidence that served as the basis for each of its recommendations.

### Topics Included in the Guideline

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The panel identified tobacco use as the targeted condition and all tobacco users as the clinical population of interest. All tobacco cessation interventions were examined, as well as 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 (see the Section in Chapter 5, Children and Adolescents: Primary Prevention of Tobacco Addiction) 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 recommended that primary prevention be addressed in a separate clinical practice guideline. In addition, community-level interventions (e.g., mass media campaigns) that were not directly relevant to primary care practice settings were not addressed.

This guideline was designed for three primary audiences: primary care clinicians, smoking cessation specialists, and health care administrators/insurers/purchasers. The guideline was also designed to be appropriate for use in a wide variety of practice settings including private practice, health maintenance organizations, public health department clinics, hospitals, school or work site clinics, and so on.

### Guideline Development Process

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This guideline was developed over 2 years beginning in late 1993. A distillation of the guideline development process is illustrated in Figure 2.

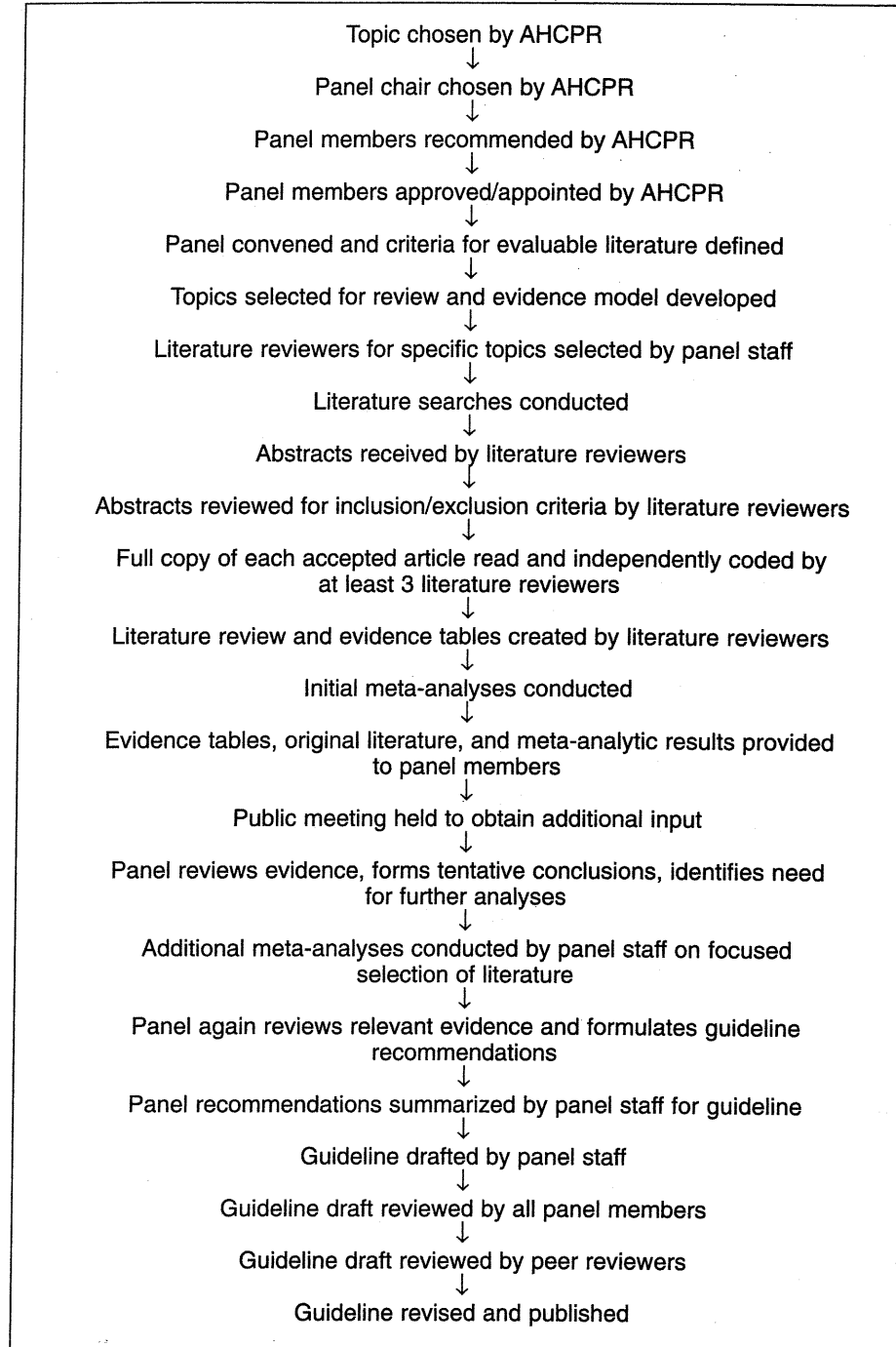
### Search and Review of the Literature

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The literature was reviewed systematically by (a) establishing a priori criteria for relevant studies, (b) reviewing abstracts and articles selected by computer searches and by scanning bibliographies, (c) compiling and reviewing the full articles, (d) compiling evidence tables summarizing these articles, and (e) conducting meta-analyses where possible.

**Inclusion Criteria.** Approximately 3,000 articles were reviewed to identify the literature appropriate for evaluation. The appropriateness of an article was determined by applying the criteria for inclusion established a priori by the panel. The criteria were that the article (a) reported the results of a randomized, controlled trial of a tobacco-use cessation intervention, (b) provided followup results at a timepoint at least 5 months after the quit date, (c) was published in a peer-reviewed journal, (d) was published between 1975 and 1994, and (e) was published in English. As a result of this review, more than 300 articles were included in our final database. A list of these references

Figure 2. Guideline development process



may be obtained by contacting AHCPR and is available for online retrieval (see Availability of Guidelines on inside back cover for more information).

When individual authors produced multiple articles meeting inclusion criteria, each article was carefully screened to ensure that it, in fact, represented an independent trial. Where two articles appeared to report data from the same group of subjects, only the most complete article was used to generate data for the analyses.

In some cases, panel conclusions were based partly on the results of previously published meta-analyses. Published meta-analyses were used when they (a) synthesized data from related sets of randomized clinical trials of smoking cessation methods, (b) were published in peer-reviewed journals, (c) were published between 1975 and 1994, and (d) were published in English.

**Selection of Evidence.** Only published, peer-reviewed randomized controlled trials were considered to provide strong evidence in support of guideline recommendations. This decision was based on the judgment that randomized controlled trials are the clearest scientific method 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.

**Preparation of Evidence Tables.** To evaluate the literature systematically, three literature reviewers independently read and scored each article that met inclusion criteria. 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.

**Analysis of Treatment Effect.** The success of a treatment studied in a randomized controlled trial can be reported in a number of ways. For instance, what percentage of patients randomized to a treatment successfully quit? This question can be answered by an intent-to-treat analysis that uses the number of patients who quit smoking (regardless of whether they remained in the study) as the numerator and the number randomized to the treatment as the denominator.

A modified intent-to-treat analysis was generally used in this guideline. The denominator for this analysis was the number of patients randomized to the treatment, but in most studies, the numerator was the number of abstinent patients who were contacted at followup. In other words, smokers who could not be contacted at followup were not considered abstinent and were not included in the numerator. This modification was made because few studies presented sufficient data to permit calculation of true intent-to-treat numbers, whereas many provided enough information to permit calculation of the modified percentage.

**Outcome Data.** A study was required to provide outcome data with followup 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 (i.e., long-term cessation). These long-term outcome data provided the basis of virtually all cessation analyses contained in this guideline. (The one exception is that the

meta-analysis of cessation treatments in pregnant women contained somewhat shorter followup periods.) Panel staff also coded the presence of biochemical confirmation of self-reported abstinence. In most major meta-analyses, panel staff investigated whether studies using biochemical confirmation yielded different results than did studies without this design feature. Including or excluding studies that lacked biochemical verification had little impact on meta-analysis results. Therefore, meta-analyses presented in the guideline reflect a pooling of studies with and without biochemical confirmation.

## **Meta-Analytic Techniques**

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**Methodology and Limitations.** 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. A complete and detailed review of the meta-analytic methods used in the guideline can be found in the technical report. The primary meta-analytic model used in the guideline was logistic regression using random effects modeling. 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 (e.g., "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 (DerSimonian and Laird, 1986).

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 (e.g., 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 (e.g., appropriate randomization), whereas other criteria were specific to the type of treatment characteristic evaluated (e.g., in the analysis of clinicians, screening ensured that differences in clinicians were not confounded by differences in pharmacotherapy status). The technical report contains lists and descriptions of all screening criteria.

Several factors can compromise the internal validity of the meta-analyses. For example, publication biases (particularly the tendency to publish only those studies with positive findings) may result in biased summary statistics. In addition, either the magnitude or the significance of the findings of the 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 occurring treatment. And, when two treatments co-occur frequently in the same groups of subjects, it is difficult to apportion statistically the impact of each.

Threats to the external validity of the meta-analysis relate primarily to the generalizability of the study populations. However, conducting separate meta-analyses based on the populations under study yielded generally similar



results across a variety of treatment dimensions. For instance, meta-analyses that involved subjects seeking out smoking cessation treatment (“self-selected”) yielded results similar to meta-analyses in which subjects received treatment without taking steps to seek it, such as when it is an integral part of a health care visit (“all-comers”). No other population characteristics (e.g., years smoked, packs per day) were explored in meta-analyses.

In summary, with the exception of the caveats discussed above, the meta-analytic techniques provide a valid synthesis of smoking cessation treatment outcome data and identify treatment features or elements that are effective across a group of related investigations.

### **Strength of Evidence**

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Every recommendation made by the panel bears a strength-of-evidence rating that indicates the quality and quantity of empirical support for the recommendation. The three 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, either few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation. An example of the last point would be the case where trials were conducted using a study population that differed from the target population of 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 panel declined to make recommendations when there was no relevant evidence or the evidence considered was too weak or inconsistent.

Not every evidence statement is used to support a recommendation. Therefore, a recommendation may be directly relevant to only a subset of the evidence statements in the same guideline section. Thus, within a section, some evidence statements may carry different strength ratings than does a particular recommendation.

### **Interpretation of Meta-Analysis Results**

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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 x 2 table. Table 1 contains data showing the relation between maternal smoking and low birth weight in infants. Data are extracted from Hosmer and Lemeshow (1989).

**Table 1. Relation between maternal smoking and low birth weight in infants**

		Maternal smoking		
		Yes	No	
Low birth weight	Yes	30	29	59
	No	44	86	130
		74	115	189

The odds of a low birth weight infant if the mother smokes are 30:44, or 0.68 to 1. The odds of a low birth weight 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 risk of a low birth weight infant is about double for women who smoke compared with those who do not.

Once odds ratios were obtained from meta-analyses, the statistical methodologist estimated 95 percent confidence intervals around the odds ratios. An odds ratio is only an estimate of a relation between variables. The 95 percent confidence interval presents an estimate of the accuracy of the particular odds ratio obtained. If the confidence interval for a given odds ratio does not include "1," then the odds ratio represents a statistically significant effect at the .05 level. The confidence intervals will generally not be perfectly symmetrical around an odds ratio because of the distributional properties of the odds ratio.

After computing the odds ratios and their confidence intervals, the statistical methodologist then converted the odds ratios to cessation percentages and their 95 percent confidence intervals. Cessation percentages indicate the estimated long-term smoking cessation rate achieved under the tested treatment or treatment characteristic. The cessation percentage results are approximate estimates derived from the odds ratio data (Eddy and Hasselblad, 1997). Therefore, they essentially duplicate the odds ratio results but are presented because their meaning may be clearer for some readers.

### 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 durations of treatment (in weeks) on outcome (see the section in Chapter 3, Interventions). In this table, the comparison condition, or "reference group," for determining the impact of different treatment durations, was smokers given brief cessation interventions—ones lasting less than 2 weeks (all sessions were delivered within a 2-week period). The "Estimated odds

**Table 2. Efficacy of and cessation rates for various durations of treatment (*n* = 55 studies)**

Duration	Number of arms	Estimated odds ratio (95% C.I.)	Estimated cessation rate (95% C.I.)
< 2 weeks (reference group)	101	1.0	10.4
2 to < 4 weeks	14	1.6 (1.3–2.0)	15.6 (12.9–18.3)
4–8 weeks	12	1.6 (1.2–2.1)	16.1 (12.4–19.7)
> 8 weeks	15	2.7 (2.2–3.2)	23.8 (20.6–27.1)

ratio” column reveals that treatment groups receiving treatments lasting either 2–4 weeks or 4–8 weeks both had odds ratios of 1.6. In both cases, the odds ratio indicates a significant effect, because the lower boundary of the confidence interval did not include “1.” Treatments lasting more than 8 weeks had the largest odds ratio (2.7). This odds ratio means that when a smoker receives long-duration treatments (greater than 8 weeks), in contrast to treatments lasting fewer than 2 weeks, the likelihood is more than doubled that he or she will quit smoking. This effect is significant, because the lower confidence interval boundary (2.2) does not include “1.”

The column labeled “Estimated cessation rate” shows the cessation percentages for the various treatment durations. For instance, the reference group conditions (duration less than 2 weeks) in the analyzed data set were associated with a smoking cessation abstinence rate of 10.4 percent. As suggested by the odds ratio data reviewed above, treatment durations lasting 2–8 weeks produced moderate increases in cessation rates (to about 16 percent), whereas the longest treatments (greater than 8 weeks) produced substantial increases (to over 23 percent). The statistical significance of the three longer treatment durations is indicated by the fact that their confidence intervals do not overlap the cessation rate produced by the less-than-2-week (reference group) condition.

The column labeled “Number of arms” lists the number of treatment conditions or groups across all analyzed studies that fell within the various treatment duration categories (e.g., in 15 treatment arms, treatment exceeded 8 weeks). Therefore, this column depicts the number of treatment conditions or groups relevant to each analyzed category.

Two additional factors deserve to be highlighted regarding the data tables in this guideline. First, all outcome data (both odds ratios and cessation rates) are based exclusively on studies that provided long-term followup, defined as quit rates at 5 months or greater followup points. When quit rates were provided for multiple long-term endpoints, efficacy data from the endpoint closest to 6 months were used. Second, all outcome data are based on all studies that met inclusion criteria (see Methodology

## *Smoking Cessation*

and Limitations subsection above). Therefore, the outcome data in the tables include studies with "all-comers" (individuals who did not choose to be part of a smoking cessation intervention) and "self-selected" populations, as well as studies with and without biochemical confirmation. As previously mentioned, there were essentially no differences identified when these comparison populations, or studies with different biochemical confirmation statuses, were analyzed separately. Despite the present results, biochemical confirmation may contribute to the internal validity of controlled clinical trials.

### **Caveats to Recommendation Use**

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In applying these guideline recommendations, the reader should note some caveats. First, an absence of studies should not be confused with a proof of lack of efficacy. In certain situations, there was little direct evidence regarding the efficacy of various treatments, and in these cases the panel usually rendered no opinion.

Moreover, 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 of those interventions that are efficacious. Second, selection or use of particular intervention techniques or strategies is usually a function of practical influences: time available, training of the clinician, patient preference, cost, and so on. The panel believed that clinicians should choose from among the efficacious interventions those that are feasible 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, although numerous studies have investigated the efficacy of both the nicotine patch and nicotine gum relative to placebo treatments, no published randomized trials directly compared the efficacy of these two 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 other intervention. For instance, although even minimal person-to-person contact can increase smoking cessation rates over no-treatment conditions, there is little doubt that longer person-to-person interactions have an even greater impact.

## Eliciting and Addressing Public Opinion

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At the start of the second panel meeting, an open forum was held in Washington, DC, on November 9, 1994, to receive input from the general public. This open forum meeting was publicized in the *Federal Register*. A variety of issues were raised by individuals from many disciplines, including physicians, nurses, and psychologists; professional groups; individual medical consumers; and other concerned parties. Suggestions from the public forum were reviewed and incorporated into the guideline when appropriate.

## External Review of the Guideline

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The panel and AHCPR invited 155 outside reviewers to peer review the guideline draft. In addition, AHCPR placed a notice in the *Federal Register* inviting individuals to review and comment on the draft guideline. A total of 71 reviewers provided comments. Peer reviewers included clinicians, health care program directors, social workers, counselors, health educators, researchers with clinical experience, consumers, and key personnel at selected Federal agencies (CDC, National Institute on Drug Abuse, NCI, Food and Drug Administration [FDA]) among others. Reviewers were asked to evaluate the guideline based on five criteria: validity, reliability, clarity, clinical applicability, and utility. The reviewers were encouraged to provide additional comments. Comments of the peer reviewers were evaluated by the panel and panel staff and were incorporated into the guideline when appropriate.

## 2 Recommendations for Three Target Audiences

### Primary Care Clinicians

#### Background

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Primary care and other clinicians are uniquely poised to assist patients who smoke, in that they have extraordinary access to this population. At least 70 percent of smokers see a physician each year and more than 50 percent see a dentist (Hayward, Meetz, Shapiro, et al., 1989; Tomar, Husten, and Manley, 1996). Moreover, 70 percent of smokers report that they want to quit and have made at least one self-described serious attempt to quit (CDC, 1994). Finally, smokers cite a physician's advice to quit as an important motivator for attempting to stop (NCI, 1994; Ockene, 1987; Pederson, 1982). The importance of clinical intervention with patients who use tobacco is highlighted by its inclusion as a national health goal in *Healthy People 2000: National Health Promotion and Disease Prevention Objectives* (DHHS, 1991).

Unfortunately, clinicians are not capitalizing fully on this unique opportunity. Only about half of current smokers report having ever been asked about their smoking status or urged to quit (Anda, Remington, Sienko, et al., 1987; CDC, 1993b; Frank, Winkleby, Altman, et al., 1991). Fewer still have received specific advice on how to quit smoking successfully.

Why don't clinicians consistently confront tobacco use among their patients? Some clinicians' reluctance to intervene may be attributed, in part, to time constraints, a perceived lack of skills to be effective in this role, frustration owing to low success rates, or even a belief that smoking cessation is not an important professional responsibility (Jaen, Stange, and Nutting, 1994). Several changes have been proposed to increase clinicians' intervention with smokers: (a) health care delivery practices must change so that smoking cessation interventions are institutionalized, (b) clinicians and their patients must be reimbursed by insurers for smoking cessation counseling and pharmacotherapy, (c) clinicians must adjust their goals so that motivational interventions are offered to smokers who are not yet committed to quitting (Biener and Abrams, 1991; Curry, Wagner, and Grothaus, 1990; Prochaska and Goldstein, 1991), and (d) standards of health care delivery must reflect the health care system's obligation to intervene in a timely and appropriate manner with patients who smoke (Fiore and Baker, 1995; Kottke and Solberg, 1995).

In this section of the guideline, specific recommendations relevant to primary care clinicians (physicians, nurses, dentists, respiratory therapists, etc.) are presented. The goals of these recommendations are clear: to change clinical culture and practice patterns to ensure that every patient who smokes is offered treatment. The recommendations in this section are selected from

among the findings presented in Chapter 3. The recommendations underscore a central theme: It is essential to provide a brief but effective cessation intervention for 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 smoke are identified for intervention (see section below on Health Care Administrators, Insurers, and Purchasers). Second, the compelling time limitations on practicing primary care physicians in the United States today (median visit = approximately 12 minutes; Gilchrist, Miller, Gillanders, et al., 1993) often require brief interventions, although more intensive interventions produce greater success. Third, although many smokers are reluctant to seek out intensive cessation programs (Lichtenstein and Hollis, 1992), they nevertheless can receive treatment even if they visit any type of clinician.

### **Training Clinicians To Intervene With Their Patients Who Smoke**

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Clinicians must be trained in effective smoking cessation interventions if these 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 smoke (Cummings, Giovino, Sciandra, et al., 1987; Scott and Neighbor, 1985; Wechsler, Levin, Idelson, et al., 1983).

Training should be directed at clinicians-in-training as well as practicing clinicians. For clinicians-in-training, most disciplines do not currently provide training, or require competency, in smoking cessation interventions. For example, a recent NCI expert panel found that medical schools do not consistently train students in effective smoking cessation interventions (Fiore, Epi, and Manley, 1994). The panel recommended that a specific curriculum devoted to smoking cessation be included as part of each medical student's education. Similar recommendations would be relevant to virtually all other clinical disciplines. Training in smoking intervention should not only transmit essential treatment skills but also inculcate the belief that smoking cessation treatment is a standard of good practice (Kottke, Solberg, Brekke, et al., 1992).

Practicing clinicians would also benefit from continuing education that addresses smoking cessation. This guideline recommends that clinicians be reimbursed for smoking cessation treatment and that their intervention activities be tracked. Either of these policies should foster increased interest in smoking cessation training among practicing clinicians.

Several factors would promote the training of clinicians to intervene in smoking cessation activities:

- Inclusion of smoking cessation interventions in the required curricula of all clinical disciplines.

- Inclusion of questions on effective smoking cessation interventions in licensing and certification exams for all clinical disciplines.
- Adoption by specialty societies of a uniform standard of competence in smoking cessation intervention for all members.

Finally, clinicians who smoke should participate in an additional type of education or training—they should enter smoking cessation treatment programs in order to stop smoking permanently. Clinicians have an important role as non-smoking models for their patients. An encouraging finding has been the dramatic decrease in smoking rates reported among many types of clinicians. In a recent report on tobacco-use prevalence by occupation, the rate of smoking was noted to be 5.5 percent among physicians, 7.4 percent among dentists, 8.7 percent among physical therapists, and 22.0 percent among registered nurses (Nelson, Emont, Brackbill, et al., 1994). All of these prevalence rates are lower than tobacco-use rates in the general population. All clinicians who currently smoke should seek out effective smoking cessation treatments recommended in this guideline.

### **Recommendations for Primary Care Clinicians**

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Recommendations for primary care clinicians are based on the evidence described in the first four sections of Chapter 3, as well as on panel opinion. These recommendations assume that office systems will be implemented to institutionalize smoking cessation assessment and intervention (see section on Health Care Administrators, Insurers, and Purchasers). They also are designed to be brief, requiring 3 minutes or less of direct clinician time. Finally, these recommendations are consistent with those produced by NCI (Glynn and Manley, 1990) and the American Medical Association (AMA) (American Medical Association, 1994), as well as others (e.g., Kottke, Solberg, and Brekke, 1990; Mecklenburg, Christen, Gerbert, et al., 1991).

The AHCPR guideline recommendations emphasize the importance of systematically identifying all smokers (see For the Primary Care Clinician: Strategy 1), strongly advising all smokers to quit (see For the Primary Care Clinician: Strategy 2), and determining patients' willingness to make a quit attempt (see For the Primary Care Clinician: Strategy 3). The patient not willing to commit to quitting should receive a motivational intervention to promote subsequent quit attempts (see Chapter 4, Promoting the Motivation to Quit). When the patient is willing to make a quit attempt, primary care clinicians may assist by asking the patient to set a quit date, preparing the patient for the quit date, encouraging nicotine replacement therapy, providing self-help materials, and providing key advice (see For the Primary Care Clinician: Strategy 4). The clinician should refer the patient to intensive treatments when the clinician views such treatments as appropriate (e.g., if the patient has relapsed repeatedly following minimal interventions) or if the patient prefers such treatments (see next section). All patients attempting quitting should have followup contact scheduled (see For the Primary Care Clinician: Strategy 5).





**For the primary care clinician:**

**Strategy 3. Identify smokers willing to make a quit attempt**

Action	Strategies for implementation
<p>Ask every smoker if he or she is willing to make a quit attempt at this time.</p>	<ul style="list-style-type: none"> <li>■ If the patient is willing to make a quit attempt at this time, provide assistance (see Strategy 4 for the Primary Care Clinician).</li> <li>■ If the patient prefers a more intensive treatment or the clinician believes intensive treatment is appropriate, refer to interventions administered by a smoking cessation specialist and follow up with the patient regarding quitting (see Strategy 5 for the Primary Care Clinician and Chapter 2, second section).</li> <li>■ If the patient clearly states he/she is not willing to make a quit attempt at this time, provide a motivational intervention (see Chapter 4, first section). Also, if the patient is a member of a special population (e.g., adolescent, pregnant smoker, racial/ethnic minority), additional information is provided in Chapter 5.</li> </ul>

**Tobacco Cessation Specialists and Programs**

**Background**

Smoking cessation specialists are not defined by their professional affiliation or by the field in which they trained. Rather, the specialist views smoking cessation as a critical professional role, possesses skills relevant to cessation activities, and is often affiliated with programs offering intensive cessation interventions or services (programs with staff dedicated to smoking interventions, where treatment involves multiple counseling sessions, and so on).

Specialists are a vital resource in smoking cessation efforts. For example, many effective smoking cessation strategies now widely disseminated (e.g., skills for coping with urges to smoke) were developed by specialists conducting intensive intervention programs. As major contributors to cessation research, specialists exert a cumulative effect greater than their number.

Also, specialists play an important role in service delivery—especially through the provision of intensive cessation interventions. Some smokers seek out and prefer the intensive interventions offered by specialists. There is substantial evidence that such programs produce higher success rates than do less intensive interventions (as indicated by several findings of the present guideline). In addition, the cessation interventions offered by specialists are important because many nonspecialists do not consistently and reliably intervene with smokers.

Although the specialist definitely contributes greatly to smoking cessation efforts, constraints limit the impact of the specialist's service delivery activities. Only a minority of smokers participate in the intensive programs

**For the primary care clinician:  
Strategy 4. Assist—aid the patient in quitting**

Action	Strategies for implementation
<p>Help the patient with a quit plan.</p>	<p>Set a <i>quit date</i> — Ideally, the quit date should be within 2 weeks, taking patient preference into account.</p> <p><i>A patient's preparations for quitting:</i></p> <ul style="list-style-type: none"> <li>■ <i>Inform</i> family, friends, and co-workers of quitting and request understanding and support.</li> <li>■ <i>Remove</i> cigarettes from your environment. Prior to quitting, avoid smoking in places where you spend a lot of time (e.g., home, car).</li> <li>■ <i>Review</i> previous quit attempts. What helped you? What led to relapse?</li> <li>■ <i>Anticipate</i> challenges to planned quit attempt, particularly during the critical first few weeks. These include nicotine withdrawal symptoms.</li> </ul>
<p>Encourage nicotine replacement therapy except in special circumstances.</p>	<p>Encourage the use of nicotine patch or nicotine gum therapy for smoking cessation (see General Strategies and 5 for specific instructions and precautions).</p>
<p>Give key advice on successful quitting.</p>	<p><i>Abstinence</i> — Total abstinence is essential. "Not even a single puff after the quit date."</p> <p><i>Alcohol</i> — Drinking alcohol is highly associated with relapse. Those who stop smoking should review their alcohol use and consider limiting/abstaining from alcohol during the quit process.</p> <p><i>Other smokers in the household</i> — The presence of other smokers in the household, particularly a spouse, is associated with lower success rates. Patients should consider quitting with their significant others and/or developing specific plans to stay quit in a household where others still smoke.</p>
<p>Provide supplementary materials.</p>	<p><i>Sources</i> — Federal agencies, including AHCPR, nonfederal agencies (ACS, ALA, AHA); or local/State health departments (see Attachment for details).</p> <p><i>Type</i> — Culturally/racially/educationally/age appropriate for the patient.</p> <p><i>Location</i> — Readily available in every clinic office.</p>

**For the primary care clinician:  
Strategy 5. Arrange—schedule followup contact**

Action	Strategies for implementation
<p>Schedule followup contact, either in person or via telephone.</p>	<p><i>Timing</i> — Followup contact should occur soon after the quit date, preferably during the first week. A second followup contact is recommended within the first month. Schedule further followup contacts as indicated.</p> <p><i>Actions during followup visit</i> — Congratulate success. If smoking 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 nicotine replacement therapy use and problems. Consider referral to a more intense or specialized program (see Chapter 4, second section).</p>

typically offered by specialists (Fiore, Novotny, Pierce, et al., 1990). Moreover, not enough resources are available to offer intensive programs to all smokers wanting to quit. Such considerations suggest that, in the future, the specialist may contribute to smoking cessation efforts through activities in addition to service delivery per se, such as the following:

- Serving as a resource to nonspecialists who offer smoking cessation services as part of general health care delivery. This might include training nonspecialists in counseling strategies, providing consultation on difficult cases, and providing specialized assessment services.
- Developing and evaluating changes in office/clinic procedures that increase the rates at which smokers are identified and treated.
- Conducting evaluation research to determine the effectiveness of ongoing smoking cessation activities in relevant institutional settings.
- Developing and evaluating innovative treatment strategies that increase the effectiveness of smoking cessation interventions. For example, “treatment matching” (e.g., Hall, Munoz, and Reus, 1994; Zelman, Brandon, Jorenby, et al., 1992), “stepped-care” approaches (Abrams, Orleans, Niaura, et al., 1993, in press; Orleans, 1993), smoking cessation interventions for patients with psychiatric comorbidity (Hughes and Frances, 1995; Hurt, Eberman, Croghan, et al., 1994), the treatment of severely dependent smokers (Hurt, Dale, Offord, et al., 1992), and proactive telephone counseling during followup (Zhu, Stretch, Balabanis, et al., 1996) represent five such innovative approaches.

## **Recommendations for Tobacco Cessation Specialists and Programs**

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Given that the specialist may assume diverse roles regarding smoking cessation—treatment, assessment, training of nonspecialists, and program development and evaluation—it is apparent that virtually all of the information in the guideline might be important to the specialist. However, highlighted in For the Specialist: Strategy 1 are guideline findings that see particularly relevant to the specialist's implementation of intensive cessation programs. The above findings lead to the following recommendations regarding intensive smoking cessation programs (see For the Specialist: Strategy 2). Of course, implementation of these recommendations depends on factors such as resource availability, time constraints, and so on.

## **Health Care Administrators, Insurers, and Purchasers**

### **Background**

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Although clinical practice guidelines have traditionally focused on the role of the individual clinician, promoting smoking cessation in the United States requires a broader approach involving health care delivery administrators, insurers, and purchasers. Why broaden the scope of this document beyond the individual clinician? Smoking cessation efforts directed solely to the individual clinician have yielded disappointing results. National data suggest that, in a given visit with a clinician, most smokers are not advised and assisted with cessation (CDC, 1993b). Factors that contribute to this problem include failure to (a) include smoking assessment and cessation in the performance expectations of clinicians and (b) provide clinicians with an environment that supports systematic intervention with smokers. Without supportive systems, policies, and environmental prompts, the individual clinician cannot be counted on to assess and treat tobacco use reliably. In addition, an increasing number of Americans are receiving their health care in managed care settings. The structure of managed care environments provides new opportunities to identify and treat patients who smoke. These factors indicate that responsibility for smoking cessation treatment must be redistributed; just as every clinician has a professional responsibility to assess and treat tobacco users, health care administrators, insurers, and purchasers have a responsibility to craft policies, provide resources, and display leadership fostering smoking cessation efforts.

It is important to emphasize that smoking cessation treatments (both pharmacotherapy and counseling) are not consistently provided as paid services for subscribers of health insurance packages (Group Health Association of America, 1993), with one survey demonstrating that as few as 11 percent of health insurance carriers provided coverage for treatment of nicotine

**For the specialist:**

**Strategy 1. Findings relevant to the specialist's implementation of intensive cessation programs**

- There is a strong dose-response relation between counseling intensity and cessation success. In general, the more intense the cessation 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 and number of weeks over which treatment is delivered.
- Valid predictors of outcome are available. For instance, high levels of dependence, psychiatric comorbidity, and low levels of motivation to quit all predict greater likelihood of relapse. These measures might be used to adjust treatment intensity, to match patients with particular types of treatment, or for research purposes.
- Many different types of cessation providers (physicians, nurses, dentists, psychologists, pharmacists, etc.) are effective in increasing rates of smoking cessation, and involving multiple types of providers appears to enhance cessation rates.
- Both individual and group counseling are effective smoking cessation formats.
- Particular counseling contents are especially effective. Problem-solving/skills-training approaches and the provision of intratreatment support are associated with significant increases in cessation rates, as are aversive smoking techniques (e.g., rapid smoking).
- Pharmacotherapy in the form of nicotine patch or nicotine gum therapy consistently increases smoking cessation rates regardless of the level of adjuvant behavioral or psychosocial interventions. Therefore, its use should be encouraged.
- Smoking cessation interventions are effective across diverse populations: across gender, racial, and ethnic groups; across age groups; in pregnant women; etc.

addiction (Gelb, 1985). This lack of coverage is particularly surprising given that studies have shown that physician counseling against smoking is at least as cost-effective as several other preventive medical practices, including the treatment of mild or moderate hypertension or high cholesterol (Cummings, Rubins, and Oster, 1989). These and other findings resulted in the recent addition of a new objective to the national health promotion and disease prevention objectives for the year 2000.

Increase to 100 percent the proportion of health plans that offer treatment of nicotine addiction (e.g., tobacco use cessation counseling by health care providers, tobacco use cessation classes, prescriptions for nicotine replacement therapies, and/or other cessation services) (DHHS, 1995).

**Cost-Effectiveness of Smoking Cessation Interventions \_\_\_\_\_**

Smoking cessation treatments are not only clinically effective, they have economic benefits as well. It is vital that all three audiences targeted in this

**For the specialist:  
Strategy 2. Recommendations regarding intensive smoking cessation programs**

Assessment	Assessments should determine whether smokers are motivated to quit smoking via an intensive cessation program. Other assessments can provide information useful in counseling (e.g., stress level, presence of comorbidity; see Chapter 3, Specialized Assessment).
Program clinicians	Multiple types of clinicians should be used. One strategy would be to have a medical/health care clinician deliver messages about health risks and benefits, and nonmedical clinicians deliver psychosocial or behavioral interventions.
Program intensity	Because of evidence of a strong dose-response relationship, the intensity of the program should be: <i>Session length</i> — at least 20–30 min in length <sup>a</sup> <i>Number of sessions</i> — at least 4–7 sessions <i>Length in weeks</i> — at least 2 w, preferably more than 8
Program format	Either individual or group counseling may be used. Use of adjuvant self-help material is optional. Followup assessment procedures should be used (see Chapter 3).
Counseling content	Counseling should involve either or both problem-solving skills-training content as well as social support delivered during treatment sessions (see Chapter 3, subsection on Content of Smoking Cessation Interventions). In addition, content should target motivation to quit and relapse prevention (see Chapter 4).
Pharmacotherapy	Except in special circumstances, every smoker should be offered nicotine replacement.  Encourage the use of nicotine patch or nicotine gum therapy for smoking cessation (see General Strategies and 5 for specific instructions and precautions).
Population	Intensive intervention programs may be used with all smokers willing to enter such programs.

<sup>a</sup> Session length of 20–30 min was recommended because most trials of effective smoking cessation counseling used sessions of at least this length.

guideline recognize that smoking cessation treatments ranging from brief clinician advice to specialist-delivered intensive programs are cost-effective in relation to other sorts of medical interventions. Cost-effectiveness analyses (Cummings, Rubin, and Oster, 1989; Eddy, 1981, 1986; Oster, Huse, Delea, et al., 1986) have shown that smoking cessation treatment compares quite favorably with routine medical interventions such as the treatment of hypertension and hypercholesterolemia and preventive interventions such as

periodic mammography. In fact, Eddy referred to smoking cessation treatment as the "gold standard" of preventive interventions (Eddy, 1992).

Although only a minority of smokers will achieve success in response to a single application of treatment, clinicians, specialists, and administrators should not forget or ignore the significant health and economic benefits of cessation treatments relative to their costs. The cost-effectiveness of guideline recommendations for smoking cessation will be addressed in detail in an ancillary document sponsored by AHCPR.

### **Recommendations for Health Care Administrators, Insurers, and Purchasers**

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Health care delivery administrators, insurers, and purchasers can promote tobacco cessation through a systems approach. Purchasers (usually corporations, companies, or other consortia that purchase health care benefits for a group of individuals) should consider making tobacco assessment, counseling, and treatment a contractual obligation of the health care insurers and/or providers that sell them services. In addition, health care administrators and insurers must provide clinicians with assistance to ensure that institutional changes promoting smoking cessation interventions are universally and systematically implemented. A number of institutional policies would facilitate these interventions:

- Implement a tobacco-user identification system in every clinic (see For Health Care Administrators, Insurers, and Purchasers: Strategy 1).
- Provide education, resources, and feedback to promote provider intervention (see For Health Care Administrators, Insurers, and Purchasers: Strategy 2).
- Dedicate staff to provide smoking cessation treatment identified as effective in this document and assess the delivery of this treatment in staff performance evaluations (see For Health Care Administrators, Insurers, and Purchasers: Strategy 3).
- Promote hospital policies that support and provide smoking cessation services (see For Health Care Administrators, Insurers, and Purchasers: Strategy 4).
- Include smoking cessation treatment (both pharmacotherapy and counseling), identified as effective in this guideline, as paid services for all subscribers of health insurance packages (see For Health Care Administrators, Insurers, and Purchasers: Strategy 5).
- Reimburse fee-for-service clinicians for delivery of effective smoking cessation treatments and include these interventions among the defined duties of salaried clinicians (see For Health Care Administrators, Insurers, and Purchasers: Strategy 6).



**For health care administrators, insurers, and purchasers:**

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

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><b>Office system change:</b> Expanding the <i>Vital Signs</i> to include tobacco use (see Strategy 1 for Primary Care Clinician).</p>																												
	<p><b>Responsible staff:</b> Nurse, medical assistant, receptionist, or other individual already responsible for measuring the vital signs—no additional staff requirements. These staff must be instructed regarding the frequency and importance of this activity.</p>																												
	<p><b>Frequency of utilization:</b> Every visit for every patient regardless of the reason that brought the individual to the clinic.<sup>a</sup> In other words, whenever health care staff collect the traditional vital signs data they also query and document tobacco use.</p>																												
	<p><b>System implementation steps:</b> <i>Preprint</i> progress note paper or program computer record for every patient visit to include tobacco use along with the traditional vital signs. A vital sign stamp can also be effective. Alternatives to the vital sign stamp are to place tobacco-use status stickers on all patient charts to indicate smoking status using computer reminder systems.</p>																												
<table border="1"> <thead> <tr> <th colspan="4">VITAL SIGNS</th> </tr> </thead> <tbody> <tr> <td>Blood Pressure:</td> <td colspan="3">_____</td> </tr> <tr> <td>Pulse: _____</td> <td>Weight:</td> <td colspan="2">_____</td> </tr> <tr> <td>Temperature:</td> <td colspan="3">_____</td> </tr> <tr> <td>Respiratory Rate:</td> <td colspan="3">_____</td> </tr> <tr> <td>Tobacco Use:</td> <td>Current</td> <td>Former</td> <td>Never</td> </tr> <tr> <td></td> <td colspan="3" style="text-align: center;">(circle one)</td> </tr> </tbody> </table>		VITAL SIGNS				Blood Pressure:	_____			Pulse: _____	Weight:	_____		Temperature:	_____			Respiratory Rate:	_____			Tobacco Use:	Current	Former	Never		(circle one)		
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Tobacco Use:	Current	Former	Never																										
	(circle one)																												

<sup>a</sup> Repeated assessment is not necessary in the case of the adult who has never smoked or smoked for many years, and for whom this information is clearly documented in the medical record.

**For health care administrators, insurers, and purchasers:  
Strategy 2. Provide education, resources, and feedback to promote  
provider intervention**

Action	Strategies for implementation
<p>Health care systems should ensure that clinicians have the knowledge and training to treat smoking, that clinicians and patients have cessation resources, and that clinicians are given feedback about their cessation practices.</p>	<p><i>Educate</i> — On a regular basis, offer lectures/seminars/in-services with CME and other credit for smoking cessation treatment.</p> <p><i>Resources</i> — Have patient self-help materials, as well as nicotine replacement "starter kits," readily available in every exam room.</p> <p><i>Provide feedback</i> — Drawing on data from chart audits, electronic medical records, computerized patient data-bases, and so on, evaluate the degree to which clinicians are identifying, documenting, and treating patients who smoke, and provide feedback to clinicians about their level of intervention.</p>

**For health care administrators, insurers, and purchasers:  
Strategy 3. Dedicate staff to provide smoking cessation treatment and  
assess the delivery of this treatment in staff performance evaluations**

Action	Strategies for implementation
<p>Clinical sites should communicate to staff the importance of intervening with smokers and should designate one staff person (e.g., nurse, medical assistant, or other clinician) to coordinate and deliver smoking cessation treatments.</p>	<p><i>Communicate</i> to each staff member (e.g., nurse, medical assistant, or other clinician) his or her responsibilities in the delivery of smoking cessation services.</p> <p><i>Designate</i> a smoking cessation treatment coordinator for every clinical site.</p> <p><i>Delineate</i> the responsibilities of the smoking cessation coordinator, including instructing patients on the effective use of cessation treatments (e.g., nicotine replacement therapy, telephone calls to and from prospective quitters, and scheduled followup visits, especially in the immediate post-quit period).</p>

**For health care administrators, insurers, and purchasers:  
Strategy 4. Promote hospital policies that support and provide smoking cessation services**

Action	Strategies for implementation
<p>Provide smoking cessation inpatient consultation services to all smokers admitted to a hospital.</p>	<p><i>Implement</i> a system to identify and document the tobacco use status of all hospitalized patients.</p> <p><i>Offer</i> cessation treatment to all hospitalized patients who use tobacco.</p> <p><i>Identify</i> a clinician(s) to deliver smoking cessation inpatient consultation services for every hospital.</p> <p><i>Reimburse</i> providers for smoking cessation inpatient consultation services.</p> <p><i>Expand</i> hospital formularies to include effective smoking cessation pharmacotherapy such as the nicotine patch and nicotine gum.</p> <p><i>Ensure</i> compliance with JCAHO regulations mandating that all sections of the hospital be entirely smoke-free.</p> <p><i>Educate</i> all hospital staff regarding nicotine withdrawal, including effective treatments such as nicotine replacement therapy and counseling.</p>

**For health care administrators, insurers, and purchasers:  
Strategy 5. Include smoking cessation treatments (both pharmacotherapy and counseling), identified as effective in this guideline, as paid services for all subscribers of health insurance packages**

Action	Strategies for implementation
<p>Provide all insurance subscribers coverage for effective smoking cessation treatments, including pharmacotherapy (nicotine replacement therapy) and counseling.</p>	<p><i>Cover</i> — Include effective smoking cessation treatment (both pharmacotherapy and counseling) as part of the basic benefits package for all individual, group, and HM insurance packages.</p> <p><i>Evaluate</i> — Include the provision of smoking cessation treatment as part of "report cards" for managed care organizations and other insurers [e.g., Health Plan Employer Data and Information Set (HEDIS)].</p> <p><i>Educate</i> — Inform subscribers of the availability of cover smoking cessation services and encourage patients to use these services.</p>

**For health care administrators, insurers, and purchasers:  
Strategy 6. Reimburse fee-for-service clinicians for delivery of effective  
smoking cessation treatments and include these interventions among  
the defined duties of salaried clinicians**

Action	Strategies for implementation
Reimburse fee-for-service clinicians for delivery of effective smoking cessation treatments; include smoking cessation treatments in the defined duties of salaried clinicians.	<i>Include smoking cessation treatment as a reimbursable activity for fee-for-service providers.</i>  <i>Inform fee-for-service clinicians that they will be reimbursed for using effective smoking cessation treatments with every patient who uses tobacco.</i>  <i>Include smoking cessation intervention in the job description and performance evaluation of salaried clinicians.</i>

# 3 Evidence

## Background

The recommendations summarized in Chapter 2 are the result of a review and analysis of the extant tobacco cessation literature. Chapter 3 reports the results of this review and analysis and describes the efficacy of various treatments, assessments, and strategies for their implementation. This chapter, therefore, addresses such questions as: Does the professional discipline of the treatment clinician make a difference in the efficacy of the intervention? Are physicians, nurses, dentists, psychologists, and health educators all effective in delivering interventions? Similarly, are minimal interventions, such as clinician advice to quit smoking, effective or are more intensive interventions required? Does the duration of an intervention in weeks or the number of treatment sessions substantially influence efficacy? Which screening strategies result in the reliable identification of smokers? Are pharmacologic interventions effective, and if so, which ones? In short, which treatments or assessments are efficacious and how should they be implemented?

The panel examined the relation between outcomes and 12 major assessment or treatment characteristics or strategies. These 12 characteristics or strategies, and the categories within each, are listed in Table 3. Type of outcome varied across the different strategies being analyzed. For instance, in the analysis of strategies for screening for tobacco use, one outcome was the percent of smokers identified, whereas in the analysis of treatment strategies, the outcome was long-term smoking cessation (cessation for 5 months or more). The panel analyzed treatment or assessment strategies that seemed rationally related to efficacy and that constituted distinct approaches that exist in current clinical practice.

The panel chose categories within strategies according to three major concerns. First, some categories reflected generally accepted dimensions or taxonomies. An example of this is the categorical nature of the clinician types (physician, psychologist, 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 (e.g., Intensity of Person-to-Person Contact, Duration of Treatment) were determined so that relevant studies were apportioned appropriately for statistical analysis. Information on the coding of articles according to these dimensions is located in the technical report.

In ideal circumstances, the panel could evaluate each category by consulting randomized controlled trials relevant to the category 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

**Table 3. Analyzed treatment and assessment strategies**

Strategies analyzed	Categories
Screen for tobacco use	No screening system in place Screening system in place
Advice to quit	No advice to quit Physician advice to quit
Specialized assessment	Nicotine dependence Psychiatric comorbidity Motivation Readiness to change Self-efficacy Environmental risk Stress
Clinician interventions	No clinician/self-administered Nonmedical health care provider (e.g., psychologist, counselor, social worker, graduate student) Nonphysician medical health care provider (e.g., dentist, nurse, health counselor, pharmacist) Physician
Format	No contact Self-help/self-administered (e.g., pamphlet, audiotape, video, mailed information, computer program) Individual counseling/contact Group counseling/contact
Self-help materials	No self-help intervention Pamphlets/booklets/manuals Video Audio Referral to 12-step program, support group, etc. List of community programs Hotline/helpline Computer program
Intensity of person-to-person clinical contact	No person-to-person intervention Minimal contact (longest session ≤ 3 min in duration) Brief counseling (longest session > 3 min and ≤ 10 min in duration) Counseling/psychosocial intervention (longest session > 10 min)

*(Table continues on next page)*

Table 3. (continued)

Strategies analyzed	Categories
Content of the intervention	No person-to-person intervention or minimal contact General—problem-solving/coping skills/relapse prevention/stress management approach Negative affect/depression component Weight/diet/nutrition component Exercise/fitness component Extratreatment social support component Intratreatment social support intervention Contingency contracting/instrumental contingencies Aversive smoking Cue exposure/extinction Cigarette fading/smoking reduction prequit Relaxation/breathing Motivation Quit day Hypnosis Acupuncture
Duration of the intervention/ number of person-to-person treatment sessions	Duration of person-to-person treatment in weeks Number of person-to-person treatment sessions
Pharmacologic interventions	No pharmacotherapy Transdermal nicotine replacement Nicotine gum Other nicotine replacement Clonidine Antidepressants Anxiolytics/benzodiazepines Other pharmacotherapies
Followup assessment and procedures	Followup cessation intervention Motivational intervention
Reimbursement for smoking cessation treatment	Paid services via health insurance/managed care Reimbursement for clinicians

categories within these treatment or assessment strategies. Moreover, strategy categories are frequently confounded with one another. For example, comparisons among clinicians are almost always confounded with the content, format, and intensity of the interventions. Psychologists tend to deliver relatively intensive, psychosocial interventions, often in a group format, whereas physicians tend to deliver brief advice to individuals. More intensive interventions may result in higher cessation rates, such that psychologists appear to be more effective in promoting smoking cessation than do physicians, when in fact, the intensity of the intervention rather than the type of clinician may result in higher cessation rates. Therefore, direct, unconfounded comparisons of categories within a particular strategy were often impossible. These strategies were nevertheless analyzed because of their clinical importance and because it was possible to

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reduce confounding by careful selection of studies and by statistical control of confounding factors.

Panel meta-analyses were used as the primary source of data for evaluating most strategies. For two topics, however, pharmacotherapies and interventions for pregnant smokers, high-quality published meta-analyses already existed and were the primary source of data. Individual articles for these analyses were evaluated whenever necessary. Details of the meta-analytic techniques can be found in the technical report.

Some meta-analyses were conducted to evaluate strategies with respect to the population under study and the type of outcome data used in the study. The relative efficacy of various treatment characteristics was largely unaffected by differences in the population under study (i.e., all-comers vs. self-selected analyses) and the type of outcome data (i.e., intent-to-treat vs. other studies and studies with vs. without biochemical confirmation).

The following sections of Chapter 3 address the 12 treatment and assessment strategies outlined in Table 3. For each strategy analyzed, background information, clinical recommendations, and the evidentiary basis for those recommendations are provided.

### 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. (Strength of Evidence = A)

**Recommendation:** Clinic screening systems such as expanding the visit signs to include smoking status, or the use of smoking status chart stickers, are essential for consistent assessment and documentation of smoking. (Strength of Evidence = B)

The panel conducted meta-analyses to determine the impact of systems that screen for smoking on two outcomes: the rate of smoking cessation intervention by clinicians and the rate of cessation by patients who smoke.

#### Identifying Smokers: Impact on Clinical Intervention \_\_\_\_\_

Nine studies met selection criteria 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 4. Implementing clinic systems designed to increase the assessment and documentation of smoking status markedly increases the rate at which clinicians intervene with their patients who smoke.

#### Identifying Smokers: Impact on Smoking Cessation \_\_\_\_\_

Three studies met selection criteria and were analyzed using a random effects meta-analysis to assess the impact of identifying smokers on actual



**Table 4. Impact of having a smoking 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% C.I.)	Estimated intervention rate (95% C.I.)
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)

rates of smoking cessation. The results of this meta-analysis are shown in Table 5. 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.

**Evidence.** The following statements support the above recommendations:

- Screening systems that systematically identify and document smoking status result in higher rates of smoking cessation interventions by clinicians. (Strength of Evidence = A)
- Screening systems that systematically identify and document smoking status appear to result in higher quit rates among patients who smoke. (Strength of Evidence = C)

Strategy 1 for the Primary Care Clinician and Strategy 1 for Health Care Administrators, Insurers, and Purchasers detail an approach for including tobacco-use status as a new vital sign. This approach is designed to produce consistent assessment and documentation of tobacco use. Evidence from randomized controlled trials shows that this approach increases the probabili-

**Table 5. Impact of having a smoking status identification system in place on the rates of cessation among patients who smoke ( $n = 3$  studies)**

Screening system	Number of arms	Estimated odds ratio (95% C.I.)	Estimated cessation rate (95% C.I.)
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)

ty that tobacco use is consistently assessed and documented (Fiore, Jorenb Schensky, et al., 1995; Robinson, Laurent, and Little, 1995).

## Advice To Quit Smoking

**Recommendation:** All *physicians* should strongly advise every patient who smokes to quit. (Strength of Evidence = A)

**Recommendation:** All *clinicians* should strongly advise their patients who smoke 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. (Strength of Evidence = C)

Nine studies met selection criteria for assessing the efficacy of clinician advice to quit smoking. For the purpose of this analysis, advice was defined as clinical intervention lasting 3 minutes or less. Seven of these studies examined the impact of physician advice, a number sufficient to assess this variable using meta-analytic techniques. The meta-analysis was unable to address the impact of advice to quit by other nonphysician clinicians, because only two studies addressed this issue and were limited to pregnant patients. Results from the meta-analysis are shown in Table 6. Given the large number of smokers who visit a clinician each year, the potential public health impact of universal advice to quit is substantial.

**Evidence.** The following statements support the above recommendation:

- Physician advice to quit smoking increases quit rates compared with the absence of such advice. (Strength of Evidence = A)
- Insufficient data exist to assess the efficacy of advice to quit smoking when the advice is given by nonphysician clinicians. However, it is likely that such advice is efficacious. Therefore, all clinicians should advise their patients who smoke to quit. (Strength of Evidence = C)

## Specialized Assessment

**Recommendation:** Clinicians should routinely assess both the smoking status of all of their patients and the appropriateness of cessation interventions such as nicotine replacement therapy. (Strength of Evidence = A)

**Recommendation:** Cessation treatment is effective without specialized assessments. Clinicians, therefore, should intervene with every patient who smokes even if specialized assessments are not available. (Strength of Evidence = A)

**Recommendation:** Clinicians may engage in specialized assessments in order to gauge potential for successful quitting. (Strength of Evidence = C)

Every individual entering a health care setting should receive an assessment that determines his or her smoking status and interest in quitting. Studies

**Table 6. Efficacy of advice to quit by a clinician (*n* = 7 studies)**

Advice	Number of arms	Estimated odds ratio (95% C.I.)	Estimated cessation rate (95% C.I.)
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)

an assessment is a necessary first step in treatment. In addition, every patient should be assessed for physical or medical conditions that may affect the use of planned treatments (e.g., nicotine replacement therapy).

The clinician may also wish to perform specialized assessments of individual and environmental attributes that provide information for tailoring treatment. Specialized assessments refer to the use of formal instruments (e.g., 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 in specialized assessments that are associated with differential cessation rates are listed in Table 7.

Several considerations should be kept in mind regarding the use of specialized assessments. First, there was little strong or consistent evidence that a smoker's status on a specialized assessment predicted the relative efficacy of the various interventions. The one exception is that persons high in nicotine dependence may benefit more from 4 mg as opposed to 2 mg of nicotine gum (see section in Chapter 3, Smoking Cessation Pharmacotherapy). More

**Table 7. Variables associated with lower cessation rates<sup>a</sup>**

Variable	Examples
High nicotine dependence	Smoker reports severe withdrawal during previous quit attempts
Psychiatric comorbidity	Depression, schizophrenia, alcoholism, other chemical dependency
Low motivation	Smoker reports low motivation to quit
Low readiness to change	Smoker reports not being ready to quit
Low self-efficacy	Smoker reports perceived inability to quit
Environmental risks	Other smokers in the home/workplace
High stress level	Stressful life circumstances and/or recent, major life change (e.g., divorce, job change)

<sup>a</sup> Although these variables are associated with relatively lower cessation rates, cessation treatment nevertheless remains effective in the presence of such variables.

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 cessation interventions should not depend on specialized assessments. Finally, little consistent research evidence shows how treatment should be tailored based on the results of these assessments. However, the panel recognizes that some effective interventions such as general problem solving (see section in Chapter 3, Content of Smoking Cessation Interventions) entail treatment tailoring based on a systematic assessment of individual patient characteristics.

The reviewed evidence suggested that treatment is effective despite the presence of risk factors for relapse (e.g., severe previous withdrawal, depression, other smokers in the home), but quit rates in smokers with these characteristics tend to be lower than rates in those without these characteristics.

## Interventions

### Type of Clinician \_\_\_\_\_

**Recommendation:** Smoking cessation interventions delivered by a variety of clinicians and health care personnel increase cessation rates. Clinician involvement in smoking cessation interventions should be based on factors such as access to smokers, level of training, and interest rather than on membership in a specific professional discipline. (Strength of Evidence = B)

**Recommendation:** All health care personnel and clinicians should repeatedly and consistently deliver smoking cessation interventions to their patients. Smoking cessation interventions should be delivered by many clinicians and types of clinicians as is feasible given available resources. (Strength of Evidence = A)

There were 41 studies that met selection criteria for analyses examining the effectiveness of various types of providers of smoking cessation interventions. These analyses compared the efficacy of interventions delivered by specific types of providers and by multiple providers with interventions where there was no provider (e.g., where there was no intervention or intervention consisted of self-help materials only). Please note that "multiple providers" refers to the number of different types of providers, not the number of total providers regardless of type. The latter information was rarely ever available from the study reports. Results are shown in Table 8.

**Evidence.** The following statements support the above recommendation:

- Smoking cessation interventions delivered by any single type of health care provider or by multiple providers increase cessation rates relative to self-help interventions where there is no provider (e.g., self-help interventions). Results are consistent across diverse provider groups, with no clear advantage to any single provider type. (Strength of Evidence = A)

**Table 8. Efficacy of and estimated cessation rates for interventions delivered by various types of providers ( $n = 41$  studies)**

Type of provider	Number of arms	Estimated odds ratio (95% C.I.)	Estimated cessation rate (95% C.I.)
No provider (reference group)	38	1.0	8.2
Multiple providers	14	3.8 (2.6–5.6)	25.5 (18.1–32.7)
Nonmedical health care provider (psychologist, social worker, counselor)	23	1.8 (1.5–2.2)	14.1 (12.0–16.3)
Physician provider	36	1.5 (1.2–1.9)	12.0 (9.6–14.3)
Nonphysician medical health care provider (dentist, nurse, health counselor, pharmacist)	20	1.4 (1.1–1.8)	11.5 (9.0–14.0)

- Smoking cessation interventions delivered by the following types of providers or clinicians have been shown to increase cessation rates relative to interventions where there is no provider: physician provider (e.g., primary care physician, cardiologist), nonphysician medical health care provider (e.g., dentist, nurse, health counselor, pharmacist), and nonmedical health care provider (e.g., psychologist, social worker, counselor). (Strength of Evidence = A)
- Smoking cessation interventions delivered by multiple types of providers markedly increase cessation rates relative to those produced by interventions where there is no provider. (Strength of Evidence = A)

### Treatment Formats

**Recommendation:** To be most effective, smoking cessation interventions should include either individual or group counseling/contact. (Strength of Evidence = A)

Twenty-five studies met selection criteria and were included in the analysis comparing different types of formats for smoking cessation interventions. Results of this analysis are shown in Table 9.

**Evidence.** The following statements support the above recommendation:

- Smoking cessation interventions delivered by means of self-help materials appear to increase cessation rates relative to no intervention.

**Table 9. Efficacy of and estimated cessation rates for various formats (n = 25 studies)**

Format	Number of arms	Estimated odds ratio (95% C.I.)	Estimated cessation rate (95% C.I.)
No intervention (reference group)	23	1.0	7.6
Self-help	8	1.2 (1.0–1.6) <sup>a</sup>	9.3 (7.3–11.4)
Individual counseling	26	2.2 (1.9–2.4)	15.1 (13.6–16.5)
Group counseling	15	2.2 (1.6–3.0)	15.3 (11.4– 19.2)

<sup>a</sup> Actual 95% lower confidence estimate equals 0.97.

However, their impact is smaller and less certain than that of individual or group counseling. (Strength of Evidence = B)

- Smoking cessation interventions delivered by means of individual counseling (involving person-to-person contact) increase cessation rates relative to no intervention. (Strength of Evidence = A)
- Smoking cessation interventions delivered by means of group counseling/contact increase cessation rates relative to no intervention (Strength of Evidence = A)

There is insufficient evidence to assess telephone counseling/contact. Telephone counseling/contact was defined as proactive clinician-initiated telephone calls. (Compare with “hotline/helpline” [Table 10], which involve patient-initiated telephone calls.)

### **Efficacy of Self-Help Treatment Alone**

**Recommendation:** Where feasible, smokers should be provided with access to support through a telephone hotline/helpline as a self-help intervention. (Strength of Evidence = B)

**Types of Self-Help Intervention.** In general, smoking cessation interventions delivered by means of self-help materials may increase cessation rates relative to no intervention (Curry, 1993). However, their impact is smaller and less certain than that of individual or group counseling.

Twelve studies met selection criteria for evaluations of specific types of self-help materials. These studies involved self-help treatments used by themselves (with no non-self-help treatment modality). To estimate the effect of various types of self-help, we included all 12 studies in a single meta-analysis using a random-effects model (Table 10). In this analysis, the various types of self-help interventions were compared with a control condition or reference group in which subjects received no treatment.

**Table 10. Efficacy of and cessation rates for various types of self-help formats when used alone ( $n = 12$  studies)**

Self-help format	Number of arms	Estimated odds ratio (95% C.I.)	Estimated cessation rate (95% C.I.)
No self-help (reference group)	8	1.0	7.9
Hotline/helpline	3	1.4 (1.1–1.8)	11.1 (8.7–13.4)
Video- or audiotapes	5	1.3 (0.6–2.9)	10.9 (3.6– 18.2)
List of community programs	2	1.1 (0.8–2.5)	8.8 (6.9–10.8)
Pamphlets/booklets/ manuals	22	1.0 (0.8–1.2)	8.1 (6.7–9.5)

**Evidence.** The following statements support the above recommendation:

- Written self-help materials (pamphlets/booklets/manuals) when used alone do not increase cessation rates relative to no self-help materials. (Strength of Evidence = A)
- Videotapes and audiotapes when used alone do not increase cessation rates relative to no self-help materials. However, these methods deserve further examination because very few studies addressed these types of self-help materials. (Strength of Evidence = B)
- Provision of a list of community programs when used alone does not increase cessation rates relative to no self-help materials. (Strength of Evidence = B)
- Hotlines/helplines (patient-initiated telephone calls for cessation counseling or aid) when used alone increase smoking cessation rates relative to no self-help materials. (Strength of Evidence = B)

No randomized clinical trials that addressed the efficacy of computer programs for smoking cessation met our selection criteria. Further research should be done on such innovative approaches to self-help (e.g., computerized, personalized interventions) (Strecher, Kreuter, Den Boer, et al., 1994).

**Multiple Types of Self-Help Materials.** An additional random-effects model assessed the efficacy of multiple types of self-help interventions versus no self-help, as shown in Table 11. These results are based on the 12 self-help studies, 6 of which contained at least one treatment arm in which subjects received multiple types of self-help materials (e.g., audiocassette, television program).

**Evidence.** The results suggest an increasing effect with an increase in the number of types of self-help interventions. However, the estimate for combining three different types of self-help materials is based on a single study. (Strength of Evidence = C)

**Table 11. Efficacy of multiple types of self-help materials ( $n = 12$  studies)**

Number of types of self-help materials	Number of arms	Estimated odds ratio (95% C.I.)	Estimated cessation rate (95% C.I.)
No self-help (reference group)	8	1.0	7.9
One type	15	1.0 (0.9–1.3)	8.1 (6.7–9.6)
Two types	7	1.2 (0.9–1.6)	9.6 (7.0–12.1)
Three types <sup>a</sup>	1	1.9 (1.2–2.9)	14.5 (8.9–19.1)

<sup>a</sup> Based on a single study.

### Intensity of Person-to-Person Clinical Intervention

**Recommendation:** There is a strong dose–response relationship between the intensity of person-to-person contact and successful cessation outcome. Intensive interventions are more effective and should be used when resources permit. (Strength of Evidence = A)

**Recommendation:** Every smoker should be offered at least a minimal brief intervention whether or not the smoker is referred to an intensive intervention. (Strength of Evidence = B)

Fifty-six studies met selection criteria for comparisons among various intensity levels of person-to-person contact. Whenever possible, intensity was defined based on the amount of time the clinician spent with a smoker at a single contact. Minimal-contact interventions were defined as 3 minutes or less, brief counseling was defined as greater than 3 minutes to less than or equal to 10 minutes, and counseling/psychosocial interventions were defined as greater than 10 minutes. Intense interventions could involve multiple patient–clinician contacts. 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 (e.g., self-help-only conditions). Results are shown in Table 12.

**Evidence.** The following statements support the above recommendation:

- As the intensity level of person-to-person contact increases, efficacy also increases. (Strength of Evidence = A)
- Smoking cessation interventions utilizing counseling/psychosocial interventions (sessions lasting more than 10 minutes) markedly increase cessation rates relative to no-contact interventions. (Strength of Evidence = A)
- Smoking cessation interventions utilizing brief counseling (session lasting 3–10 minutes) increase cessation rates over no-contact interventions. (Strength of Evidence = A)



**Table 12. Efficacy of and cessation rates for various intensity levels of person-to-person contact ( $n = 56$  studies)**

Level of contact	Number of arms	Estimated odds ratio (95% C.I.)	Estimated cessation rate (95% C.I.)
No contact (reference group)	49	1.0	8.8
Minimal contact ( $\leq 3$ min)	14	1.2 (1.0–1.5) <sup>a</sup>	10.7 (8.9–12.5)
Brief counseling ( $> 3$ to $\leq 10$ min)	26	1.4 (1.2–1.7)	12.1 (10.0–14.3)
Counseling ( $> 10$ min)	60	2.4 (2.1–2.7)	18.7 (16.8–20.6)

<sup>a</sup> Actual 95% lower confidence estimate equals 1.03.

- Smoking cessation interventions utilizing minimal contact (sessions lasting less than 3 minutes) increase cessation rates over no-contact interventions. (Strength of Evidence = B)

### Content of Smoking Cessation Interventions \_\_\_\_\_

**Recommendation:** Smoking cessation interventions should help smokers recognize and cope with problems encountered in quitting (problem solving/skills training) and should provide social support as part of treatment. (Strength of Evidence = B)

**Recommendation:** Smoking cessation interventions that use some type of aversive smoking procedure (rapid smoking, rapid puffing, other aversive smoking) increase cessation rates and may be used with smokers who desire such treatment or who have been unsuccessful using other interventions. (Strength of Evidence = B)

**Primary Content Types.** Thirty-nine studies met selection criteria for analyses examining the effectiveness of interventions utilizing various types of content. Results are shown in Table 13.

**Evidence.** Three specific content categories yield statistically significant increases in cessation rates relative to no contact (e.g., untreated control conditions). These categories follow:

1. Smoking cessation interventions including content on general problem solving (problem solving/skills training/relapse prevention/stress management) increase cessation rates. (Strength of Evidence = B)
2. Smoking cessation interventions including a supportive component administered during a smoker's direct contact with a clinician (intratreatment social support) increase cessation rates. Please note

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that this refers only to support delivered during direct contact with clinician and does not refer to a social support component implemented outside of this contact, such as attempting to increase social support in the smoker's environment. (Strength of Evidence = B)

3. Smoking cessation interventions including aversive smoking procedure (rapid smoking, rapid puffing, other smoking exposure) increase cessation rates. (Strength of Evidence = B)

The strength of evidence for the various content categories did not warrant an "A" rating for several reasons. First, smoking cessation interventions rarely used a particular content in isolation. Second, various types of content tended to be correlated with other treatment characteristics. For instance, some types of content were more likely to be delivered using a greater number of sessions across longer time periods. Third, it must be noted that all these contents were being compared with no-contact/control conditions. Therefore, the control conditions in this meta-analysis did not control for nonspecific or placebo effects of treatment. This further restricted the ability to attribute efficacy to particular contents, *per se*.

Smoking cessation counseling interventions that included two content areas (general problem solving/skills training and intratreatment social support) were significantly associated with higher smoking cessation rates. General Strategies 1 and 2 outline elements of problem solving and supportive treatments to help the clinician using these treatment components. It must be noted, however, that these two treatment labels are nonspecific and include heterogeneous treatment elements. The third content area associated with superior outcomes was aversive smoking. This involves sessions of guided smoking where the patient smokes intensively, often to the point of discomfort or malaise. Some aversive smoking techniques, such as rapid smoking, may constitute a health risk and should be conducted only with appropriate medical screening and supervision. Aversive smoking interventions have largely been replaced by nicotine replacement strategies.

**Other Content Types—Negative Affect, Cue Exposure, Hypnosis**  
**Acupuncture.** The content areas of acupuncture, hypnosis, negative affect and cue exposure were examined separately because too few studies met selection criteria for inclusion in the primary meta-analysis (reported in Table 13). The efficacy of treatments directed at reduction of negative affect (11 studies) and treatments utilizing cue exposure (four studies) was assessed through a direct review of relevant studies.

Psychiatric comorbidity and negative affect are risk factors for relapse. Preliminary but insufficient evidence suggested that cessation rates can be improved by treatments specifically addressing these issues.

Cue exposure treatment is intended to reduce smoking motivation through repeated exposure to smoking cues without the opportunity to smoke. None of the four cue exposure studies found this treatment superior to comparison treatments. However, these studies all suffered from methodological limitations.