Smoking Cessation
Clinical Guideline Number 18

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The Agency for Health Care Policy and Research (AHCPR) was established in December 1989 under Public Law 101-239 (Omnibus Budget Reconciliation Act of 1989) to enhance the quality, appropriateness, and effectiveness of health care services and access to these services. AHCPR carries out its mission by conducting and supporting general health services research, including medical effectiveness research, facilitating development of clinical practice guidelines, and disseminating research findings and guidelines to health care providers, policymakers, and the public.

The legislation also established within AHCPR the Office of the Forum for Quality and Effectiveness in Health Care (the Forum). The Forum has primary responsibility for facilitating the development, periodic review, and updating of clinical practice guidelines. The guidelines will assist practitioners in the prevention, diagnosis, treatment, and management of clinical conditions.

The Centers for Disease Control and Prevention (CDC) promotes health and quality of life by preventing and controlling disease, injury, and disability. In acknowledgment of the important role clinical practice guidelines can play in reduction of tobacco use, CDC has collaborated with AHCPR as a partner in the development of this Clinical Practice Guideline.

Guidelines are available in formats suitable for health care practitioners, the scientific community, educators, and consumers. AHCPR invites comments and suggestions from users for consideration in development and updating of future guidelines. Please send written comments to Director, Office of the Forum for Quality and Effectiveness in Health Care, AHCPR, Willco Building, Suite 310, 6000 Executive Boulevard, Rockville, MD 20852

Guideline Development and Use

Guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical conditions. This guideline was developed by a private-sector panel convened by the Agency for Health Care Policy and Research (AHCPR) and the Centers for Disease Control and Prevention (CDC). The panel employed an explicit science-based methodology and expert clinical judgment to develop specific statements on smoking cessation.

Extensive literature searches were conducted, and critical reviews and syntheses were used to evaluate empirical evidence and significant outcomes. Peer review was undertaken to evaluate the reliability and utility of the guideline in clinical practice. The panel's recommendations are primarily based on the published scientific literature. When the scientific literature was incomplete or inconsistent in a particular area, the recommendations reflect the professional judgment of panel members and consultants.

The guideline reflects the state of knowledge, current at the time of publication, on effective and appropriate care. Given the inevitable changes in the state of scientific information and technology, periodic review, updating, and revision will be done.

We believe that this AHCPR and CDC-assisted clinical practice guideline will make positive contributions to the quality of care in the United States. We encourage practitioners and patients to use the information provided in the guideline. The recommendations may not be appropriate for use in all circumstances. Decisions to adopt any particular recommendation must be made by the practitioner in light of available resources and circumstances presented by individual patients.

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Publication of this guideline does not necessarily represent endorsement by the U.S. Department of Health and Human Services.

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Abstract

This guideline contains strategies and recommendations designed to assist clinicians, smoking cessation specialists, and health care administrators/insurers/purchasers in identifying tobacco users and supporting and delivering effective smoking cessation interventions. These recommendations were made as a result of an exhaustive and systematic review and analysis of the scientific literature. The primary analytic technique used was meta-analysis. The strength of evidence that served as the basis for each recommendation is clearly indicated in the guideline. Public testimony and a peer review were also part of the guideline's development process, as well as a notice in the Federal Register inviting review. The guideline's principal findings are:

- Every person who smokes should be offered smoking cessation treatment at every office visit.
- Clinicians should ask and record the tobacco-use status of every patient.
- Cessation treatments even as brief as 3 minutes a visit are effective.
- More intense treatment is more effective in producing long-term abstinence from tobacco.
- Nicotine replacement therapy (nicotine patches or gum), clinician-delivered social support, and skills training are particularly effective components of smoking cessation treatment.[a]

Health care systems should make institutional changes that result in the systematic identification of, and intervention with, all tobacco users at every visit.

The guideline proposes strategies for carrying out each of its specific recommendations. For clinicians, these recommendations are (1) systematically identify tobacco users and document their status; (2) strongly urge all smokers to quit; (3) identify smokers willing to make a quit attempt; (4) aid the patient in quitting by helping with a quit plan, offering nicotine replacement therapy, giving advice, and providing supplementary information; and (5) schedule followup contact. Recommendations for smoking cessation specialists are (1) assess the smoker who has entered an intervention program; (2) use a variety of clinical specialists; (3) ensure that the program is sufficiently intensive; (4) use a variety of program formats; (5) include effective counseling techniques; (6) target the smoker's motivation to quit; (7) provide relapse prevention intervention; (8) offer nicotine replacement therapy; and (9) arrange followup contact. Recommendations for health insurance purchasers and health care 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.

[a] As this guideline went to press, nicotine nasal spray was approved for use in the United States by the Food and Drug Administration, joining the nicotine patch and gum as effective available interventions.

Acknowledgments

Many organizations and individuals made significant contributions during the development of this guideline. Although they are too numerous to mention here, the Contributors section lists individual consultants, peer reviewers, and support staff. This guideline would not have been possible without their collaborative efforts.

All persons, organizations, and agencies with an interest in the smoking cessation guideline were invited to participate at a public meeting held in Bethesda, Maryland, on November 9, 1994. The panel gratefully acknowledges the valuable input received during that session.

The panel gratefully acknowledges the extraordinarily supportive efforts of Ernestine W. Murray, RN, MAS, panel project officer from the Office of the Forum for Quality and Effectiveness in Health Care, Agency for Health Care Policy and Research (AHCPR). We also wish to thank Cheryl Campbell of Technical Resources International, Inc., and Sharon Sokoloff, PhD, of Mikalix and Company for their collaboration and cooperation with this project.

The panel particularly thanks the three key consultants in this project: Timothy Baker, PhD, Senior Scientific Advisor; Victor Hasselblad, PhD, Statistical Methodologist; and David Schriger, MD, MPH, Methodologist.

Finally, the panel extends its gratitude and appreciation to the Wisconsin and Alabama staff members for their tireless efforts in bringing this project to completion. In particular, we thank David Wetter, PhD, Project Director; Connie Kohler, PhD, Project Co-Director; Lisa Wetter, Project Manager; Kathleen Reardon, Project Co-Manager; and Sarah Trost, Project Co-Manager.

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: (1) nicotine replacement therapy (nicotine patches or gum), (2) social support (clinician-provided encouragement and assistance), and (3) 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. 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

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

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

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

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 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

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

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

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 1contains data showing the relation between maternal smoking and low birth weight in infants. Data are extracted from Hosmer and Lemeshow (1989). 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, 1992). 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 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 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

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

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

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

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 every time they visit any type of clinician.

Training Clinicians To Intervene With Their Patients Who Smoke

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, Levine, 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, Epps, 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 nonsmoking 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

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).

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 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

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 seem 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

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 at 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 in 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 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, Rubin, 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 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

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).

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 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 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 from 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 vital 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 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 probability that tobacco use is consistently assessed and documented (Fiore, Jorenby, 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 of 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 recommendations:

* 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. Such 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 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 = A)

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 as 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, if ever, available from the study reports. Results are shown in Table 8.

Evidence.

The following statements support the above recommendations:

* Smoking cessation interventions delivered by any single type of health care provider or by multiple providers increase cessation rates relative to 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)
* 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. 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 involves 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.

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)

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 or 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 in 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 recommendations:

* 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 (sessions lasting 3-10 minutes) increase cessation rates over no-contact interventions. (Strength of Evidence = A)
* 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 that this refers only to support delivered during direct contact with a 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 procedures (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 of 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 (three 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 problems and were based on small samples. Hence, at present it would be premature to evaluate cue exposure/extinction interventions.

Separate meta-analyses were conducted for the content categories of hypnosis and acupuncture. Only three acceptable studies examined hypnosis. Because the studies were of poor quality and their results were inconsistent, the evidence was insufficient to assess the effectiveness of hypnosis.

Similarly, evidence was inadequate to support the efficacy of acupuncture as a smoking cessation treatment. The acupuncture meta-analysis comparing "active" acupuncture with "control" acupuncture revealed no difference in efficacy between the two types of procedures, and the odds ratio for active acupuncture was actually smaller than that of control acupuncture. These results suggest that any effect of acupuncture might be produced by factors such as positive expectations about the procedure.

The six studies included in the analysis of acupuncture were examined individually in order to explore acupuncture efficacy further. Of these six studies, five involved nonacupuncture control conditions. Two of these showed acupuncture to be more effective than control conditions, and three showed no difference. Therefore, active acupuncture was not consistently more effective than either placebo/control acupuncture or nonacupuncture control conditions. The panel concluded that there was relatively little evidence available regarding acupuncture and that the existing evidence was inconclusive.

Person-to-Person Treatment: Duration and Number of Sessions

Recommendation: In general, the greater the number of weeks over which person-to-person counseling or treatment is delivered, the more effective it is. Therefore, the duration of smoking cessation interventions should last as many weeks as is feasible given available resources. (Strength of Evidence = A)

Recommendation: Person-to-person treatment delivered over four to seven sessions appears especially effective in increasing cessation rates. Therefore, if available resources permit, clinicians should strive to meet at least four times with quitting smokers. (Strength of Evidence = A)

Duration of Treatment.

Fifty-five studies met selection criteria for the analysis addressing the duration of smoking cessation interventions. Duration of treatment was categorized as less than 2 weeks, 2 weeks to less than 4 weeks, 4 weeks to 8 weeks, and greater than 8 weeks. Less than 2 weeks was used as the reference group. Results are shown in Table 14.

Because the duration of treatment was associated with the intensity of person-to-person contact (length of treatment sessions), an additional analysis examined the effect of duration after controlling for intensity of person-to-person contact. The trend for increasing efficacy with increasing duration remained after controlling for the intensity of person-to-person contact, but only the longest duration showed a significant effect (data not shown).

Evidence.

The efficacy of a smoking cessation intervention increases with longer duration of treatment. The duration of treatment independently contributes to the efficacy of smoking cessation interventions over and above the contribution of the intensity of

person-to-person contact. (Strength of Evidence = A)

Number of Treatment Sessions.

Fifty-five studies involving at least some person-to-person contact met selection criteria for the analysis addressing the impact of number of treatment sessions. The number of treatment sessions was categorized as one or fewer sessions, two to three sessions, four to seven sessions, and greater than seven sessions. One or fewer sessions was used as the reference group. Results are shown in Table 15.

Because number of treatment sessions was associated with the intensity of person-to-person contact (length of treatment sessions), an additional analysis that examined the effect of the number of sessions after controlling for intensity of person-to-person contact was also conducted. Only four to seven sessions remained statistically significant after controlling for the intensity of person-to-person contact.

Evidence.

Multiple treatment sessions increase smoking cessation rates over those produced by one or fewer sessions. The evidence suggests that four to seven sessions may be the most effective range. These results also suggest that the number of treatment sessions, at least four to seven sessions, contributes to the efficacy of smoking cessation interventions over and above the contribution of the intensity of person-to-person contact. (Strength of Evidence = A)

Smoking Cessation Pharmacotherapy

Evaluation of various pharmacotherapies for smoking cessation was conducted using several sources of information. For transdermal nicotine and nicotine gum, several high-quality published meta-analyses were available. For clonidine, sources of information were an existing published meta-analysis, a meta-analysis conducted by guideline staff, and examination of individual studies. For all other pharmacotherapies, the source of information was examination of individual studies.

Recommendation: Patients should be encouraged to use nicotine replacement therapy (patch or gum) for smoking cessation except in the presence of special circumstances (see General Strategies 3 and 5). (Strength of Evidence = A)

Recommendation: Transdermal nicotine (the nicotine patch) is an efficacious smoking cessation treatment that patients should be encouraged to use. The nicotine patch is effective across diverse settings and populations and when used with a variety of psychosocial interventions. (Strength of Evidence = A)

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

Transdermal Nicotine (the nicotine patch).

Five meta-analyses of the efficacy of the nicotine patch have been published (Fiore, Smith, Jorenby, et al., 1994;Gourlay, 1994;Po, 1993;Silagy, Mant, Fowler, et al., 1994;Tang, Law, and Wald, 1994). The primary results of these meta-analyses are summarized in Table 16. Suggestions regarding clinical use of the nicotine patch are provided in General Strategies 3 and 4. General Strategy 4suggests criteria for the use of nicotine replacement therapy.

Evidence.

The following statements are based on published meta-analyses and panel opinion:

* Transdermal nicotine approximately doubles 6- to 12-month abstinence rates over those produced by placebo interventions. Five meta-analyses have concluded that the nicotine patch is a highly effective aid to smoking cessation. (Strength of Evidence = A)
* Transdermal nicotine is consistently more efficacious than placebo treatment regardless of the intensity of any adjuvant psychosocial interventions. However, intensive psychosocial interventions increase absolute abstinence rates among individuals given either placebo or active patch treatment. (Strength of Evidence = A)
* Patients are more likely to comply with transdermal nicotine instructions than with nicotine gum instructions. (Strength of Evidence = C)

Nicotine Gum.

More than 50 studies on the efficacy of nicotine gum have been published, making nicotine gum by far the most extensively investigated pharmacologic treatment for smoking cessation. This body of research has now been summarized by four major meta-analyses (Cepeda-Benito, 1993;Lam, Sze, Sacks, et al., 1987; Silagy, Mant, Fowler, et al., 1994; Tang, Law, and Wald, 1994). Primary results of the three most recent nicotine gum meta-analyses are summarized in Table 17.

Evidence.

The following statements are based on published meta-analyses and panel opinion:

* Nicotine gum improves smoking cessation rates by approximately 40-60 percent compared with control interventions through 12 months of followup.
* Three meta-analyses found the gum to be efficacious in assisting smokers to quit, and this improvement is observed in both self-referred and unselected populations. (Strength of Evidence = A)
* Nicotine gum is consistently more efficacious than control interventions regardless of the intensity of any adjuvant psychosocial intervention, although efficacy is greater when combined with an intensive psychosocial intervention. (Strength of Evidence = B)

* The 4-mg gum is more efficacious than the 2-mg gum as an aid to smoking cessation in highly dependent smokers. (Strength of Evidence = B)

Although nicotine chewing gum is an efficacious smoking cessation treatment, problems with compliance, ease of use, social acceptability, and unpleasant taste have been noted by investigators. Because transdermal nicotine replacement is not associated with these problems, the patch may be more acceptable for most smokers. General Strategy 4contains guidelines for the differential recommendation of the nicotine patch and nicotine gum.

Most side effects of gum use are relatively mild and transient, and many can be resolved by simply correcting the user's chewing technique. Some patients may desire to continue nicotine replacement therapy for periods longer than usually recommended. For instance, studies suggest that when patients are given free access to nicotine gum, 15-20 percent of successful abstainers continue to use the gum for a year or longer (Hajek, Jackson, and Belcher, 1988;Hughes, Wadland, Fenwick, et al., 1991). Although weaning should be encouraged, continued use of nicotine replacement is clearly preferable to a return to smoking with respect to health consequences. This is because, unlike smoking, nicotine replacement products do not (a) contain nonnicotine toxic substances (e.g., "tar"), (b) produce dramatic surges in blood nicotine levels, and (c) produce strong dependence (Henningfield, 1995). Suggestions regarding the clinical use of nicotine gum are provided in General Strategy 5.

Other Nicotine Replacement Interventions.

Two new nicotine replacement interventions, a nicotine nasal spray and a nicotine inhaler, have been developed and tested. Published data on these products are limited, but studies demonstrate a significant benefit compared with placebo interventions (Hjalmarson, Franzon, Westin, et al., 1994;Sutherland, Stapleton, Russell, et al., 1992;Tonnesen, Norregaard, Mikkelsen, et al., 1993). At present, these products are not licensed for prescription use in the United States, and there are limited data regarding their use. Therefore, the panel drew no conclusions about their efficacy and made no recommendations regarding their use. [As this guideline went to press, nicotine nasal spray was approved for use in the United States by the FDA.]

Over-the-Counter Nicotine Replacement Therapy.

The FDA approved nicotine gum for over-the-counter (OTC) use in April 1996, and the nicotine patch may be approved for OTC use by the end of 1996. Although the OTC status of these medications will no doubt increase their availability, this does not reduce the clinician's essential responsibility to intervene with smokers. Once OTC nicotine replacement products are available, the clinician will also continue to have specific responsibilities regarding these products, such as encouraging their use when appropriate, providing counseling, and offering instruction on appropriate use. In addition, the clinician may advise patients regarding the use of an OTC product versus a non-OTC product such as a new nicotine replacement treatment or antidepressant therapy.

Clonidine.

Evidence for the efficacy of clonidine as a smoking cessation intervention was derived from an examination of individual studies, a published meta-analysis, and a fixed-effect meta-analysis conducted by guideline staff that examined clonidine use in women only. The use of a fixed-effects model, opposed to a random-effects model, is a departure from the typical guideline analytic strategy. The fixed-effects meta-analysis was used because of the very small number of studies available for analysis and the different statistical assumptions of the two models (see the technical report).

Evidence.

There is little support for the use of clonidine either as a primary or as an adjunctive pharmacologic treatment for smoking cessation. (Strength of Evidence = B)

Seven clinical trials on clonidine were identified in the initial literature review, but only two fulfilled selection criteria for meta-analysis. Based on these two studies, the guideline meta-analysis suggested that clonidine may be effective with female patients (odds ratio = 3.0, 95 percent C.I. = 1.5-5.9). However, no recommendations were made with respect to clonidine because of the following concerns. First, of the seven trials examining the effectiveness of clonidine for smoking cessation, only two provided adequate long-term followup information. Second, only three of the seven clonidine studies presented results by gender, and only two of these three met meta-analytic selection criteria. Thus, the success of clonidine among women may be the reason for the presentation of results by gender in these studies; that is, there may be a selection bias. Finally, side effects are common with clonidine use, and as many as 25 percent of patients may discontinue clonidine therapy for this reason.

Antidepressants.

Smoking is significantly more prevalent among individuals with a history of depression, and these individuals have more difficulty quitting smoking than do smokers without a history of depression (Anda, Williamson, Escobedo, et al., 1990;Breslau, Kilbey, and Andreski, 1992; Glassman, Helzer, Covey, et al., 1990). Some trials have investigated the use of antidepressants for smoking cessation, but no published articles met selection criteria for review. Because of a paucity of data, the panel drew no conclusions about antidepressant therapy for smoking cessation.

Anxiolytics/Benzodiazepines.

A few trials have evaluated anxiolytics as a treatment for smoking cessation. Individual trials of propranolol (a beta-blocker) and diazepam did not reveal a beneficial effect for these drugs compared with control interventions. Only one study using an anxiolytic (buspirone) revealed evidence of efficacy in smoking cessation. Because of a lack of data, no conclusion was drawn regarding the efficacy of anxiolytics in smoking cessation.

Silver Acetate.

The three randomized clinical trials of silver acetate that met selection criteria revealed no beneficial effects for smoking cessation.

Evidence. The use of silver acetate as either a primary or an adjunctive treatment for smoking cessation was not supported. (Strength of Evidence = B)

Followup Assessment and Procedures

Recommendation: All patients who receive an intervention should be assessed for abstinence at the completion of treatment or during subsequent clinic visits. (1) for abstinent patients, all should receive relapse prevention treatment (see section in Chapter 4, Relapse Prevention). (2) For patients who have relapsed, assess their willingness to quit (Strength of Evidence = C):

* If willing to quit, provide or arrange an additional intervention (see section in Chapter 3, Interventions).
* If not willing to quit at the current time, provide an intervention designed to promote the motivation to quit (see section in Chapter 4, Promoting the Motivation to Quit).

All patients should be assessed with respect to their smoking status at least at the completion of treatment. Additional assessments within the first 2 weeks of quitting should also be considered (Kenford, Fiore, Jorenby, et al., 1994). Abstinent patients should receive relapse prevention treatment (see General Strategy 8) including reinforcement for their decision to quit, congratulations on their success at quitting, and encouragement to remain abstinent. Clinicians should also inquire about current and future threats to abstinence and provide appropriate suggestions for coping with these threats.

Patients who have relapsed should be assessed for their willingness to quit. Patients who are currently motivated to make another quit attempt should be provided with an intervention (see section in Chapter 3, Interventions). Clinicians may wish to increase the intensity of psychosocial treatment at this time or refer the patient to a smoking cessation specialist/program for a more intensive treatment if the patient is willing. In addition, nicotine replacement should be offered to the patient. If the previous cessation attempt included nicotine replacement, the clinician should review whether the patient used these medications in an effective manner and consider use of another form (see General Strategies 3 and 5).

Patients who are unwilling to quit at the current time should receive a brief intervention designed to promote the motivation to quit (see General Strategy 6).

Reimbursement for Smoking Cessation Treatment

Recommendation: Smoking cessation treatments (both pharmacotherapy and counseling) should be provided as paid services for subscribers of health

insurance/managed care. (Strength of Evidence = C)

Recommendation: Clinicians should be reimbursed for delivering effective smoking cessation treatments. (Strength of Evidence = C)

Primary care clinicians frequently cite insufficient insurance reimbursement as a barrier to the provision of preventive services such as smoking cessation treatment (Henry, Ogle, and Snellman, 1987; Orleans, Schoenbach, Salmon, et al., 1989.). Insurance coverage has been shown to increase rates of cessation services utilization and therefore increase rates of quitting. For example, the presence of prepaid or discounted prescription drug benefits increases patients' receipt of nicotine gum, the duration of gum use (Johnson, Hollis, Stevens, et al., 1991), and smoking cessation rates (Cox and McKenna, 1990; Hughes, Wadland, Fenwick, et al., 1991). In addition, an 8-year insurance industry study found that reimbursing physicians for provision of preventive care resulted in reported increases in exercise, seat belt use, and weight loss, as well as decreased alcohol use and a trend (because of small sample size) toward decreased smoking Logsdon, Lazaro, and Meier, 1989).

4. Promoting the Motivation To Quit and Preventing Relapse

Promoting the Motivation To Quit

Recommendation: For patients not willing to initiate a quit attempt at the time of their health care visit, clinicians should engage in a brief intervention designed to promote motivation to quit. (Strength of Evidence = C)

Enhancing the motivation to quit requires some initial steps described in detail earlier in this guideline. Specifically, patients entering a health care setting should have their smoking status assessed regularly. As a result of a systematic, institutionalized assessment of smoking status, clinicians should advise all smokers to quit and assist those willing to make a quit attempt.

Despite receiving a clinician's advice to quit smoking, many patients are not willing to make a commitment to quit. These patients may be uninformed, concerned about the effects of quitting, or demoralized because of previous relapse. Such patients may respond to a motivational intervention. Motivational interventions are characterized by the "4 Rs": relevance, risks, rewards, and repetition. Clinical components of the 4 Rs are shown in General Strategy 6. Finally, some patients may be discouraged by previous relapses. These patients should be informed that most smokers make repeated cessation attempts before achieving long-term abstinence.

Relapse Prevention

Recommendation: When clinicians encounter a recent quitter, they should reinforce the patient's decision to quit, review the benefits of quitting, and assist the patient in resolving any residual problems arising from quitting. (Strength of Evidence = C)

Although most relapse occurs early in the quitting process (Kenford, Fiore, Jorenby, et al., 1994), some relapse occurs months or even years after the quit date (Hatziandreu, Pierce, Lefkopoulou, et al., 1990). Therefore, clinicians should engage in relapse prevention interventions designed to reduce the long-term risks of relapse (Brandon, Tiffany, and Baker, 1986). Interventions should be delivered to former smokers who no longer consider themselves actively engaged in the quitting process. (For information on how to reduce relapse risk among those actively engaged in quitting, see General Strategies 1 and 2.)

Relapse prevention interventions can be delivered by means of either prearranged telephone calls or clinic visits, or any time the clinician encounters an ex-smoker. It is vital that a systematic, institutionalized mechanism be in place to identify ex-smokers, because that is a necessary first step in delivering relapse prevention messages.

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

Minimal Practice

Minimal relapse prevention interventions should be part of every primary care encounter with a patient who has recently quit (General Strategy 7). Because most relapse occurs within the first 3 months after quitting, relapse prevention is especially appropriate during this period (DHHS, 1994). Relapse prevention activities can easily be incorporated into cessation treatments such as problem-solving counseling (see General Strategy 1).

Prescriptive Interventions

These relapse prevention components are individualized based on information obtained about problems the patient has encountered in maintaining abstinence (General Strategy 8). These more intensive relapse prevention interventions may be delivered through primary care or through a specialized clinic or program.

5. Special Populations and Topics

Background

Many factors could potentially affect the choice, delivery, and efficacy of cessation interventions. This possibility raises numerous questions. For instance, should interventions be tailored or modified on the basis of gender, age, or hospitalization status? Should pregnant smokers receive nicotine replacement therapy? Do smoking cessation interventions work with smokeless tobacco users? How do cessation and intervention affect weight, and should treatment be modified with those effects in mind? These special issues are considered in this chapter. It is important to note that many health care specialties can have a key role in addressing these issues (e.g., obstetrics and family practice for pregnant smokers; gynecology and family practice for preconceptional counseling and general health maintenance; pediatrics for children and

adolescents; internal medicine (including cardiology, pulmonology, and oncology) and family practice for hospitalized patients; and dentistry and orthodonture for smokeless tobacco users).

Gender

Recommendation: The same smoking cessation treatments are effective for both men and women. Therefore, the same interventions can be used with both sexes. (Strength of Evidence = B)

One important question regarding quitting smoking is whether men and women should receive different cessation interventions. Smoking cessation clinical trials reveal that the same treatments benefit both men and women. Moreover, epidemiologic studies do not show a consistent gender difference in quit attempts and success rates. Few studies have examined programs specifically tailored to one gender, however. Although research suggests that women benefit from the same interventions as do men, women may face different stressors and barriers to quitting that may be addressed in treatment. These include greater likelihood of depression, weight control concerns, and issues surrounding child care.

Evidence.

There is no consistent evidence of gender differences in response to smoking cessation treatments. (Strength of Evidence = B)

Racial and Ethnic Minorities

Recommendation: Members of racial and ethnic minorities should be provided smoking cessation treatments shown to be effective in this guideline. (Strength of Evidence = B)

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

Ethnic and racial minority groups in the United States -- African Americans, American Indians/Native Americans, Alaskan Natives, Asian and Pacific Islanders, Hispanics -- experience higher mortality in a number of disease categories compared with the white majority. For example, African Americans experience substantial excess mortality from cancer, cardiovascular disease, and infant death, all of which are directly affected by tobacco use (CDC, 1987). American Indians and Alaskan Native subgroups have some of the highest documented rates of infant mortality caused by sudden infant death syndrome (Coultas, Gong, Grad, et al., 1994). Therefore, there is a critical need to deliver effective smoking intervention to ethnic and racial minorities.

There are well-documented differences between racial and ethnic minorities and the white majority in smoking patterns and in smoking and quitting prevalence (Orleans,

Schoenbach, Salmon, et al., 1989;Stotts, Glynn, and Baquet, 1991). In addition, smoking prevalence and patterns vary substantially among minority subgroups (Coultas, Gong, Grad, et al., 1994). Racial and ethnic minorities also differ from whites in awareness of health effects of smoking (Brownson, Jackson-Thompson, Wilkerson, et al., 1992) and a sense of fatalism that may affect disease prevention efforts. On the other hand, both nicotine addiction and desire to quit appear to be prevalent across all racial and ethnic groups (Orleans, Schoenbach, Salmon, et al., 1989; Royce, Hymowitz, Corbett, et al., 1993; Stotts, Glynn, and Baquet, 1991).

Few studies have examined interventions specifically tailored to particular ethnic or racial groups, and there is no consistent evidence that tailored cessation programs result in higher quit rates in these groups. Moreover, smoking cessation interventions developed for the general population have been effective with racial and ethnic minority participants. Therefore, clinicians who see minority group patients should offer them treatments identified as effective in this guideline. Clinicians should remain sensitive, however, to individual differences and health beliefs that may affect treatment acceptance and success (see section in Chapter 3, Specialized Assessment).

Because of the small amount of research on this topic, there is currently little support for the obligatory tailoring of cessation treatments for minority populations. Logically, however, tailoring may be necessary at times for effective intervention. For instance, cessation counseling or self-help materials must be conveyed in a language understood by the smoker. Additionally, culturally appropriate models or examples may increase the smoker's acceptance of treatment. Certainly, practices with multiethnic or multiracial populations should make culturally appropriate materials available whenever resources permit.

Among subgroups of racial and ethnic minorities, some smoke at exceptionally high rates and suffer high rates of smoking-attributable morbidity and mortality (Coultas, Gong, Grad, et al., 1994;Sugarman, Warren, Oge, at al., 1992). Yet, there is relatively little extant research on optimal interventions or on the specific barriers or impediments to successful cessations for these populations (e.g., relatively low educational attainment, inadequate access to medical care). These are important topics for future research.

Evidence.

The following statements support the above recommendations:

* Smoking cessation treatments identified as effective in this guideline increase smoking cessation rates among members of ethnic and racial minorities. (Strength of Evidence = B)
* Smoking is especially prevalent among some racial and ethnic minority subgroups and results in mortality and morbidity. (Strength of Evidence = A)
* Although little research has been done on the effectiveness of treatment tailoring for ethnic and racial minority populations, some types of tailoring such as the use of language-appropriate materials should increase treatment effectiveness. (Strength of

Evidence = C)

Pregnancy

Recommendation: Pregnant smokers should be strongly encouraged to quit throughout pregnancy. Because of the serious risks of smoking to the pregnant smoker and fetus, pregnant smokers should be offered intensive counseling treatment. (Strength of Evidence = A)

Recommendation: Minimal interventions should be used if more intensive interventions are not feasible. (Strength of Evidence = C)

Recommendation: Motivational messages regarding the impact of smoking on both the pregnant smoker and fetus should be given. (Strength of Evidence = C)

Recommendation: Nicotine replacement should be used during pregnancy only if the increased likelihood of smoking cessation, with its potential benefits, outweighs the risk of nicotine replacement and potential concomitant smoking. (Strength of Evidence = C)

Smoking in pregnancy imparts risks to both the woman and the fetus. Many women are motivated to quit during pregnancy, and health care professionals can take advantage of this motivation by reinforcing the notion that cessation will be best for the fetus, with postpartum benefits for both mother and children. On the other hand, clinicians should be aware that some pregnant women may try to hide their smoking status.

Quitting smoking prior to conception or early in the pregnancy is most beneficial, but health benefits result from cessation at any time. Therefore, a pregnant woman who still smokes should continue to be encouraged and helped to quit. Women who quit smoking during pregnancy have a high rate of relapse in the postpartum period. Relapse is common in the postpartum period even among women who have maintained total abstinence from tobacco for 6 or more months during pregnancy. Relapse postpartum may be decreased by continued emphasis on the relationship between maternal smoking and poor health outcomes (sudden infant death syndrome, respiratory infections, asthma, and middle ear disease) in infants and children. General Strategy 9 outlines clinical factors to address when counseling pregnant women about smoking.

No clinical trials have assessed the benefits and risks of nicotine replacement therapy as an aid to smoking cessation in pregnant women. In a review of this topic Benowitz (1991) concluded that, for pregnant women, the benefits of nicotine replacement therapy outweigh the risks of both continued smoking and nicotine replacement itself. Benowitz limited this conclusion, however, to those pregnant women who cannot stop without replacement therapy and suggested that benefits would be the greatest for heavy smokers.

To assess the effectiveness of smoking cessation during pregnancy, the panel used both a published meta-analysis (Mullen, Ramirez, and Groff, 1994) and a meta-analysis

conducted by panel staff (Table 18). The meta-analysis conducted by panel staff was based on six studies evaluating the effectiveness of smoking cessation counseling in pregnant smokers. The effectiveness of counseling interventions in these studies was compared with either "no treatment" or "usual care" conditions. The latter usually consisted of a recommendation to stop smoking that was often supplemented by provision of self-help material or referral to a stop-smoking program. Because of the small number of studies available for analysis, only the impact of counseling (greater than 10 minutes of person-to-person contact) was examined in the meta-analysis. Less intense interventions, such as those involving "minimal contact" or "brief counseling" (see subsection in Chapter 3, Intensity of Person-to-Person Clinical Intervention), were not examined because of a lack of relevant studies. Both the panel meta-analysis and the published meta-analysis yielded essentially the same finding -- smoking cessation interventions during pregnancy are effective and should be used to benefit both the woman and the fetus.

Evidence.

The following statements support the above recommendations:

* A published meta-analysis and a meta-analysis conducted by panel staff (n = 14 studies) suggest that counseling interventions during pregnancy increase quit rates above those of pregnant women who do not receive such interventions. (Strength of Evidence = A)
* Because of the small number of studies examining minimal counseling in pregnant smokers, no focused statistical tests were possible on this topic. However, the panel concluded that minimal counseling has a beneficial effect and should be used if more intensive counseling is not feasible. (Strength of Evidence = C)

Hospitalized Smokers

Recommendation: For every hospitalized patient, the following steps should be taken: (a) ask each patient on admission if he/she smokes and document smoking status; (b) for current smokers, list smoking status on the admission problem list and as a discharge diagnosis; (c) assist all smokers with quitting during the hospitalization, using treatments identified as effective in this guideline, including nicotine replacement therapy if appropriate; and (d) provide advice and assistance on how to remain abstinent after discharge. (Strength of Evidence = C)

It is vital that hospitalized patients attempt to quit smoking, because smoking may interfere with their recovery. Among cardiac patients, second heart attacks are more common in those who continue to smoke (Multiple Risk Factor Intervention Trial Research Group, 1990). Lung, head, and neck cancer patients who are successfully treated, but who continue to smoke, are at elevated risk for a second cancer (Browman, Wong, Hodson, et al., 1993). Smoking negatively affects bone and wound healing (Jones, 1985).

Every hospital in the United States must now be smoke free if it is to be accredited by

the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). As a result, hospitalized patients may be particularly motivated to make a quit attempt for two reasons. First, the illness resulting in hospitalization may have been caused or exacerbated by smoking, highlighting the patient's personal vulnerability to the health risks of smoking. Second, motivation may be enhanced during hospitalization because the smoker is temporarily housed in a smoke-free environment. For these reasons, clinicians should use hospitalization as an opportunity to promote smoking cessation in their patients who smoke (Hurt, Lauger, Offord, et al., 1991; Stevens, Glasgow, Hollis, et al., 1993). Patients in long-term care facilities should also receive cessation interventions identified as efficacious in this guideline.

Specifically, clinicians and hospital administrators should collaborate to ensure that systems are in place that identify the smoking status of all patients admitted to a hospital and that provide at least a brief clinical intervention to every hospitalized patient who smokes.

Finally, smokers may experience nicotine withdrawal symptoms during a hospitalization. Clinicians should consider providing temporary nicotine patch therapy during a hospitalization to reduce such symptoms.

Efficacy of Inpatient Hospital Smoking Cessation Treatment

Five studies met selection criteria for analyses examining the effectiveness of inpatient hospital smoking cessation treatment compared with usual care. Because of the limited number of studies, no attempt was made to separate the level or type of treatment. Results are shown in Table 19.

Evidence.

Smoking cessation interventions among hospitalized patients increase rates of smoking cessation. (Strength of Evidence = A)

Smokers With Psychiatric Comorbidity

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

Recommendation: Although it is not necessary to assess for psychiatric comorbidity prior to initiating smoking treatment, such assessment may be helpful in that it allows the clinician to prepare for an increased likelihood of smoking relapse or for exacerbation of the comorbid condition in response to nicotine withdrawal. (Strength of Evidence = C)

The term "psychiatric comorbidity" refers to the co-occurrence of smoking with another psychiatric disorder. Psychiatric comorbidity is important to the assessment and treatment of smokers for several reasons:

* Psychiatric disorders are more common among smokers than in the general population. For instance, as many as 30-50 percent of patients seeking smoking cessation services may have a history of depression, and 20 percent or more may have a history of alcohol abuse or dependence (Brandon, 1994; Glassman, Stetnes, Walsh, et al., 1988; Hall, Munoz, Reus, et al., 1993; also cf. Breslau, 1995; Breslau, Kilbey, and Andreski, 1994).

* Smoking cessation or nicotine withdrawal may exacerbate a patient's comorbid condition. For instance, smoking cessation may elicit or exacerbate depression among patients with a prior history of affective disorder (Glassman, 1993;Glassman, Covey, Dalack, et al., 1993).

* As noted in the Specialized Assessment section in Chapter 3, smokers with psychiatric comorbidities have heightened risk for relapse to smoking after a cessation attempt (Brandon, 1994; Glassman, Covey, Dalack, et al., 1993; Hall, Munoz, Reus, et al., 1993).

Although psychiatric comorbidity places smokers at increased risk for relapse, there is also evidence that such smokers can be helped by smoking cessation treatments (Breckenridge, 1990; Burling, Marshall, and Seidner, 1991; Hall, Munoz, and Reus, 1994;Hartman, Jarvik, and Wilkins, 1989; Hartman, Leong, Glynn, et al., 1991). There is currently too little evidence to determine whether smokers with psychiatric comorbidity benefit more from specialized or tailored cessation treatments than from standard treatments (e.g., Hall, Munoz, and Reus, 1994;Zelman, Brandon, Jorenby, et al., 1992). Even though some smokers may experience exacerbation of a comorbid condition upon quitting smoking, most evidence suggests that cessation entails little adverse impact. For instance, patients in inpatient psychiatric units are able to stop smoking with few adverse effects (e.g., little increase in aggression, or nonadherence to treatment; Hurt, Eberman, Slade, et al., 1993; Resnick, 1993). Additionally, there is little evidence that patients with other chemical dependencies relapse to other drug use when they stop smoking (Hurt, Eberman, Slade, et al., 1993). Finally, stopping smoking may affect the pharmacokinetics of certain psychiatric agents (e.g., Hughes, 1993). Therefore, clinicians may wish to monitor closely the actions or side effects of psychiatric medications in smokers making a quit attempt.

Weight Gain After Smoking Cessation

Recommendation: The clinician should inform smokers that they are likely to gain weight when they stop smoking. The clinician should recommend that smokers not take strong measures (e.g., strict dieting) to counteract weight gain during a quit attempt. Moreover, ex-smokers should wait until they are confident that they will not return to smoking before trying to reduce their weight. (Strength of Evidence = C)

Recommendation: For smokers who are greatly concerned about weight gain, the clinician may prescribe or recommend nicotine gum, which has been shown to delay weight gain after quitting. (Strength of Evidence = A)

Key facts about smoking, smoking cessation, and weight gain follow:

* The majority of smokers who quit smoking gain weight. Most will gain fewer than 10 pounds, but there is a broad range of weight gain, with as many as 10 percent of quitters gaining as much as 30 pounds (Williamson, Madans, Anda, et al., 1991).

* Women tend to gain slightly more weight than men, and for both sexes, African Americans, people under age 55, and heavy smokers (those smoking more than 25 cigarettes/day) are at elevated risk for major weight gain (Emont and Cummings, 1987;Williamson, Madans, Anda, et al., 1991).

* For many smokers, especially women, concerns about weight or fears about weight gain are motivators to start smoking or continue smoking (Gritz, Klesges, and Meyers, 1989; Klesges and Klesges, 1988;Klesges, Meyers, Klesges, et al., 1989).

* Weight gain that follows smoking cessation is a negligible health threat compared with the risks of continued smoking (DHHS, 1990; Williamson, Madans, Anda, et al., 1991).

* No experimentally validated strategies or treatments are effective in preventing postcessation weight gain. In fact, some evidence suggests that attempts to prevent weight gain (e.g., strict dieting) may undermine the attempt to quit smoking (Hall, Tunstall, Vila, et al., 1992; Perkins, 1994; Pirie, McBride, Hellerstedt, et al., 1992).

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

* Postcessation weight gain appears to be caused both by increased intake (e.g., eating, alcohol consumption) and by metabolic adjustments. The involvement of metabolic mechanisms suggests that even if quitting smokers do not increase their caloric intake, they will still gain some weight (Hatsukami, LaBounty, Hughes, et al., 1993; Hofstetter, Schutz, Jequier, et al., 1986; Klesges and Shumaker, 1992; Moffatt and Owens, 1991; Schwid, Hirvonen, and Keesey, 1992).

* Once a quitting smoker relapses and begins smoking at precessation levels, he or she will usually lose some or all of the weight gained during the quit attempt (Moffatt and Owens, 1991;Noppa and Bengtsson, 1980; Stamford, Matter, Fell, et al., 1986).

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

Recommendations To Address Weight Gain

How should the clinician deal with concerns about weight gain? First, the clinician should neither deny the likelihood of weight gain nor minimize its significance to the patient. Rather, the clinician should inform the patient about the likelihood of weight gain and prepare the patient for its occurrence. However, the clinician should counter exaggerated fears about weight gain given the relatively moderate weight gain that

typically occurs. Certain types of information may help prepare the patient for postcessation weight gain (see General Strategy 10).

Second, before and during the quit attempt the clinician should stress that quitting smoking is the patient's primary, immediate priority, and that the patient will be most successful in the long run if he or she does not take strong measures (e.g., strict dieting) to counteract weight gain during a quit attempt (see General Strategy 10).

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

Smokeless Tobacco Use

Recommendation: Smokeless tobacco (chewing tobacco and snuff) users should be identified and strongly encouraged to quit. (Strength of Evidence = C)

Recommendation: Smokeless tobacco users should be treated with the same psychosocial cessation interventions recommended for smokers. (Strength of Evidence = B)

Like cigarette smoking, the use of smokeless tobacco, such as chewing tobacco and snuff, produces addiction to nicotine and has serious health consequences. Consumption of smokeless tobacco products has increased in recent years (Glover and Glover, 1992; Marcus, Crane, Shopland, et al., 1989), especially among young males. Clinicians should offer quitting advice and assistance to their patients who use smokeless tobacco.

There is a need for smokeless tobacco information and assistance, but currently little research-based information is available on these topics. A small number of studies have evaluated both multicomponent and brief psychosocial interventions for smokeless tobacco cessation. Results of these evaluations suggest that the same cessation interventions that are effective with smokers are effective with smokeless tobacco users. Currently, there is little evidence on the effectiveness of pharmacologic treatments for smokeless tobacco use. However, nicotine replacement may help smokeless tobacco users just as it does smokers. This is an important area for further research.

Evidence.

There is limited evidence that nonpharmacologic treatments used for smoking cessation are also effective in smokeless tobacco cessation. (Strength of Evidence = B)

Children and Adolescents: Primary Prevention of Tobacco Addiction

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

Recommendation: Cessation interventions shown to be effective with adults should be considered for use with children and adolescents. The content of these interventions should be modified to be developmentally appropriate. Nicotine replacement should be considered only when there is clear evidence of nicotine dependence and a clear desire to quit tobacco use. (Strength of Evidence = C)

The onset of tobacco use is a pediatric concern. Among adult daily smokers, 90 percent tried their first cigarette and 70 percent were daily users at or before age 18. Among high school seniors who had used smokeless tobacco, 79 percent had first done so by the ninth grade (DHHS, 1994). Young people begin to smoke or use tobacco for a variety of reasons related to social norms, advertising, peer pressure, parental smoking, and curiosity, but evidence suggests that nicotine addiction is established rapidly (CDC, 1995).

About three out of every four adolescent smokers have made at least one serious attempt to quit smoking and have failed (Moss, Allen, Giovino, et al., 1992). About 20 percent of high school seniors smoke daily (Green, 1979; Johnston, O'Malley, and Bachman, 1995). Among seniors who smoke daily and expect that they will not be smoking in 5 years, 73 percent are still smoking when surveyed 5-6 years after their senior year (DHHS, 1994).

Prevention of Tobacco Use

Efforts to prevent tobacco use should be conducted by many types of individuals and groups (e.g., parents, teachers, clergy, government officials, medical societies) and in diverse venues (e.g., home, school, church, youth group). The clinician can target children and adolescents both inside and outside the clinical setting. In the clinical setting, discussion of tobacco-related issues should begin before the onset of adolescence, and preferably before entry into junior high school. These efforts should continue throughout high school. Patient charts should clearly reflect that tobacco has been discussed, and should indicate the smoking status of the patient and parents or caretakers. Clinical prevention activities are listed in General Strategy 11. Prevention strategies useful in more general settings can be found in the recent Institute of Medicine Report, "Growing Up Tobacco Free" (Lynch, Bonnie, and Institute of Medicine Committee on Preventing Nicotine Addiction in Children and Adults, 1994) and Healthy People 2000: National Health Promotion and Disease Prevention Objectives (DHHS, 1991).

Tobacco Use Cessation in Children and Adolescents

Little research evidence exists regarding either the effectiveness of psychosocial cessation interventions with children and adolescents or the safety and efficacy of pharmacological interventions with this population. Because there is no evidence that nicotine replacement is harmful for children and adolescents, clinicians should consider its use when nicotine dependence is obvious. However, because of the psychosocial and behavioral aspects of smoking in adolescents, clinicians should be confident of the patient's genuine nicotine dependence and desire to quit before instituting pharmacotherapy. Factors such as degree of dependence and body weight should be considered when selecting nicotine replacement therapy dosage.

Children and adolescents may benefit from community- and school-based intervention activities designed especially for these age groups. The messages delivered by these programs should be reinforced by the clinician (DHHS, 1994). Treatment of adolescents and children who smoke is an important research area. Along with clinical trials of interventions, studies of the "experimenters" or occasional tobacco users in this population are needed.

Evidence.

Most adolescent tobacco users are addicted to nicotine and report they want to quit but are unable to do so; they experience relapse rates and withdrawal symptoms similar to those reported by adults. Little intervention research involves children and adolescent tobacco users. (Strength of Evidence = C)

Glossary

All-comers.: Individuals included in a smoking cessation study regardless of whether they sought to participate. For example, if cessation treatment was delivered to all smokers visiting a primary care clinic, the treatment population would be coded as "all-comers." Presumably, individuals who seek to participate in smoking cessation studies are more likely motivated to quit, and studies limited to these individuals may produce higher quit rates.

Anxiolytic.: A pharmacologic agent used to reduce anxiety symptoms.

Aversive smoking.: Several types of therapeutic techniques that involve smoking in an unpleasant or concentrated manner. These techniques pair smoking with negative associations or responses. Notable examples include rapid smoking, rapid puffing, focused smoking, and satiation smoking.

Biochemical confirmation.: The use of assays of smoking-related biochemical compounds such as thiocyanate, cotinine, nicotine, and carboxyhemoglobin to verify smokers' reports of abstinence.

Cessation percentage.: The percentage of smokers who achieve long-term abstinence from smoking. The major cessation measure for this guideline was the percentage of smokers in a group or treatment condition who were abstinent at a followup point that occurred at least 5 months after treatment.

Cigarette fading/smoking reduction prequit.: Interventions that reduce the number of cigarettes smoked or nicotine intake prior to a patient's quit date. This may be accomplished through advice to cut down or by systematically restricting access to cigarettes. This category includes interventions using computers and/or devices to accomplish nicotine reduction prequit.

Clinician.: A professional directly providing health care assistance.

Clinic screening system/system intervention.: The strategies used in clinics and practices for the delivery of clinical services. Clinic screening system interventions involve changes in staff protocols designed to enhance the identification of and intervention with patients who smoke. Examples include affixing smoking status stickers to patients' charts, expanding the vital signs to include smoking, and incorporating smoking status items into patient questionnaires.

Clonidine.: An alpha-2-adrenergic agonist typically used as an antihypertensive agent, but also used as a pharmacotherapy for smoking cessation. The Food and Drug Administration has not approved clonidine as a smoking cessation aid.

Contingency contracting/instrumental contingencies.: Interventions where individuals earn rewards for cigarette abstinence and incur costs or unpleasant consequences for smoking. To receive this classification code, actual, tangible consequences had to be contingent upon smoking or abstinence. Thus, simple agreements about a quit date, or other agreements between treatment providers and patients without specifiable consequences, were not included in this category. Deposits refunded based on study attendance and/or other incentives that are not contingent upon smoking abstinence or relapse did not receive this code.

Cue exposure/extinction.: Interventions that repeatedly expose patients to smoking-related cues in the absence of nicotine reinforcement in an attempt to extinguish affective/motivational responding to such cues. This includes treatments where patients are encouraged to perform the smoking self-administration ritual, excepting inhalation.

Diazepam.: A benzodiazepine anxiolytic.

Exercise/fitness component.: Includes any intervention that contains a component related to exercise/fitness. The intensity of interventions falling within this category varied from the mere provision of information/advice about exercise/fitness to the classes.

Extratreatment social support component.: Interventions or elements of an intervention wherein patients are provided with the tools to find social support on their own outside of treatment. This category is distinct from intratreatment social support, in which social support is delivered by treatment staff.

Formats.: Refers to the context in which a smoking cessation intervention is delivered. May be either self-help, individual counseling, or group counseling.

Hotline/helpline.: A telephone line dedicated to over-the-phone smoking intervention. A hotline/helpline treatment occurs when a hotline/helpline number is provided or a referral to a hotline/ helpline is made.

Intent-to-treat analysis.: Treatment outcome analyses where abstinence percentages are based

on all subjects randomized to treatment conditions, rather than on just those subjects who completed the intervention or who could be contacted at followup.

Intratreatment social support.: Refers to an intervention component that provides support, help, or encouragement as part of the treatment.

Logistic regression.: Statistical technique to determine the statistical association or relation between/among two or more variables, and where one of the variables, the dependent variable, is dichotomous (has only two levels of magnitude) (e.g., abstinent vs. smoking).

Meta-analysis.: A statistical technique that estimates the impact of a treatment or variable across a set of related investigations.

Minimal contact.: Minimal contact refers to interventions that involved very brief contact between clinicians and patients. It was coded based on the length of contact between clinicians and patients (3 minutes or less). If that information was unavailable, it was coded based on the content of the contact between clinicians and patients.

Motivation.: Includes interventions designed to bolster patients' resolve to quit through manipulations such as setting a quit date, use of a contract with a specified quit date, reinforcement correspondence (letters mailed from clinical/study staff after initial contact congratulating patient on decision to quit or on early success), providing information about the health risks of smoking, and so on.

Negative affect/depression component.: Interventions in this category are designed to train patients to cope with negative affect after cessation. The intensity of the interventions in this category may vary from prolonged counseling to the simple provision of information about postquit mood and suggestions for dealing with it. To receive this code, interventions targeted depressed mood, not simply stress. Interventions aimed at teaching subjects to cope with stressors were coded as problem solving. When it was unclear whether an intervention was directed at negative affect/depression or at psychosocial stress, problem solving was the default code.

Nicotine replacement therapy.: Refers to nicotine pharmacotherapy for smoking cessation. The two nicotine replacement therapy delivery systems currently approved for use in the United States are nicotine chewing gum and the nicotine patch.

Odds ratio.: The odds of an outcome on one variable, given a certain status on another variable(s). This ratio expresses the increase in risk of a given outcome if the variable is present.

Oral mucosa.: The mucous membranes that line the mouth.

Person-to-person intervention.: In-person contact between a clinician and a patient(s) for the purpose of smoking intervention or assessment.

Primary care provider.: Practitioner in one of the health professions (e.g., medicine, nursing, psychology, dentistry/oral health, physical and respiratory therapy) who provides health care services for problems other than smoking per se. Primary care providers are encouraged to identify smokers and to intervene with them, regardless of whether smoking cessation is the

patient's presenting problem.

Problem solving/skills training.: Refers to a smoking cessation intervention in which smokers are trained to identify and cope with events or problems that increase the likelihood of their smoking. For example, quitters might be trained to anticipate stressful events and to use coping skills such as distraction or deep breathing to cope with an urge to smoke. Related and similar interventions are coping skill training, relapse prevention, and stress management.

Purchaser.: A corporation, company, or other consortium that purchases health care benefits for a group of individuals.

Propranolol.: A beta-adrenergic blocker often used as an antihypertensive agent.

Quit day.: The day of a given cessation attempt during which a patient tries to abstain totally from smoking. Also refers to a motivational intervention whereby a patient commits to quit tobacco use on a specified day.

Randomized controlled trial.: For the purposes of this guideline, a study in which subjects are assigned to conditions on the basis of chance, and where at least one of the conditions is a control or a comparison condition.

Reference group.: In meta-analyses, refers to the group against which other groups are compared.

Relaxation/breathing.: Interventions in which patients are trained in relaxation techniques. Interventions using meditation, breathing exercises, and so on, fit this category. This category should be distinguished from the category of problem solving, which includes a much wider range of stress-reduction/management strategies.

Self-selected.: Refers to a patient population that sought out or agreed to participate in a study of smoking cessation.

Serum cotinine.: Blood levels of cotinine, nicotine's major metabolite. This is often used to estimate a patient's tobacco/nicotine self-administration prior to quitting, and to confirm abstinence self-reports during followup.

Serum nicotine.: Blood levels of nicotine. This is often used to assess a patient's tobacco/nicotine self-administration prior to quitting, and to confirm abstinence self-reports during followup.

Silver acetate.: Silver acetate reacts with cigarette smoke to produce an unpleasant taste and has been investigated as a deterrent to smoking.

Specialized assessments.: Refers to assessment of patient characteristics such as nicotine dependence and motivation for quitting that may allow clinicians to tailor interventions to the needs of the individual patient.

Starter kits.: Self-help materials and/or programs provided by a pharmaceutical company to assist patients in successfully quitting smoking while using a pharmaceutical agent.

Stepped-care.: The practice of initiating treatment with a low-intensity intervention and then referring treatment failures to successively more intense interventions.

Transdermal nicotine.: Refers to delivery of nicotine by diffusion through the skin. Often used as a synonym for "nicotine patch."

Treatment matching.: Differential assignment of patients to treatments based on their pretreatment characteristics. Treatment matching is based on the notion that particular types of smokers are most likely to benefit from particular types of treatments.

Weight/diet/nutrition component.: Any program dealing with weight issues. Interventions that teach nutrition/diet/weight management strategies, incorporate daily/weekly weight monitoring (for reasons other than routine data collection), require or suggest energy intake maintenance/reduction, and/or convey nutritional information/tips/counseling receive this code.

Contributors

Smoking Cessation Guideline Panel

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Dr. Bailey is clinically active in the treatment of patients with pulmonary disease. He is the Principal Investigator of research projects in the areas of asthma, tuberculosis, and smoking cessation and is the author of numerous articles, chapters, and books on these topics. In addition to his positions at the University of Alabama at Birmingham, he currently serves as the Tuberculosis Control Officer at the Veterans Affairs Medical Center in Birmingham. From 1989 to 1992, Dr. Bailey served as the Chairman of the National Heart, Lung, and Blood Institute (NHLBI) Task Force on the Prevention of Asthma. He received the NHLBI Preventive Pulmonary Academic Award from 1989 through 1994.

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Dorfman holds degrees in economics from Harvard/Radcliffe Universities, a master's degree in Health Services Administration and an M.D. from Stanford University, and trained in reproductive health epidemiology at the Centers for Disease Control and Prevention. She is board certified both in obstetrics and gynecology and in public health/general preventive medicine. Dr. Dorfman has consulted for state, regional, national, and international organizations and was Commissioner of Health for Orange County, NY, from 1988 to 1994. She also has published and presented extensively for professional and lay audiences, serves

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Mr. Tommasello, a pharmacist, is an Associate Professor of Clinical Pharmacy at the University of Maryland School of Pharmacy, and Director, Office of Substance Abuse Studies, which he founded. He has worked in the addiction field since 1973 and acquired advanced degrees in both pharmacology and epidemiology, specializing in drug abuse and addiction. He is active in clinical research and treatment in addictions and has created educational programs that have served as national models for pharmacists and other health and human service providers. He is the president of the Maryland Pharmacists' Rehabilitation Committee, which provides advocacy and treatment access for impaired pharmacists. He has published in the areas of general principles of assessment and treatment, methadone maintenance care, and adolescent drug abuse and addiction. Mr. Tommasello is a Ph.D. candidate in Policy Sciences at UMBC, where his focus has been on health policy analysis. His dissertation is entitled, "The Effects of State Policies on Addiction Intervention in the Health Professions: The Case of Pharmacy."

Louise Villejo, MPH, CHES

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As the Director of the Patient Education Office at the M.D. Anderson Cancer Center, Ms. Villejo is responsible for the design, implementation, evaluation, and management of patient and family education programs. She has assisted in the writing, publication, and production of more than 100 patient education booklets and videotapes. For the past 10 years, she has served on the National Cancer Institute's Patient Education Committee and Network as well as on numerous other Federal and private advisory and planning boards and committees. Ms. Villejo's publications include articles on smoking cessation and cancer patient education.

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Dr. Wewers, an Adult Nurse Practitioner, has been conducting smoking cessation research since completing her Ph.D. in Nursing at the University of Maryland in 1986. She is funded by the National Institutes of Health to investigate reinforcement for nicotine in both human and animal models of dependence. Her clinical research has examined nurse-managed smoking cessation interventions. Dr. Wewers is Chair-elect of the Nursing Assembly of the American Thoracic Society and serves as Director of the Nursing Center for Tobacco Intervention at Ohio State University.