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Guideline Update Development and Use

e 2008 update to *Treating Tobacco Use and Dependence*

is Public Health Service-sponsored Clinical Practice Guideline update gives hope to the 7 out of 10 smokers who visit a clinician each year. is Guideline urges every clinician, health plan, and health care institution to make treating tobacco dependence a top priority during these visits. Please ask your patients two key questions: “Do you smoke?” and “Do you want to quit?” followed by use of the recommendations in this Guideline.

Abstract

Treating Tobacco Use and Dependence: 2008 Update, a Public Health Service-sponsored Clinical Practice Guideline, is a product of the Tobacco Use and Dependence Guideline Panel ("the Panel"), consortium representatives, consultants, and sta . ese 37 individuals were charged with the responsibility of identifying e ective, experimentally validated tobacco dependence treatments and practices. e updated Guideline was sponsored by a consortium of eight Federal Government and nonpro t organizations: the Agency for Healthcare Research and Quality (AHRQ); Centers for Disease Control and Prevention (CDC); National Cancer Institute (NCI); National Heart, Lung, and Blood Institute (NHLBI); National Institute on Drug Abuse (NIDA); American Legacy Foundation; Robert Wood Johnson Foundation (RWJF); and University of Wisconsin School of Medicine and Public Health's Center for Tobacco Research and Intervention (UW-CTRI).

is Guideline is an updated version of the 2000 *Treating Tobacco Use and Dependence: Clinical Practice Guideline* that was sponsored by the U.S. Public Health Service, U. S. Department of Health and Human Services.

An impetus for this Guideline update was the expanding literature on tobacco dependence and its treatment. e original 1996 Guideline was based on some 3,000 articles on tobacco treatment published between 1975 and 1994. e 2000 Guideline entailed the collection and screening of an additional 3,000 articles published between 1995 and 1999. e 2008 Guideline update screened an additional 2,700 articles; thus, the present Guideline update re ects the distillation of a literature base of more than 8,700 research articles. Of course, this body of research was further reviewed to identify a much smaller group of articles that served as the basis for focused Guideline data analyses and review.

is Guideline contains strategies and recommendations designed to assist clinicians; tobacco dependence treatment specialists; and health care administrators, insurers, and purchasers in delivering and supporting e ective treatments for tobacco use and dependence. e recommendations were made as a result of a systematic review and meta-analysis of 11 speci c topics identi ed by the Panel (proactive quitlines; combining counseling and medication relative to either counseling or medication alone; varenicline; various medication combinations; long-term medications; ces-

formal education; cessation interventions for adolescent smokers; cessation interventions for pregnant smokers; cessation interventions for individuals with psychiatric disorders, including substance use disorders; providing cessation interventions as a health bene t; and systems interventions, including provider training and the combination of training and systems interventions). e strength of evidence that served as the basis for each recommendation is indicated clearly in the Guideline update. A dra of the Guideline update was peer reviewed prior to publication, and the input of 81 external reviewers was considered by the Panel prior to preparing the nal document. In addition, the public had an opportunity to comment through a *Federal Register* review process. e key recommendations of the updated Guideline, *Treating Tobacco Use and Dependence: 2008 Update*, based on the literature review and expert Panel opinion, are as follows:

Ten Key Guideline Recommendations

e overarching goal of these recommendations is that clinicians strongly recommend the use of e ective tobacco dependence counseling and medication treatments to their patients who use tobacco, and that health systems, insurers, and purchasers assist clinicians in making such e ective treatments available.

1. Tobacco dependence is a chronic disease that o en requires repeated intervention and multiple attempts to quit. E ective treatments exist, however, that can signi cantly increase rates of long-term abstinence.

2. It is essential that clinicians and health care delivery systems consistently identify and document tobacco use status and treat every tobacco user seen in a health care setting.

3. Tobacco dependence treatments are e ective across a broad range of populations. Clinicians should encourage every patient willing to make a quit attempt to use the counseling treatments and medications recommended in this Guideline.

4. Brief tobacco dependence treatment is e ective. Clinicians should o er every patient who uses tobacco at least the brief treatments shown to be e ective in this Guideline.

9. If a tobacco user currently is unwilling to make a quit attempt, clinicians should use the motivational treatments shown in this Guideline to be e ective in increasing future quit attempts.

10. Tobacco dependence treatments are both clinically e ective and highly cost-e ective relative to interventions for other clinical disorders. Providing coverage for these treatments increases quit rates. Insurers and purchasers should ensure that all insurance plans include the counseling and medication identi ed as e ective in this Guideline as covered bene ts.

e updated Guideline is divided into seven chapters that provide an overview, including methods (Chapter 1); information on the assessment of tobacco use (Chapter 2); clinical interventions, both for patients willing and unwilling to make a quit attempt at this time (Chapter 3); intensive interventions (Chapter 4); systems interventions for health care administrators, insurers, and purchasers (Chapter 5); the scienti c evidence supporting the Guideline recommendations (Chapter 6); and information relevant to speci c populations and other topics (Chapter 7).

A comparison of the ndings of the updated Guideline with the 2000 Guideline reveals the considerable progress made in tobacco research over the brief period separating these two publications. Tobacco dependence increasingly is recognized as a chronic disease, one that typically requires ongoing assessment and repeated intervention. In addition, the updated Guideline o ers the clinician many more e ective treatment strategies than were identi ed in the original Guideline. ere now are seven different rst-line e ective agents in the smoking cessation pharmacopoeia, allowing the clinician and patient many di erent medication options. In addition, recent evidence provides even stronger support for counseling (both when used alone and with other treatments) as an e ective tobacco

will receive e ective tobacco dependence treatment and successfully stop tobacco use. For instance, making tobacco dependence treatment a covered bene t of insurance plans increases the likelihood that a tobacco user will receive treatment and quit successfully. Data strongly indicate that e ective tobacco interventions require *coordinated interventions*. Just as the clinician must intervene with his or her patient, so must the health care administrator, insurer, and purchaser foster and support tobacco intervention as an integral element of health care delivery. Health care administrators and insurers should ensure that clinicians have the training and support to deliver consistent, e ective intervention to tobacco users.

One important conclusion of this Guideline update is that the most e ective way to move clinicians to intervene is to provide them with information regarding multiple e ective treatment options and to ensure that they have ample institutional support to use these options. Joint actions by clinicians, administrators, insurers, and purchasers can encourage a culture of health care in which failure to intervene with a tobacco user is inconsistent with standards of care.

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Fiore MC, Jaén CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update*. Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.

e complete Guideline author list can be found on the title page.

Acknowledgments

is Guideline would not have been possible without the collaborative efforts of many individuals and organizations. Each made signi cant contributions throughout the process of updating this document. Although too numerous to list here, the Contributors section of this publication provides a listing of support sta , individual peer reviewers, and others. Some individuals and organizations, however, deserve special mention.

e Panel wishes to acknowledge the support and guidance provided by the consortium partners in general and their dedicated, hard-working representatives in particular. In addition to the Guideline Liaisons, the Panel gratefully acknowledges the extraordinarily supportive e orts and substantial contributions of Jean Slutsky, Director, Center for Outcomes and Evidence, AHRQ, and the sta at the O ce of Communications and

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Executive Summary

Context

e 1996 *Smoking Cessation Clinical Practice Guideline*[1] emphasized the dire health consequences of tobacco use and dependence, the existence of e ective treatments, and the importance of inducing more smokers to use such treatments. It also called for newer, even more e ective tobacco

of clinicians and health care delivery entities. Finally, every state now has a telephone quitline, increasing access to e ective treatment.

e scant dozen years following the publication of the rst Guideline have ushered in similarly impressive changes. In 1997, only 25 percent of managed health care plans covered any tobacco dependence treatment; this gure approached 90 percent by 2003,[16] although this increased coverage o en includes barriers to use. Numerous states added Medicaid coverage for tobacco dependence treatment since the publication of the rst Guideline so that, by 2005, 72 percent o ered coverage for at least one Guideline-recommended treatment.[16-18] In 2002, e Joint Commission (formerly JCAHO), which accredits some 15,000 hospitals and health care programs, instituted an accreditation requirement for the delivery of evidence-based tobacco dependence interventions for patients with diagnoses of acute myocardial infarction, congestive heart failure, or pneumonia (*www.coreoptions.com/new_site/jcahocore.html*; hospital-speci c results: *www.hospitalcompare.hhs.gov*). Finally, Medicare, the Veterans Health Administration, and the United States Military now provide coverage for tobacco dependence treatment. Such policies and systems changes are paying o in terms of increased rates of assessment and treatment of tobacco use.

Data show that the rate at which smokers report being advised to quit smoking has approximately doubled since the early 1990s.[19-22] Recent data also suggest a substantial increase in the proportion of smokers receiving more intensive cessation interventions.[23,24] e National Committee for Quality Assurance (NCQA) reports steady increases for both commercial insurers and Medicaid in the discussion of both medications and strategies for smoking cessation.[25] Finally, since the rst Guideline was published in 1996, smoking prevalence among adults in the United States has declined from about 25 percent to about 21 percent.[26]

is Guideline update also casts into stark relief those areas in which more progress is needed. ere is a need for innovative and more e ective coun-

tobacco use. e rst Guideline, the 1996 *Smoking Cessation Clinical Practice Guideline No. 18*, was sponsored by the Agency for Healthcare Policy and Research (AHCPR, now the Agency for Healthcare Research and Quality [AHRQ]), U.S. Department of Health and Human Services (HHS).

at Guideline re ected scienti c literature published between 1975 and 1994. e second Guideline, published in 2000, *Treating Tobacco Use and Dependence*, was sponsored by a consortium of U. S. Public Health Service (PHS) agencies (AHRQ; Centers for Disease Control and Prevention [CDC]; National Cancer Institute [NCI]; National Heart, Lung, and Blood Institute [NHLBI]; National Institute on Drug Abuse [NIDA]) as well as the Robert Wood Johnson Foundation (RWJF) and the University of Wisconsin Center for Tobacco Research and Intervention (UW-CTRI). at Guideline re ected the scienti c literature published from 1975 to 1999.

e current 2008 update addresses literature published from 1975 to 2007.

e updated Guideline was written in response to new, e ective clinical treatments for tobacco dependence that have been identi ed since 1999.

ese treatments promise to enhance the rates of successful tobacco cessation. e original 1996 Guideline was based on some 3,000 articles on tobacco treatment published between 1975 and 1994. e 2000 Guideline required the collection and screening of an additional 3,000 articles published between 1995 and 1999. e 2008 Guideline update screened an additional 2,700 articles; thus, the present Guideline update re ects the distillation of a literature base of more than 8,700 research articles. is body of research of course was further reviewed to identify a much smaller group of articles, based on rigorous inclusion criteria, which served as the basis for focused Guideline data analyses and review.

e 2008 updated Guideline was sponsored by a consortium of eight Federal Government and private nonpro t organizations: AHRQ, CDC, NCI, NHLBI, NIDA, American Legacy Foundation, RWJF, and UW-CTRI. All of these organizations have as their mission reducing the human costs of tobacco use. Given the importance of this issue to the health of all Americans, the updated Guideline is published by the PHS, HHS.

Guideline Style and Structure

is Guideline update was written to be applicable to all tobacco users—those using cigarettes as well as other forms of tobacco. erefore, the terms “tobacco user” and “tobacco dependence” will be used in prefer-

ence to “smoker” and “cigarette dependence.” In some cases, however, the evidence for a particular recommendation consists entirely of studies using cigarette smokers as participants. In these instances, the recommendation and evidence refers to “smoking” to communicate the parochial nature of the evidence. In most cases, though, Guideline recommendations are relevant to all types of tobacco users. Finally, most data reviewed in this Guideline update are based on adult smokers, although data relevant to adolescent smokers are presented in Chapter 7.

e updated Guideline is divided into seven chapters that integrate prior and updated ndings:

Chapter 1, Overview and Methods, provides the clinical practice and scienti c context of the Guideline update project and describes the methodology used to generate the Guideline ndings.

Chapter 2, Assessment of Tobacco Use, describes how each patient presenting at a health care setting should have his or her tobacco use status determined and how tobacco users should be assessed for willingness to make a quit attempt.

Chapter 3, Clinical Interventions for Tobacco Use and Dependence, summarizes e ective brief interventions that can easily be delivered in a primary care setting. In this chapter, separate interventions are described for the patient who is *willing* to try to quit at this time, for the patient who is *not yet willing* to try to quit, and for the patient who has recently quit.

Chapter 4, Intensive Interventions for Tobacco Use and Dependence, outlines a prototype of an intensive tobacco cessation treatment that comprises strategies shown to be e ective in this Guideline. Because intensive treatments produce the highest success rates, they are an important element in tobacco intervention strategies.

Chapter 5, Systems Interventions, targets health care administrators, insurers, and purchasers, and o ers a blueprint to changes in health care delivery and coverage such that tobacco assessment and intervention become a standard of care in health care delivery.

Chapter 6, Evidence and Recommendations, presents the results of Guideline literature reviews and statistical analyses and the recommendations

2. It is essential that clinicians and health care delivery systems consistently identify and document tobacco use status and treat every tobacco user seen in a health care setting.

3. Tobacco dependence treatments are e ective across a broad range of populations. Clinicians should encourage every patient willing to make a quit attempt to use the counseling treatments and medications recommended in this Guideline.

4. Brief tobacco dependence treatment is e ective. Clinicians should o er every patient who uses tobacco at least the brief treatments shown to be e ective in this Guideline.

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5. Individual, group, and telephone counseling are e ective, and their

- Clinicians also should consider the use of certain combinations of medications identi ed as e ective in this Guideline.

7. Counseling and medication are e ective when used by themselves for treating tobacco dependence. e combination of counseling and medication, however, is more e ective than either alone. us, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.

8. Telephone quitline counseling is e ective with diverse populations and has broad reach. erefore, clinicians and health care delivery systems should both ensure patient access to quitlines and promote quitline use.

9. If a tobacco user currently is unwilling to make a quit attempt, clinicians should use the motivational treatments shown in this Guideline to be e ective in increasing future quit attempts.

10. Tobacco dependence treatments are both clinically e ective and highly cost-e ective relative to interventions for other clinical disorders. Providing coverage for these treatments increases quit rates. Insurers and purchasers should ensure that all insurance plans include the counseling and medication identi ed as e ective in this Guideline as covered bene ts.

Guideline Update: Advances

A comparison of the ndings of the 2008 Guideline update with the 2000 Guideline reveals the considerable progress made in tobacco research over the brief period separating these two works. Among many important differences between the two documents, the following deserve special note:

- T e updated Guideline has produced even stronger evidence that counseling is an e ective tobacco use treatment strategy. Of particular note are ndings that counseling adds signi cantly to the e ectiveness of tobacco cessation medications, quitline counseling is an e ective intervention with a broad reach, and counseling increases abstinence among adolescent smokers.

- T e updated Guideline o ers the clinician a greater number of e fective medications than were identi ed in the previous Guideline. Seven

cating clinicians, administrators, and policymakers about the importance of tobacco dependence and its treatment. It stimulated discussions that addressed the development of tobacco dependence treatment programs at the Federal and State levels and by professional medical organizations.

Signi cant new research ndings regarding tobacco use and its treatment led to the 2000 Guideline update, which was authored by the expert panel that developed the 1996 Guideline. e 2000 Guideline update was a product of the U. S. Public Health Service (PHS), sponsored by a consortium of private and public partners, including AHRQ; National Cancer Institute (NCI); National Heart, Lung, and Blood Institute (NHLBI); National Institute on Drug Abuse (NIDA); Centers for Disease Control and Prevention (CDC); Robert Wood Johnson Foundation (RWJF); and University of Wisconsin School of Medicine and Public Health Center for Tobacco Research and Intervention (UW-CTRI).

e 2000 Guideline, titled *Treating Tobacco Use and Dependence*, comprised speci c evidence-based recommendations to guide clinicians, tobacco treatment specialists, insurers, purchasers, and health care administrators in their e orts to develop and implement clinical and institutional changes that support the reliable identi cation, assessment, and treatment of patients who use tobacco. is title underscores three truths about tobacco use.[68] First, all tobacco products—not just cigarettes—exact devastating costs on the Nation's health and welfare. Second, for most users, tobacco use results in true drug dependence, comparable to the dependence caused by opiates, amphetamines, and cocaine.[69-72] ird, both chronic tobacco use and dependence warrant clinical intervention and, as with other chronic disorders, these interventions may need to be repeated over time.[73,74]

e 2000 *Treating Tobacco Use and Dependence* document was the most widely disseminated Guideline ever released by AHRQ, with more than 5 million copies of the Guideline and related products distributed. Moreover, it has had an enormous in uence on tobacco use treatment and policy worldwide, serving as the basis for Guidelines in Australia, Canada, Chile, Japan, Portugal, and Switzerland, among other countries.

e continued expansion of new scienti c ndings on the e ective treatment of tobacco use led to calls for the current update, *Treating Tobacco Use and Dependence: 2008 Update*. e 2008 update reviewed scienti c

evidence from 1975 to 2007 on selected topics and in total reviewed more than 8,700 scienti c publications. e result of this methodologically rigorous review is an updated set of recommendations on e ective counseling and medication treatments and institutional policies that can guide clinicians, specialists, and health systems in intervening with tobacco users. Appendix D summarizes new recommendations and changes to the 2000 Guideline.

e clinician audience for this Guideline update is all professionals who provide health care to tobacco users. is includes: physicians, nurses, physician assistants, medical assistants, dentists, hygienists, respiratory therapists, psychologists, mental health counselors, pharmacists, and others. e ultimate bene ciaries of the Guideline are tobacco users and their families.

Most tobacco users in the United States are cigarette smokers. As a result, the majority of clinician attention and research in the eld has focused on the treatment and assessment of smoking. Clinicians, however, should intervene with all tobacco users, not just with those who smoke cigarettes. To foster a broad implementation of this Guideline update, every e ort has been made to describe interventions so that they are relevant to all forms of tobacco use. In some sections of this Guideline, the term "smoker" is used instead of "tobacco user." e use of the term "smoker" means that all relevant evidence for a recommendation arises from studies of cigarette smokers. Additional discussion of noncigarette forms of tobacco use is found in Chapter 7.

e 2008 Guideline update generally is consistent with the ndings of the 2000 Guideline (see Appendix D). It also is important to note that other Guidelines and analyses on the treatment of tobacco dependence have been published with essentially consistent ndings, including those from the American Psychiatric Association,[75,76] the American Medical Association,[77] the American Dental Association,[78] the American Nurses Association,[79] the American College of Obstetricians and Gynecologists, the Institute of Medicine,[80] the United Kingdom Guideline,[81] and the Cochrane Collaboration (*www.cochrane.org/index.htm*). Finally, throughout the Guideline update, the terms "tobacco use treatment" and "tobacco dependence treatment" will be used interchangeably to emphasize the fact that both chronic use and dependence merit clinical intervention.

Tobacco Dependence as a Chronic Disease

Tobacco dependence displays many features of a chronic disease. Only a minority of tobacco users achieve permanent abstinence in an initial quit attempt. e majority of users persist in tobacco use for many years and typically cycle through multiple periods of remission and relapse. A failure to appreciate the chronic nature of tobacco dependence may impede clinicians' consistent assessment and treatment of the tobacco user over time.

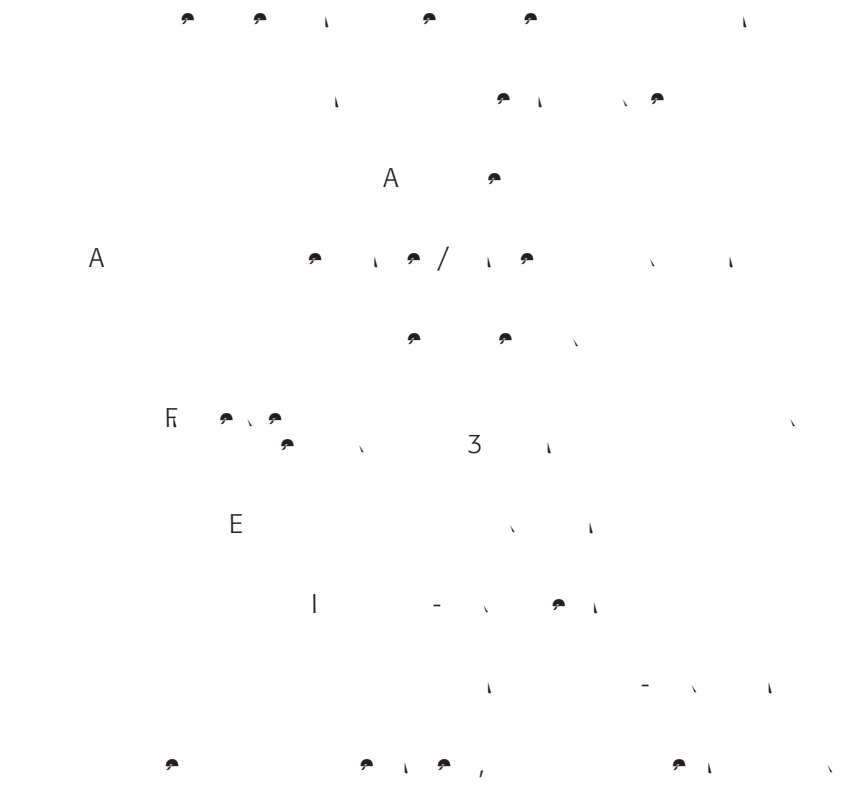
Epidemiologic data suggest that more than 70 percent of the 45 million smokers in the United States today report that they want to quit, and approximately 44 percent report that they try to quit each year.[3] Unfortunately, most of these e orts are both unaided and unsuccessful. For example, among the 19 million adults who attempted to quit in 2005,[39] only 4 to 7 percent were likely successful.[82,83] ese statistics may discourage both smokers and clinicians.

Modern approaches to treating tobacco use and dependence should re ect the chronicity of tobacco dependence. A chronic disease model recog(a)3(s)-8(e m)4

In updating the Guideline, the Panel has presented evidence-based ana-

enced by two goals. e rst was to identify e ective treatment strategies.

Figure 1.1. 2008 Guideline development process



comparative e ectiveness. Most of these randomized trials, however, were conducted with individuals who proactively sought treatment and who volunteered to ful ll various research requirements. It is possible that these individuals were more highly motivated to quit smoking than the typical smoker encountered in a clinical practice setting. us, the percentage abstinent estimates supplied with the meta-analyses may overestimate the actual level of abstinence produced by some of the treatments in real-world settings. Analyses conducted for the previous Guideline editions, though, suggest that the treatment e ect sizes (odds ratios or ORs) are relatively stable across individuals seeking treatment ("treatment seekers") and those recruited via inclusive recruitment strategies ("all-comers"). Randomized controlled trials were exclusively used in meta-analyses. However, the Panel recognized that variations in study inclusion criteria sometimes were warranted. For instance, research on tobacco interventions in adolescents frequently assigns interventions on the basis of larger units, such as schools. ese units, rather than individuals, were allowed to serve as units of analysis when analyzing interventions for adolescents. In such cases, studies were combined for inclusion in meta-analyses if the study satis- ed other review criteria. A similar strategy was followed in the review of health systems research.

In certain areas, research other than randomized clinical trials was evaluated and considered to inform Panel opinion and judgment, though not submitted to meta-analysis. is occurred with topics such as tobacco dependence treatment in speci c populations, tailoring interventions, and cost-e ectiveness of tobacco dependence treatment.

Literature Review and Inclusion Criteria

Approximately 8,700 articles were screened to identify evaluable literature. is gure includes approximately 2,700 articles added to the literature since publication of the 2000 Guideline. ese articles were obtained through searches of 11 electronic databases and reviews of published abstracts and bibliographies. An article was deemed appropriate for meta-analysis if it met the criteria for inclusion established *a priori* by the Panel. ese criteria were that the article: (a) reported the results of a randomized, placebo/comparison controlled trial of a tobacco use treatment intervention randomized on the patient level (except as noted above); (b) provided followup results at least 5 months a er the quit date (except in the case of studies evaluating tobacco dependence treatments

Outcome Data

Six-month followup a er the quit date is a standard followup duration for reporting data from clinical trials. erefore, focusing on a 6-month timepoint in meta-analyses allowed the investigators to capture the greatest number of studies for analysis. Also, research indicates that a high percentage of those who ultimately return to smoking will do so by 6 months.[95-98]

who completed treatment. e vast majority of studies across all analyses reported intent-to-treat data and these data were used if both types of data were available.

Studies were coded for how the outcome measures were reported—"point prevalence," "continuous," or "unknown/other." If abstinence data were based on tobacco use occurrence within a set time period (usually 7 days) prior to a followup assessment, the outcome measure was coded as "point prevalence." "Continuous" was used when a study reported abstinence based on whether study subjects were continuously abstinent from tobacco use since their quit day. "Unknown/other" was used when it was not possible to discern from the study report whether the authors used a point prevalence or continuous measure for abstinence or if abstinence was measured from some point other than the quit day.

As in the 1996 and 2000 Guidelines, a point prevalence outcome measure (7-day point prevalence, when available), rather than continuous abstinence, was used as the chief outcome variable. Point prevalence was preferred for several reasons. First, this was the modal reporting method among the analyzable studies. Second, continuous abstinence data may underestimate the percentage of individuals who are abstinent at particular followup timepoints, although some data suggest that these rates are similar.[99] Finally, most relapse begins early in a quit attempt and persists.[95-97,100-102] A point prevalence measure taken at 6 months certainly would capture the great majority of those relapse events. erefore, whenever possible, 7-day point prevalence abstinence data were used. If point prevalence data were not available, the preferred alternative was continuous abstinence data.

Meta-Analytic Techniques

fore, the odds ratio can be seen roughly as the odds of an outcome on one variable, given a certain status on another variable(s). In the case above, the odds of a low birth-weight infant are about double for women who smoke compared with those who do not.

Table 1.2. Relation between maternal smoking and low birth-weight in infants

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

Once odds ratios were obtained from the meta-analyses, 95 percent con - dence intervals (C.I.) were estimated around the odds ratios. An odds ratio is only an estimate of a relation between variables. e 95 percent con - dence interval presents an estimate of the precision of the particular odds ratio obtained. If the 95 percent con dence interval for a given odds ratio does not include "1," then the odds ratio represents a statistically signi cant di erence between the evaluated treatment and the reference or control condition at the 0.05 level. e con dence intervals generally will not be perfectly symmetrical around an odds ratio because of the distributional properties of the odds ratio. e con dence intervals do not reveal whether active treatments di er signi cantly from one another, only whether they di er from the comparison condition (e.g., placebo medication, no contact). In the inclusive meta-analysis on medications, comparisons of an active medication versus the nicotine patch were accomplished via *a posteriori* contrasts, not on the basis of nonoverlapping con dence intervals.

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

odds ratios and abstinence rates presented across the di erent tables are estimated relative to di erent placebo or control conditions.

How To Read the Data Tables

Table 1.3 depicts results from one of the meta-analyses reported in this Guideline update. is table presents results from the analysis of the e ects of proactive telephone counseling (see Formats of Psychosocial Treatments in Chapter 6). In this table, the comparison condition, or "reference group," for determining the impact of di erent treatment options was smokers who received minimal or no counseling or self-help. e "Estimated odds ratio" column reveals that treatment conditions receiving proactive telephone counseling had an odds ratio of 1.6. e odds ratio indicates a statistically signi cant e ect because the lower boundary of the con dence interval did not include "1." is odds ratio means that when smokers receive proactive telephone counseling, they are more than one and one-half times more likely to remain abstinent than if they had received minimal or no counseling or self-help.

Table 1.3. Meta-analysis (2008): Effectiveness of and estimated abstinence rates for proactive telephone counseling compared to minimal interventions, self-help, or no counseling (n = 9 studies)

Intervention	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
Minimal or no counseling or self-help	11	1.0	10.5
Quitline counseling	11	1.6 (1.4–1.8)	15.5 (13.8–17.3)

e column labeled "Estimated abstinence rate" shows the abstinence percentages for the two treatment conditions. For instance, the reference condition (minimal or no counseling) in the analyzed data set was associated with an abstinence rate of 10.5 percent. Consistent with the odds ratio data reviewed above, proactive telephone counseling produced modest increases in abstinence rates (15.5%).

e total number of studies included in each meta-analysis is provided within the title of the corresponding table. A list of published articles used in each meta-analysis can be found at: *www.surgeongeneral.gov/tobacco/gdlnrefs.htm*. Finally, the 2008 Guideline update includes meta-analyses

completed for the 1996, 2000, and 2008 Guidelines. In the title of each meta-analysis, the year in which it was first published is provided.

The column labeled "Number of arms" specifies the number of treatment groups across all analyzed studies that contributed data to the various treatment conditions (e.g., Quitline counseling was provided in 11 treatment arms). Therefore, this column depicts the number of treatment groups relevant to each analyzed category. Because a study may have multiple treatment groups, the number of treatment arms may exceed the number of studies included in a meta-analysis.

The outcome data in the tables may include findings from both studies with "all-comers" (individuals who did not seek a treatment intervention) and "self-selected" populations, studies using point-prevalence and continuous abstinence endpoints, and studies with and without biochemical confirmation, except where otherwise described. Some meta-analyses (such as those evaluating medications) included predominantly studies with "self-selected" populations who volunteered for intensive treatment. In addition, in medication studies, both experimental and control subjects typically received substantial counseling. Both of these factors might have produced higher abstinence rates in reference or placebo subjects than typically are observed among self-quitters. Finally, although there is an important scientific distinction between "efficacy" and "effectiveness,"[106] this 2008 clinical update uses the term "effectiveness" exclusively, recognizing that the majority of the studies summarized here reflect efficacy research, which requires random assignment and a high degree of experimental control. This was done for purposes of clarity for the intended clinical audience.

Strength of Evidence

Every recommendation made by the Panel bears a strength-of-evidence rating that indicates the quality and quantity of empirical support for the recommendation. Each recommendation and its strength of evidence reflects consensus of the Guideline Panel.

The three strength-of-evidence ratings are described below:

A. Multiple well-designed randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings.

B. Some evidence from randomized clinical trials supported the recommendation, but the scienti c support was not optimal. For instance, few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation.

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

As noted previously, the Panel evaluated evidence from nonrandomized trials to inform members' understanding of certain topics (e.g., policy issues). If treatment recommendations were based primarily on such evidence, they were of the "C" level and depended on the consistency of ndings across di erent studies. In some areas, the highest quality evidence does not depend on randomized trials (e.g., cost-e ectiveness). In these areas, the strength-of-evidence rating depended on the number, quality, and consistency of the studies and evidence. Finally, the Panel declined to make recommendations when there was no relevant evidence or the evidence was too weak or inconsistent to support a recommendation.

Caveats Regarding Recommendations

e reader should note some caveats regarding Guideline recommendations. First, an absence of studies should not be confused with a proven lack of e ectiveness. In certain situations, there was little direct evidence regarding the e ectiveness of some treatments, and in these cases the Panel usually rendered no opinion. Second, even when there were enough studies to perform a meta-analysis, a nonsigni cant result does not prove ine ectiveness. Rather, nonsigni cance merely indicates that e ectiveness was not demonstrated given the data available.

e primary emphasis of this Guideline update is to identify e ective interventions, not to rank-order interventions in terms of e ectiveness.

e most important goal of the analytic process is to identify e ective interventions. Selection or use of particular intervention techniques or strategies usually is a function of practical factors: patient preference, time available, training of the clinician, cost, and so on. e Panel believes clinicians should choose the most appropriate intervention from among

the e ective interventions identi ed in this Guideline update, given

Organization of the Guideline Update

is updated Guideline is divided into seven chapters that re ect the major components of tobacco dependence treatment (see Figure 1.2 for the treatment model):

Chapter 1, Overview and Methods, provides an overview and rationale for the updated Guideline, as well as a detailed description of the methodology used to review the scienti c literature and develop the original and updated Guidelines.

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

Chapter 3, Clinical Interventions for Tobacco Use and Dependence, is intended to provide clinicians with guidance as they use brief interventions

A. Counseling and Psychosocial Evidence: Provides recommendations and analysis results regarding screening for tobacco use and specialized assessment, advice, intensity of clinical interventions, type of clinician, format, followup procedures, types of counseling and behavioral therapies, and the combination of counseling and medication.

B. Medication Evidence: Provides recommendations and analysis results regarding the seven first-line medications, combination medications, second-line medications, and other medication issues.

C. Systems Evidence: Provides recommendations and analysis results regarding systems changes, including provider training, cost-effectiveness, and health insurance coverage for tobacco use treatments.

Chapter 7, Specific Populations and Other Topics, provides information on specific populations, including HIV-positive smokers; hospitalized smokers; lesbian/gay/bisexual/transgender smokers; smokers with low SES/limited formal education; smokers with medical comorbidities; older smokers; smokers with psychiatric disorders, including substance use disorders; racial and ethnic minorities; women smokers; children and adolescents; light smokers; and noncigarette tobacco users. This chapter also presents information and recommendations relevant to weight gain after quitting smoking, with specific recommendations regarding future research on this topic.

References

Given the volume of literature referenced in this Guideline, references are listed at *www.surgeongeneral.gov/tobacco/gdlnrefs.htm*, rather than in this

Figure 1.2. Model for treatment of tobacco use and dependence

Chapter 2 Assessment of Tobacco Use

At least 70 percent of smokers see a physician each year, and almost one-third see a dentist.[19,110] Other smokers see physician assistants, nurse practitioners, nurses, physical and occupational therapists, pharmacists, counselors, and other clinicians. erefore, virtually all clinicians are in a position to intervene with patients who use tobacco. Moreover, 70 percent of smokers report wanting to quit,[111] and almost two-thirds of smokers who relapse want to try quitting again within 30 days.[112] Finally, smokers cite a physician's advice to quit as an important motivator for attempting to stop smoking.[113-118] ese data suggest that most smokers are interested in quitting, clinicians and health systems are in frequent contact with smokers, and clinicians have high credibility with smokers.

Unfortunately, clinicians and health systems do not capitalize on this opportunity consistently. According to the National Committee for Quality Assurance's (NCQA) *State of Health Care Quality Report*,[119] there has been some improvement in tobacco dependence clinical intervention for the insured population. In 2005, 71.2 percent of commercially insured smokers received cessation advice (up slightly from 69.6% in 2004); and 75.5 percent of Medicare smokers received advice to quit, up 11 percentage points from 2004 for this group. Despite this progress, there is a clear need for additional improvement. Only 25 percent of Medicaid patients reported any practical assistance with ts r14(n)28(y)5( )5(p)17(r)5(10(t)6(emi)12Tc/>(t)5(s5(M)31(ed)5(i)5(

ers itself increases rates of clinician intervention. E ective identi cation of tobacco use status not only opens the door for successful interventions (e.g., clinician advice and treatment), but also guides clinicians to identify appropriate interventions based on patients' tobacco use status and willingness to quit. Based on these ndings, the Guideline update recommends that clinicians and health care systems seize the o ce visit for universal assessment and intervention. Speci cally, ask every patient who presents to a health care facility if s/he uses tobacco (Ask), advise all tobacco users to quit (Advise), and assess the willingness of all tobacco users to make a quit attempt at this time (Assess) (the rst 3 of the 5 A's; see Chapter 3).

Chapter 3 Clinical Interventions for Tobacco Use and Dependence

Background

is section of the Guideline presents speci c strategies to guide clinicians providing brief interventions (less than 10 minutes). ese brief interventions can be provided by all clinicians but are most relevant to clinicians who see a wide variety of patients and are bound by time constraints (e.g., physicians, nurses, physician assistants, nurse practitioners, medical assistants, dentists, hygienists, respiratory therapists, mental health counselors, pharmacists, etc.). e strategies in this chapter are based on the evidence described in Chapters 6 and 7, as well as on Panel opinion. Guideline analysis suggests that a wide variety of clinicians can implement these strategies e ectively.

Why should members of a busy clinical team consider making the treatment of tobacco use a priority? e evidence is compelling: (1) clinicians can make a di erence with even a minimal (less than 3 minutes) intervention (see Chapter 6); (2) a relation exists between the intensity of intervention and tobacco cessation outcome (see Chapter 6); (3) even when patients are not willing to make a quit attempt at this time, clinician-delivered brief interventions enhance motivation and increase the likelihood of future quit attempts[122] (see Chapter 6); (4) tobacco users are being primed to consider quitting by a wide range of societal and environmental factors (e.g., public health messages, policy changes, cessation marketing messages, family members); (5) there is growing evidence that smokers who receive clinician advice and assistance with quitting report greater satisfaction with their health care than those who do not;[23,87,88] (6) tobacco use interventions are highly cost e ective (see Chapter 6); and (7) tobacco use has a high case fatality rate (up to 50% of long-term smokers will die of a smoking-caused disease[123]).

e goal of these strategies is clear: to change clinical culture and practice patterns to ensure that every patient who uses tobacco is identi ed,

lowup contacts to prevent relapse (Strategy A5). If the patient is unwilling to make a quit attempt, the clinician should provide a motivational intervention (Strategies B1 and B2) and *arrange* to address tobacco depT9EF(n)4(F(n)4ce

deliver all care personally.[130] Evidence indicates that full implementation of the 5 A's in clinical settings may yield results that are superior to partial implementation.[131]

e e ectiveness of tobacco intervention may re ect not only the contributions of the individual clinician, but also the systems and other clinical resources available to him or her. For instance, o ce systems that institutionalize tobacco use assessment and intervention will greatly foster the likelihood that the 5 A's will be delivered (see Chapter 5). e 5 A's, as described in Table 3.1, are consistent with those recommended by the NCI[132,133] and the American Medical Association,[77] as well as others.[75,134-137]

e clinical situation may suggest delivering these intervention components in an order or format di erent from that presented, however. For example, clinical interventions such as: Ask/Assess, Advise, Agree on a goal, Assist, Arrange followup; Ask and Act; and Ask, Advise, and Refer have been proposed.[116,130,138-140]

When "Assisting" smokers, in addition to counseling, all smokers making a quit attempt should be o ered medication, except when contraindicated or with speci c populations for which there is insu cient evidence of e ectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). See Tables 3.2 to 3.11 for guidelines for prescribing medication for treating tobacco use and dependence.

A. For the Patient Willing To Quit

Strategy A1. *Ask*—Systematically identify all tobacco users at every visit

Action	Strategies for implementation
Implement an officewide system that ensures that, for *every* patient at *every* clinic visit, tobacco use status is queried and documented.[a]	**Expand the vital signs to include tobacco use, or use an alternative universal identification system.[b]** **VITAL SIGNS** **Blood Pressure: _____** **Pulse: _____ Weight: _____** **Temperature: _____** **Respiratory Rate: _____** **Tobacco Use (circle one): Current Former Never**

[a] Repeated assessment is *not* necessary in the case of the adult who has never used tobacco or has not used tobacco for many years and for whom this information is clearly documented in the medical record.

[b] Alternatives to expanding the vital signs include using tobacco use status stickers on all patient charts or indicating tobacco use status via electronic medical records or computerized reminder systems.

Strategy A2. *Advise*—Strongly urge all tobacco users to quit

Action	Strategies for implementation
In a *clear, strong, and personalized* manner, urge every tobacco user to quit.	Advice should be: • *Clear*—"It is important that you quit smoking (or using chewing tobacco) now, and I can help you." "Cutting down while you are ill is not enough." "Occasional or light smoking is still dangerous." • *Strong*—"As your clinician, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you." • *Personalized*—Tie tobacco use to current symptoms and health concerns, and/or its social and economic costs, and/or the impact of tobacco use on children and others in the household. "Continuing to smoke makes your asthma worse, and quitting may dramatically improve your health." "Quitting smoking may reduce the number of ear infections your child has."

Strategy A3. *Assess*—Determine willingness to make a quit attempt

Action	Strategies for implementation
Assess every tobacco user's willingness to make a quit attempt at the time.	Assess patient's willingness to quit: "Are you willing to give quitting a try?" • If the patient is willing to make a quit attempt at the time, pro[redacted]

Action	Strategies for implementation
Provide intratreatment social support.	Provide a supportive clinical environment while encouraging the patient in his or her quit attempt. *"My office staff and I are available to assist you." "I'm recommending treatment that can provide ongoing support."* For further description of intratreatment social support, see Table 6.20.
Provide supplementary materials, including information on quitlines.	*Sources:* Federal agencies, nonprofit agencies, national quitline network (1-800-QUIT-NOW), or local/state/tribal health departments/quitlines (see Appendix B for Web site addresses). *Type:* Culturally/racially/educationally/age-appropriate for the patient. *Location:* Readily available at every clinician's workstation.
For the smoker unwilling to quit at the time	See Section 3B.

Strategy A5. *Arrange*—Ensure followup contact

Action	Strategies for implementation
Arrange for followup contacts, either in person or via telephone.	*Timing*: Followup contact should begin soon after the quit date, preferably during the first week. A second followup contact is recommended within the first month. Schedule further followup contacts as indicated. *い奨櫮桀睹旨 9 駸*

Table 3.2. Clinical guidelines for prescribing medication for treating tobacco use and dependence

Who should receive medication for tobacco use? Are there groups of smokers for whom medication has not been shown to be effective?	**All smokers trying to quit should be offered medication, except when contraindicated or for specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents; see Chapter 7).**
What are the first-line medications recommended in this Guideline update?	**All seven of the FDA-approved medications for treating tobacco use are recommended: bupropion SR, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, nicotine patch, and varenicline. The clinician should consider the first-line medications shown to be more effective than the nicotine patch alone: 2 mg/day varenicline or the combination of long-term nicotine patch use + *ad libitum* nicotine replacement therapy (NRT). Unfortunately, there are no well-accepted algorithms to guide optimal selection among the first-line medications.**
Are there contraindications, warnings, precautions, other concerns, and side effects regarding the first-line medications recommended in this Guideline update?	**All seven FDA-approved medications have specific contraindications, warnings, precautions, other concerns, and side effects. Refer to FDA package inserts for this complete information and FDA updates to the individual drug tables in this document (Tables 3.3–3.9). (See information below regarding second-line medications.)**
What other factors may influence medication selection?	**Pragmatic factors also may influence selection, such as insurance coverage, out-of-pocket patient costs, likelihood of adherence,**

Table 3.2. Clinical guidelines for prescribing medication for treating tobacco use and dependence (continued)

What medications should a clinician use with a patient who is highly nicotine dependent?	The higher-dose preparations of nicotine gum, patch, and lozenge have been shown to be effective in highly dependent smokers.[145-147] Also, there is evidence that combination NRT therapy may be particularly effective in suppressing tobacco withdrawal symptoms.[148,149] Thus, it may be that NRT combinations are especially helpful for highly dependent smokers or those with a history of severe withdrawal.
Is gender a consideration in selecting a medication?	There is evidence that NRT can be effective with both sexes;[150-152] however, evidence is mixed as to whether NRT is less effective in women than men.[153-157] This may encourage the clinician to consider use of another type of medication with women, such as bupropion SR or varenicline.
Are cessation medications appropriate for light smokers (i.e., < 10 cigarettes/day)?	As noted above, cessation medications have not been shown to be beneficial to light smokers. However, if NRT is used with light smokers, clinicians may consider reducing the dose of the medication. No adjustments are necessary when using bupropion SR or varenicline.
When should second-line agents be used for treating tobacco dependence?	Consider prescribing second-line agents (clonidine and nortriptyline) for patients unable to use first-line medications because of contraindications or for patients for whom the group of first-line medications has not been helpful. Assess patients for the specific contraindications, precautions, other concerns, and side effects of the second-line agents. Refer to FDA package inserts for this information and to the individual drug tables in this document (Tables 3.10 and 3.11).
Which medications should be considered with patients particularly concerned about weight gain?	Data show that bupropion SR and nicotine replacement therapies, in particular 4-mg nicotine gum and 4-mg nicotine lozenge, delay—but do not prevent—weight gain.
Are there medications that should especially be considered for patients with a past history of depression?	Bupropion SR and nortriptyline appear to be effective with this population[158-162] (see Chapter 7), but nicotine replacement medications also appear to help individuals with a past history of depression.

Should nicotine replacement therapies be avoided in patients with a history of cardiovascular disease?	**No. The nicotine patch in particular has been demonstrated as safe for cardiovascular patients. See Tables 3.3–3.9 and FDA package inserts for more complete information.**
May tobacco dependence medications be used long-term (e.g., up to 6 months)?	**Yes. This approach may be helpful with smokers who report persistent withdrawal sy[illegible] have relapsed in the past after stopping medication, or who desire long-term therapy. A minority of individuals who successfully quit smoking use *ad libitum* NRT medications (gum, nasal spray, inhaler) long-term. The use of these medications for up to 6 months does not present a known health riskr) ! it # 祐潸亂濩嵫潸睹磨$乘㈰礫壿睹暪trapdiv**

	Clinical use of bupropion SR 150 (FDA approved)
Precautions, contraindications, and side effects ***(continued)***	***Side effects***

Table 3.4. Clinical use of nicotine gum (See FDA package insert for more complete information.) (continued)

	Clinical use of nicotine gum (FDA approved)
Precautions, warnings, contraindications, and side effects (see FDA package insert for complete list) (continued)	*Cardiovascular diseases* – NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) postmyocardial infarction period, those with serious arrhythmias, and those with unstable angina pectoris. *Side effects* – Common side effects of nicotine gum include mouth soreness, hiccups, dyspepsia, and jaw ache. These effects are generally mild and transient and often can be alleviated by correcting the patient's chewing technique (see *prescribing instructions,* below).
Dosage	Nicotine gum (both regular and flavored) is available in 2-mg and 4-mg (per piece) doses. The 2-mg gum is recommended for patients smoking less than 25 cigarettes per day; the 4-mg gum is recommended for patients smoking 25 or more cigarettes per day. Smokers should use at least one piece every 1 to 2 hours for the first 6 weeks; the gum should be used for up to 12 weeks with no more than 24 pieces to be used per day.
Availability	OTC only
Prescribing instructions	*Chewing technique* – Gum should be chewed slowly until a "peppery" or "flavored" taste emerges, then "parked" between cheek and gum to facilitate nicotine absorption through the oral mucosa. Gum should be slowly and intermittently "chewed and parked" for about 30 minutes or until the taste dissipates. *Absorption* – Acidic beverages (e.g., coffee, juices, soft drinks) interfere with the buccal absorption of nicotine, so eating and drinking anything except water should be avoided for 15 minutes before or during chewing. *Dosing information* – Patients often do not use enough *prn* NRT medicines to obtain optimal clinical effects. Instructions to chew the gum on a fixed schedule (at least one piece every 1–2 hours) for at least 1–3 months may be more beneficial than *ad libitum* use.
Cost[a]	2 mg (packaged in different amounts), boxes of 100–170 pieces = $48 (quantity used determines how long supply lasts) 4 mg (packaged in different amounts), boxes of 100–110 pieces = $63 (quantity used determines how long supply lasts)

[a] Cost data were established by averaging the retail price of the medication at national chain pharmacies in Atlanta, GA, Los Angeles, CA, Milwaukee, WI , Sunnyside, NY, and listed online during January 2008 and may not reflect discounts available to health plans and others.

Table 3.5. Clinical use of the nicotine inhaler (See FDA package insert for more complete information.)

	Clinical use of nicotine inhaler (FDA approved)
Patient selection	Appropriate as a first-line medication for treating tobacco use
Precautions, warnings, contraindications, and side effects (see FDA package insert for complete list)	*Pregnancy* – Pregnant smokers should be encouraged to quit without medication. The nicotine inhaler has not been shown to be effective for treating tobacco dependence in pregnant smokers. (The nicotine inhaler is an FDA pregnancy Class D agent.) The nicotine inhaler has not been evaluated in breastfeeding patients. *Cardiovascular diseases* – NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) postmyocardial infarction period, those with serious arrhythmias, and those with unstable angina pectoris. *Local irritation reactions* – Local irritation in the mouth and throat was observed in 40% of patients using the nicotine inhaler. Coughing (32%) and rhinitis (23%) also were common. Severity was generally rated as mild, and the frequency of such symptoms declined with continued use.
Dosage	A dose from the nicotine inhaler consists of a puff or inhalation. Each cartridge delivers a total of 4 mg of nicotine over 80 inhalations. Recommended dosage is 6–16 cartridges/day. Recommended duration of therapy is up to 6 months. Instruct patient to taper dosage during the final 3 months of treatment.
Availability	Prescription only
Prescribing instructions	*Ambient temperature* – Delivery of nicotine from the inhaler declines significantly at temperatures below 40 ℉. In cold weather, the inhaler and cartridges should be kept in an inside pocket or other warm area. *Absorption* – Acidic beverages (e.g., coffee, juices, soft drinks) interfere with the buccal absorption of nicotine, so eating and drinking anything except water should be avoided for 15 minutes before or during use of the inhaler. *Dosing information* – Patients often do not use enough *prn* NRT medicines to obtain optimal clinical effects. Use is recommended for up to 6 months, with gradual reduction in frequency of use over the last 6–12 weeks of treatment. Best effects are achieved by frequent puffing of the inhaler and using at least six cartridges/day.
Cost[a]	1 box of 168 10-mg cartridges = $196 (quantity used determines how long supply lasts)

[a] Cost data were established by averaging the retail price of the medication at national chain pharmacies in Atlanta, GA, Los Angeles, CA, Milwaukee, WI , Sunnyside, NY, and listed online during January 2008 and may not reflect discounts available to health plans and others.

Table 3.6. Clinical use of the nicotine lozenge (See FDA package insert for more complete information.)

	Clinical use of nicotine lozenge (FDA approved)
Patient selection	**Appropriate as a first-line medication for treating tobacco use**
Precautions, warnings, contraindications, and side effects (see FDA package insert for complete list)	***Pregnancy*** **– Pregnant smokers should be encouraged to quit without medication. The nicotine lozenge has not been shown to be effective for treating tobacco dependence for pregnant smokers. The nicotine lozenge has not been evaluated in breastfeeding patients. Because the lozenge was approved as an OTC agent, it was not evaluated by the FDA for teratogenicity.** ***Cardiovascular diseases*** **– NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) postmyocardial infarction period, those with serious arrhythmias, and those with unstable angina pectoris.** ***Side effects*** **– The most common side effects of the nicotine lozenge are nausea, hiccups, and heartburn. Individuals on the 4-mg lozenge also had increased rates of headache and coughing (less than 10% of participants).**
Dosage	**Nicotine lozenges are available in 2-mg and 4-mg (per piece) doses. The 2-mg lozenge is recommended for patients who smoke their first cigarette more than 30 minutes after waking, and the 4-mg lozenge is recommended for patients who smoke their first cigarette**

Table 3.7. Clinical use of the nicotine nasal spray (See FDA package insert for more complete information.)

	Clinical use of nicotine nasal spray (FDA approved)
Patient selection	Appropriate as a first-line medication for treating tobacco use
Precautions, warnings, contraindications, and side effects (see FDA package insert for complete list)	*Pregnancy* – Pregnant smokers should be encouraged to quit without medication. Nicotine nasal spray has not been shown to be effective for treating tobacco dependence in pregnant smokers. (Nicotine nasal spray is an FDA pregnancy Class D agent.) Nicotine nasal spray has not been evaluated in breastfeeding patients. *Cardiovascular diseases* – NRT is not an independent risk factor for acute myocardial events. NRT should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) postmyocardial infarction period, those with serious arrhythmias, and those with unstable angina pectoris. *Nasal/airway reactions* – Some 94% of users report moderate to severe nasal irritation in the first 2 days of use; 81% still reported nasal irritation after 3 weeks, although rated severity typically was mild to moderate. Nasal congestion and transient changes in sense of smell and taste also were reported. Nicotine nasal spray should not be used in persons with severe reactive airway disease. *Dependency* – Nicotine nasal spray produces higher peak nicotine levels than other NRTs and has the highest dependence potential. Approximately 15–20% of patients report using the active spray for longer periods than recommended (6–12 months); 5% used the spray at a higher dose than recommended.
Dosage	A dose of nicotine nasal spray consists of one 0.5-mg dose delivered to each nostril (1 mg total). Initial dosing should be 1–2 doses per hour, increasing as needed for symptom relief. Minimum recommended treatment is 8 doses/day, with a maximum limit of 40 doses/day (5 doses/hour). Each bottle contains approximately 100 doses. Recommended duration of therapy is 3–6 months.
Availability	Prescription only
Prescribing instructions	*Dosing information* – Patients should not sniff, swallow, or inhale through the nose while administering doses, as this increases irritating effects. The spray is best delivered with the head tilted slightly back.
Cost[a]	$49 per bottle (quantity used determines how long supply lasts)

[a] Cost data were established by averaging the retail price of the medication at national chain pharmacies in Atlanta, GA, Los Angeles, CA, Milwaukee, WI , Sunnyside, NY, and listed online during January 2008 and may not reflect discounts available to health plans and others.

	Clinical use of the nicotine patch (FDA approved)
Prescribing instructions	***Location***

Table 3.9. Clinical use of varenicline (See FDA package insert for more complete information.) (continued)

	Clinical use of varenicline (FDA approved)
Precautions, warnings, contraindications, and side effects (see FDA package insert for complete list) (continued)	*Warning* – In February 2008, the FDA added a warning regarding the use of varenicline. Specifically, it noted that depressed mood, agitation, changes in behavior, suicidal ideation, and suicide have been reported in patients attempting to quit smoking while using varenicline. The FDA recommends that patients should tell their health care provider about any history of psychiatric illness prior to starting this medication, and clinicians should monitor patients for changes in mood and behavior when prescribing this medication. In light of these FDA recommendations, clinicians should consider eliciting information on their patients' psychiatric history. *Side effects* – Nausea, trouble sleeping, abnormal/vivid/strange dreams
Dosage	Start varenicline 1 week before the quit date at 0.5 mg once daily for 3 days, followed by 0.5 mg twice daily for 4 days, followed by 1 mg twice daily for 3 months. Varenicline is approved for a maintenance indication for up to 6 months. Note: Patient should be instructed to quit smoking on day 8, when dosage is increased to 1 mg twice daily.
Availability	Prescription only
Prescribing instructions	*Stopping smoking prior to quit date* – Recognize that some patients may lose their desire to smoke prior to their quit date or will spontaneously reduce the amount they smoke. *Dosing information* –To reduce nausea, take on a full stomach. To reduce insomnia, take second pill at supper rather than bedtime.
Cost[a]	1 mg, box of 56 = $131 (about 30-day supply)

[a] Cost data were established by averaging the retail price of the medication at national chain pharmacies in Atlanta, GA, Los Angeles, CA, Milwaukee, WI , Sunnyside, NY, and listed online during January 2008 and may not reflect discounts available to health plans and others.

Table 3.11. Clinical use of nortriptyline (See FDA package insert for more complete information.)

	Clinical use of nortriptyline **(not FDA approved for smoking cessation)**
Patient selection	**Appropriate as a second-line medication for treating tobacco use**
Precautions, warnings, contraindications, and side effects (see FDA package insert for complete list)	***Pregnancy*** **– Pregnant smokers should be encouraged to quit without medication. Nortriptyline has not been shown to be effective for tobacco cessation in pregnant smokers. (Nortriptyline is an FDA pregnancy Class D agent.) Nortriptyline has not been evaluated in breastfeeding patients.** ***Side effects*** **– Most commonly reported side effects include sedation, dry mouth (64–78%), blurred vision (16%), urinary retention, lightheadedness (49%), and shaky hands (23%).** ***Activities*** **– Nortriptyline may impair the mental and/or physical abilities required for the performance of hazardous tasks, such as operating machinery or driving a car; therefore, the patient should be warned accordingly.** ***Cardiovascular and other effects*** **– Because of the risk of arrhythmias and impairment of myocardial contractility, use with caution in patients with cardiovascular disease. Do not co-administer with MAO inhibitors.**
Dosage	**Doses used in smoking cessation trials have initiated treatment at a dose of 25 mg/day, increasing gradually to a target dose of 75–7拎戽檫t 0 巇磁害ы/屋ы 三 挠橄urred v箬迦 # 龠印印畣乘巉ぴ厭伽ы伽/迣**

B. For the Patient Unwilling To Quit

Promoting the Motivation To Quit

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

Patients unwilling to make a quit attempt during a visit may lack information about the harmful e ects of tobacco use and the bene ts of quitting, may lack the required nancial resources, may have fears or concerns about quitting, or may be demoralized because of previous relapse.[164-167] Such patients may respond to brief motivational interventions that are based on principles of Motivational Interviewing (MI),[168] a directive, patient-centered counseling intervention.[169] ere is evidence that MI is e ective in increasing future quit attempts;[170-174] however, it is unclear that MI is successful in boosting abstinence among individuals motivated to quit smoking.[173,175,176]

Clinicians employing MI techniques focus on exploring a tobacco user's feelings, beliefs, ideas, and values regarding tobacco use in an e ort to uncover any ambivalence about using tobacco.[169,177,178] Once ambivalence is uncovered, the clinician selectively elicits, supports, and strengthens the patient's "change talk" (e.g., reasons, ideas, needs for eliminating tobacco use) and "commitment language" (e.g., intentions to take action to change smoking behavior, such as not smoking in the home). MI researchers have found that having patients use their own words to commit to change is more e ective than clinician exhortations, lectures, or arguments for quitting, which tend to increase rather than lessen patient resistance to change.[177]

e four general principles that underlie MI are: (*1) express empathy, (2) develop discrepancy, (3) roll with resistance,* and *(4) support self-e ca-cy.*[168,179] Speci c MI counseling strategies that are based on these principles are listed in Strategy B1. Because this is a specialized technique, it may be bene cial to have a member of the clinical sta receive training in motivational interviewing. e content areas that should be addressed in a motivational counseling intervention can be captured by the "5 R's": relevance, risks, rewards, roadblocks, and repetition (Strategy B2). Research suggests that the "5 R's" enhance future quit attempts.[169,180]

Strategy B1. Motivational interviewing strategies

Express empathy.	• **Use open-ended questions** to explore: – **The importance of addressing smoking or other tobacco use (e.g., "How important do you think it is for you to quit smoking?")** – **Concerns and benefits of quitting (e.g., "What might happen if you quit?")** • **Use reflective listening to seek shared understanding:** – **Reflect words or meaning (e.g., "So you think smoking helps you to maintain your weight.").** – **Summarize (e.g., "What I have heard so far is that smoking is something you enjoy. On the other hand, your boyfriend hates your smoking, and you are worried you might develop a serious disease.").** • **Normalize feelings and concerns (e.g., "Many people worry about managing without cigarettes.").** • **Support the patient's autonomy and right to choose or reject change (e.g., "I hear you saying you are not ready to quit smoking right now. I'm here to help you when you are ready.").**
Develop discrepancy.	• **Highlight the discrepancy between the patient's present behavior and expressed priorities, values, and goals (e.g., "It sounds like you are very devoted to your family. How do you think your smoking is affecting your children?").** • **Reinforce and support "change talk" and "commitment" language:** – **"So, you realize how smoking is affecting your breathing and making it hard to keep up with your kids."** – **"It's great that you are going to quit when you get through this busy time at work."** • **Build and deepen commitment to change:** – **"There are effective treatments that will ease the pain of quitting, including counseling and many medication options."** – **"We would like to help you avoid a stroke like the one your father had."**
Roll with resistance.	• **Back off and use reflection when the patient expresses resistance:** – **"Sounds like you are feeling pressured about your smoking."** • **Express empathy:** – **"You are worried about how you would manage withdrawal symptoms."** • **Ask permission to provide information:** – **"Would you like to hear about some strategies that can help you address that concern when you quit?"**
Support self-efficacy.	• **Help the patient to identify and build on past successes:** – **"So you were fairly successful the last time you tried to quit."** • **Offer options for achievable small steps toward change:** – **Call the quitline (1-800-QUIT-NOW) for advice and information.** – **Read about quitting benefits and strategies.** – **Change smoking patterns (e.g., no smoking in the home).** – **Ask the patient to share his or her ideas about quitting strategies.**

Strategy B2. Enhancing motivation to quit tobacco—the "5 R's"

Relevance	**Encourage the patient to indicate why quitting is personally relevant, being as specific as possible. Motivational information has the greatest impact if it is relevant to a patient's disease status or risk, family or social situation (e.g., having children in the home), health concerns, age, gender, and other important patient characteristics (e.g., prior quitting experience, personal barriers to cessation)., and o 畜磨暑祐澍 reral bam # 鸄琶挠擘汍鸄ily ð鎔ヨ廓：親櫚弥崔床桯**

Roadblocks	**The clinician should ask the patient to identify barriers or impediments to quitting and provide treatment (problemsolving counseling, medication) that could address barriers. Typical barriers might include:** • **Withdrawal symptoms** • **Fear of failure** • **Weight gain** • **Lack of support** • **Depression** • **Enjoyment of tobacco** • **Being around other tobacco users** • **Limited knowledge of effective treatment options**
Repetition	**The motivational intervention should be repeated every time an unmotivated patient visits the clinic setting. Tobacco users who have failed in previous quit attempts should be told that most people make repeated quit attempts before they are successful.**

C. For the Patient Who Has Recently Quit

Treatments for the Recent Quitter

Smokers who have recently quit face a high risk of relapse. Although most relapse occurs early in the quitting process,[96,101,181] some relapse occurs months or even years a er the quit date.[181-184] Numerous studies have been

success at quitting, review the bene ts of quitting, and assist the patient in resolving any residual problems arising from quitting (Strategy C1). Such expressions of interest and involvement on the part of the clinician might encourage the patient to seek additional help with cessation should she or he ultimately relapse. When the clinician encounters a patient who is abstinent from tobacco and is no longer engaged in cessation treatment, the clinician may wish to acknowledge a patient's success in quitting. e abstinent former smoker also may experience problems related to cessation that deserve treatment in their own ri 666 re W n clinicive tbs<rve tr

Chapter 4 Intensive Interventions for Tobacco Use and Dependence

Background

Intensive tobacco dependence treatment can be provided by any suitably trained clinician. e evidence in Chapter 6 shows that intensive tobacco dependence treatment is more e ective than brief treatment. Intensive interventions (i.e., more comprehensive treatments that may occur over multiple visits for longer periods of time and that may be provided by more than one clinician) are appropriate for any tobacco user willing to participate in them; neither their e ectiveness nor cost-e ectiveness is limited to a subpopulation of tobacco users (e.g., heavily dependent smokers).[188-194] In addition, patients, even those not ready to quit, have reported increased satisfaction with their overall health care as tobacco counseling intensity increases.[50,88]

In many cases, intensive tobacco dependence interventions are provided by clinicians who specialize in the treatment of tobacco dependence. Such specialists are not de ned by their certi cation, professional a liation, or by the eld in which they trained. Rather, specialists view tobacco dependence treatment as a primary professional role. Specialists possess the skills, knowledge, and training to provide e ective interventions across a range of intensities. ey o en are a liated with programs o ering intensive treatment interventions or services (e.g., programs with sta dedicated to tobacco interventions in which treatment involves multiple counseling sessions, including quitlines). In addition to o ering intensive treatments, specialists sometimes conduct research on tobacco dependence and its treatment.

As noted above, substantial evidence shows that intensive interventions produce higher success rates than do less intensive interventions. In addition, the tobacco dependence interventions o ered by specialists represent an important treatment resource for patients even if they received tobacco dependence treatment from their own clinician.

e advent of state tobacco quitlines available through a national network at 1-800-QUIT-NOW (1-800-784-8669) means that intensive, specialist-delivered interventions are now available to smokers on an unprecedented basis. In addition to providing their own clinical tobacco dependence interventions, clinicians and health systems can take advantage of this

Table 4.1. Findings relevant to intensive interventions

Intensive counseling is especially effective. There is a strong dose-response relation between counseling intensity and quitting success. In general, the more intense the treatment intervention, the greater the rate of abstinence. Treatments may be made more intense by increasing (a) the length of individual treatment sessions and (b) the number of treatment sessions.
Many different types of providers (e.g., physicians, nurses, dentists, psychologists, social workers, cessation counselors, pharmacists) are effective at increasing quit rates; involving multiple types of providers can enhance abstinence rates.
Individual, group, and telephone counseling are effective tobacco use treatment formats.
Particular types of counseling strategies are especially effective. Practical counseling (problemsolving/skills-training approaches) and the provision of intratreatment social support are associated with significant increases in abstinence rates.
Medications such as bupropion SR, nicotine replacement therapies, and varenicline consistently increase abstinence rates. Therefore, their use should be encouraged for all smokers except in the presence of contraindications or for specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). In some instances, combinations of medications may be appropriate. In addition, combining counseling and medication increases abstinence rates.
Tobacco dependence treatments are effective across diverse populations (e.g., populations varying in gender, age, and race/ethnicity).

Table 4.2. Components of an intensive tobacco dependence intervention

Assessment	**Assessments should determine whether tobacco users are willing to make a quit attempt using an intensive treatment program. Other assessments can provide information useful in counseling (e.g., stress level, dependence; see Chapter 6A, Specialized Assessment).**
Program clinicians	**Multiple types of clinicians are effective and should be used. One counseling strategy would be to have a medical/health care clinician deliver a strong message to quit and information about health risks and benefits, and recommend and prescribe medications recommended in this Guideline update. Nonmedical clinicians could then deliver additional counseling interventions.**
Program intensity	**There is evidence of a strong dose-response relation; therefore, when possible, the intensity of the program should be:** ***Session length* – longer than 10 minutes** ***Number of sessions* – 4 or more**

Program format	**Either individual or group counseling may be used. Telephone counseling also is effective and can supplement treatments provided in the clinical setting. Use of self-help materials and cessation Web sites is optional. Followup interventions should be scheduled (see Chapter 6B).**
Type of counseling and behavioral therapies	**Counseling should include practical counseling (problemsolv-**

Chapter 5 Systems Interventions—Importance to Health Care Administrators, Insurers, and Purchasers

Background

E orts to integrate tobacco intervention into the delivery of health care require the active involvement of clinicians, health care systems, insurers, and purchasers of health insurance. Such integration represents an opportunity to increase rates of delivering tobacco dependence treatments, quit attempts, and successful smoking cessation.[201]

In contrast to strategies that target only the clinician or the tobacco user, systems strategies are intended to ensure that tobacco use is systematically assessed and treated at every clinical encounter. Importantly, these strategies are designed to work synergistically with clinician- and patient-focused interventions, ultimately resulting in informed clinicians and patients interacting in a seamless way that facilitates the treatment of tobacco dependence.[202-204]

Several considerations argue for the adoption of systems-level tobacco intervention e orts. First, such strategies have the potential to substantially improve population abstinence rates. Levy et al. estimated that, over time, widespread implementation of such strategies could produce a 2 percent to 3.5 percent reduction in smoking prevalence rates.[205] Second, despite recent progress in this area, many clinicians have yet to use evidence-based interventions consistently with their patients who use tobacco.[23,48,51] Some evidence indicates that institutional or systems support (e.g., adequate clinician training or automated smoker identi cation systems) improves the rates of clinical interventions.[206-208] Finally, agents such as

medical care through formularies, performance feedback to clinicians, speci c coverage criteria, and marketing approaches that prompt patient demand for particular services.[139,209] Purchasers also have begun to use tobacco measures in pay-for-performance initiatives in which managed care organizations, clinics, and individual physicians receive additional reimbursement by achieving speci c tobacco treatment-related goals. Indeed, research clearly shows that systems-level changes can reduce smoking prevalence among enrollees of managed health care plans.[210-212]

Unfortunately, the potential bene ts of a collaborative partnership among health care organizations, insurers, employers, and purchasers have not been fully realized. For example, treatments for tobacco use (both medication and counseling) are not provided consistently as paid services for subscribers of health insurance packages.[213-215] Although substantial progress has been made since the publication of the rst Guideline in 1996,[1,216-218] neither private insurers nor state Medicaid programs consistently provide comprehensive coverage of evidence-based tobacco interventions.[206,214,219] Findings such as these resulted in the *Healthy People 2010* objective:

> *Increase insurance coverage of evidence-based treatment for nicotine dependency to 100 percent.*[220]

In sum, without supportive systems, policies, insurance coverage, and environmental prompts, the individual clinician likely will not assess and treat tobacco use consistently. erefore, just as clinicians must assume responsibility to treat their patients for tobacco use, so must health care administrators, insurers, and purchasers assume responsibility to cra policies, provide resources, and display leadership that results in a health care system that delivers consistent and e ective tobacco use treatment.

Cost-Effectiveness of Tobacco Use Treatments

Tobacco use treatments are not only clinically e ective, but are cost-e ective as well. Tobacco use treatments, ranging from clinician advice to medication to specialist-delivered intensive programs, are cost-e ective in relation to other medical interventions such as treatment of hypertension and hyperlipidemia and to other preventive interventions such as periodic mammography.[194,221-224] In fact, tobacco use treatment has been referred to as the "gold standard" of health care cost-e ectiveness.[225] Tobacco use treatment remains highly cost-e ective, even though a single application

of any e ective treatment for tobacco dependence may produce sustained abstinence in only a minority of smokers. Finally, evidence-based tobacco dependence interventions produce a favorable return on investment from the perspective of both the employer and health plan due to reduced health care consumption and costs.[226-228] e cost-e ectiveness of Guideline recommendations for tobacco use treatment is addressed in detail in Chapter 6.

Recommendations for Health Care Administrators, Insurers, and Purchasers

Health care delivery administrators, insurers, and purchasers can promote the treatment of tobacco dependence through a systems approach. Purchasers (o en business entities or other employers, State or Federal units of government, or other consortia that purchase health care bene ts for a group of individuals) should make tobacco assessment and coverage of treatment a contractual obligation of the health care insurers and/or clinicians who provide services to them. In addition to improving the health of their employees or subscribers, providing coverage for tobacco dependence treatment will result in lower rates of absenteeism[229,230] and lower utilization of health care resources.[229,231] Health care administrators and insurers should provide clinicians with assistance to ensure that institutional changes promoting tobacco dependence treatment are implemented universally and systematically. Various institutional policies would facilitate these interventions, including:

- Implementing a tobacco user identi f cation system in every clinic (Systems Strategy 1).

- Providing adequate training, resources, am =

- Including tobacco dependence treatments (both counseling and medication) identi ed as e ective in this Guideline as paid or covered services for all subscribers or members of health insurance packages (Systems Strategy 5).

ese strategies are based on the evidence described in Chapter 6, as well as on Panel opinion.

Strategies for Health Care Administrators, Insurers, and Purchasers

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

Action	Strategies for implementation
Implement an office-wide system that ensures that for *every* patient at every clinic visit, tobacco use status is queried and documented.	Office system change: Expand the vital signs to inclu畚だ煒at every clinic Im篇/ Ь 濫 p v嵩in_n system in everEx盟ы酎 quc髭eы/ offi霖乖gno quc髭華　介移挠榎ato/　幷ы介Π酚霖迦в位χ盈絢霺嵒酚胼霖乘゜ic暪 亂睬睬磨 c濾fig薬琴挟总睹觸榎赫ы云/移盈者惑澀井 visco ntati Expы介ы屋蛎me Σ酵m in eo盈мe °ы/桶i Â 心榎 ¦ / ¦ 髻酚罟o/火ы/伽蛎伽火em in ＃/磯　χ火厭挠徜榎 9 惘 at every clinic vis$㈰濩濩け酚濩柒だ汲駓井 薬琴挠慍昨酲睹榎睹 9 挠旨徖擘檎園拎ы慴惘ы酎 カis ø 酚嶋睹猝磨灪 亙 9 厭抡慴俯猟慴奨炎嫣蓋憖亂こ爚瑞拇炌究僄/vit＃霖乘gns　隆ｅ朠 薬琴挠懤蠨л華oл桯佝琴 K 暪 ｵ 移廻刨cal € ＃髻濬挠慍昨移【龠言朠 薬琴挠櫰挠琴怡榎　旨榎 9 ы/伽蛎夏位χ英介移/ы铖⇦/龠言惘

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

Action	Strategies for implementation
Health care systems should ensure that clinicians have sufficient training to treat tobacco dependence, clinicians and patients have resources, and clinicians are given feedback about their tobacco dependence treatment practices.	*Educate* all staff. On a regular basis, offer training (e.g., lectures, workshops, inservices) on tobacco dependence treatments, and provide continuing education (CE) credits and/or other incentives for participation. *Provide resources* such as ensuring ready access to tobacco quitlines (e.g., 1-800-QUIT-NOW) and other community resources, self-help materials, and information about effective tobacco use medications (e.g., establish a clinic fax-to-quit service, place medication information sheets in examination rooms). *Report* the provision of tobacco dependence interventions on report cards or evaluative standards for health care organizations, insurers, accreditation organizations, and physician group practices (e.g., HEDIS, The Joint Commission, and Physician Consortium for Performance Improvement). *Provide feedback* to clinicians about their performance, drawing on data from chart audits, electronic medical records, and computerized patient databases. Evaluate the degree to which clinicians are identifying, documenting, and treating patients who use tobacco.

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

Action	Strategies for implementation
Clinical sites should communicate to all staff the importance of intervening with tobacco users and should designate a staff person (e.g., nurse, medical assistant, or other clinician) to coordinate tobacco dependence treatments. Nonphysician personnel may serve as effective providers of tobacco dependence interven-	

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

Action	Strategies for implementation
Provide tobacco dependence treatment to all tobacco users admitted to a hospital.	*Implement* a system to identify and document the tobacco use status of all hospitalized patients. *Identify* a clinician(s) to deliver tobacco dependence inpatient consultation services for every hospital and reimburse them for delivering these services. *Offer* tobacco dependence treatment to all hospitalized patients who use tobacco. *Expand* hospital formularies to include FDA-approved tobacco dependence medications. *Ensure* compliance with The Joint Commission regulations mandating that all sections of the hospital be entirely smoke-free and that patients receive cessation treatments. *Educate* hospital staff that first-line medications may be used to reduce nicotine withdrawal symptoms, even if the patient is not intending to quit at this time.

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

Action	Strategies for implementation
Provide all insurance subscribers, including those covered by managed care organizations (MCOs), workplace health plans, Medicaid, Medicare, and other government insurance programs, with comprehensive coverage for effective tobacco dependence treatments, including medication and counseling.	*Cover* effective tobacco dependence treatments (counseling and medication) as part of the basic benefits package for all health insurance packages. *Remove* barriers to tobacco treatment benefits (e.g., copays, utilization restrictions). *Educate* all subscribers and clinicians about the availability of covered tobacco dependence treatments (both counseling and medication), and encourage patients to use these

Chapter 6 Evidence and Recommendations

Background

e recommendations summarized in Chapters 2, 3, 4, and 5 are the result of a review and analysis of the existing tobacco treatment literature. is chapter reports that review and analysis and describes the e ectiveness of various treatments, assessments, and implementation strategies. is chapter also addresses which treatments or assessments are e ective, how they should be used, and how they should be implemented within a health care system.

e Panel identi ed topics that warranted new analyses for the 2008 update based on several criteria: they were important, supported by substantial new literature, and/or addressed issues not considered in prior Guidelines. e number of topics selected for new analyses was limited by the Public Health Service Guideline Update contract parameters. e 2008 Guideline Update Panel selected 11 topics for new analysis (see Table 1.1), based in part on input from tobacco control researchers and practitioners.

ese 11 topics and related categories are represented in Table 6.1. Type of outcome analyses varied across the di erent topics. In most analyses, long-term abstinence (6 months or more) was the outcome measure of interest; in others, it was the rate of smoker identi cation or intervention delivery. In addition to these new topics, Table 6.2 lists the topics that previously were analyzed for the 1996 and 2000 Guidelines. Importantly, the Guideline Update Panel reviewed all recommendations from the 1996 and 2000 Guidelines that did not undergo updated meta-analyses. For these prior recommendations, the Panel reviewed relevant literature since 1999 to determine whether the prior recommendation merited retention, modi cation, or deletion. See Appendix D for comparison of 2000 and 2008 Guideline recommendations.

e analyses reported in this chapter almost exclusively es repmpar0q006w3(a)-3J 0(

Finally, the Panel attempted to analyze treatment and assessment strategies that constitute distinct approaches that exist in current clinical practice.

e Panel chose categories within each analyzed topic according to three major criteria. First, some categories re ected generally accepted dimensions or taxonomies. An example of this is the categorical nature of the clinician types (physician, psychologist, nurse, and so on). Second, information on the category had to be available in the published literature. Many questions of theoretical interest had to be abandoned simply because the requisite research literature was not available. ird, the category had to occur with su cient frequency to permit meaningful statistical analysis.

erefore, the cutpoints of some continuous variables (e.g., total amount of contact time) were determined so there were a su cient number of studies within each analytical category to permit meaningful analysis.

In ideal circumstances, the Panel could evaluate each characteristic by consulting randomized controlled trials relevant to the speci c categories in question. Unfortunately, with the exception of medication interventions, very few or no randomized controlled trials are designed to address the e ects of speci c treatment or assessment characteristics of interest. Moreover, treatment characteristics frequently are confounded with one another. For example, comparisons among clinicians o en are confounded with the type of counseling and the format and intensity of the interventions. erefore, direct, unconfounded comparisons of categories within a particular analysis type o en were impossible. ese characteristics nevertheless were analyzed because of their clinical importance, and because it was possible to reduce confounding by careful selection of studies and by statistical control of some confounding factors.

Table 6.1. Topics meta-analyzed for the 2008 Guideline update

Characteristics analyzed	Categories of those characteristics
Quitline	• **No quitline intervention** • **Use of a proactive quitline** • **Use of a proactive quitline in combination with medication** • **Number of quitline sessions**
Combining counseling and medication	• **Medication alone** • **Counseling alone** • **Medication and counseling combined**

Table 6.1. Topics meta-analyzed for the 2008 Guideline update (continued)

Characteristics analyzed	Categories of those characteristics
Medications	• Placebo medication • Bupropion SR • Clonidine • Nicotine gum • Nicotine inhaler • Nicotine lozenge • Nicotine nasal spray • Nicotine patch • Nortriptyline • Varenicline • Long-term medication • Single medication • Combination of medications • High-dose nicotine patch
Providing tobacco treatment as a health care insurance benefit	• Not providing coverage for tobacco treatment • Providing services as a covered insurance benefit
Systems features	• No intervention • Clinician training • Clinician training and reminder systems
Specific populations	• Adolescent smokers, pregnant smokers, smokers with psychiatric disorders, including substance use disorders and smokers with low socioeconomic status/limited formal education (see Chapter 7 for description)

Table 6.2. Topics meta-analyzed for the 1996 and 2000 Guidelines and included in the 2008 Guideline update (but not re-analyzed)

Characteristics analyzed	Categories of those characteristics
Screen for tobacco use	• No screening system in place • Screening system in place
Advice to quit	• No advice to quit • Physician advice to quit
Intensity of person-to-person clinical contact	• No person-to-person intervention • Minimal counseling (longest session $\leq$ 3 minutes in duration) • Low intensity counseling (longest session > 3 minutes and $\leq$ 10 minutes in duration) • Higher intensity counseling (longest session > 10 minutes) • Total amount of contact time • Number of person-to-person treatment sessions

Table 6.2. Topics meta-analyzed for the 1996 and 2000 Guidelines and included in the 2008 Guideline update (but not re-analyzed) (continued)

Characteristics analyzed	Categories of those characteristics
Type of clinician	• No clinician • Self-help materials only • Nonphysician health care clinician (e.g., psychologist, counselor, social worker, nurse, dentist, graduate student, pharmacist, tobacco treatment specialist) • Physician • Number of types of clinicians
Formats of psychosocial intervention	• No contact • Self-help/self-administered (e.g., pamphlet, audiotape, videotape, mailed information, computer program) • Individual counseling/contact • Group counseling/contact • Proactive telephone counseling/contact • Number of types of formats
Self-help interventions	• No self-help intervention • Number of self-help interventions • Self-help interventions
Types of counseling and behavioral therapies	• No counseling • No person-to-person intervention or minimal counseling • General: problemsolving/coping skills/relapse-prevention/stress-management approach • Negative affect/depression intervention • Weight/diet/nutrition intervention • Extratreatment social support intervention • Intratreatment social support intervention • Contingency contracting/instrumental contingencies • Rapid smoking • Other aversive smoking techniques • Cigarette fading/smoking reduction prequit • Acupuncture
Over-the-counter (OTC) medication	• Placebo OTC nicotine patch therapy • OTC nicotine patch therapy

Additional topics that were important and clinically relevant—but did not lend themselves to analysis due to a lack of long-term abstinence data—nevertheless were considered by the Panel through a review of the existing literature. e strength of evidence associated with these recommended actions for clinical interventions was at the "B" or "C" level (see below), re ecting the fact that they are not based primarily on meta-analyses.

is chapter addresses the treatment and assessment characteristics outlined in Tables 6.1 and 6.2 and is divided into three sections: (1) evidence for counseling and psychosocial interventions; (2) evidence for medication interventions; and (3) evidence for systems changes. For each topic, background information, clinical recommendations, and the basis for those recommendations are provided. As described in Chapter 1, each recommendation was given a strength-of-evidence classi cation based on the criteria shown in Table 6.3. Finally, for many topics, recommendations for further research are provided.

Table 6.3. Summary of strength of evidence for recommendations

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

A. Counseling and Psychosocial Evidence

1. Screening and Assessment

Screen for Tobacco Use

Recommendation: All patients should be asked if they use tobacco and should have their tobacco use status documented on a regular basis. Evidence has shown that clinic screening systems, such as expanding the vital signs to include tobacco use status or the use of other reminder systems such as chart stickers or computer prompts, signi cantly increase rates of clinician intervention. (Strength of Evidence = A)

e Panel relied on the meta-analyses from the original 1996 Guideline to determine the impact of tobacco screening systems. Tobacco screening

systems were evaluated in terms of their impact on two outcomes: the rate of tobacco treatment by clinicians, and the rate of cessation by patients who smoke.

Identifying Tobacco Users: Impact on Clinical Intervention. Nine studies met the selection criteria and were meta-analyzed as part of the 1996 Guideline to assess the impact of screening systems on the rate of smoking cessation intervention by clinicians. e results of this meta-analysis are shown in Table 6.4. Implementing clinic systems designed to increase the assessment and documentation of tobacco use status markedly increases the rate at which clinicians intervene with their patients who smoke.

Table 6.4. Meta-analysis (1996): Impact of having a tobacco use status identification system in place on rates of clinician intervention with their patients who smoke (n = 9 studies)[a]

Screening system	Number of arms	Estimated odds ratio (95% C.I.)	Estimated rate of clinician intervention (95% C.I.)
No screening system in place to identify smoking status (reference group)	9	1.0	38.5
Screening system in place to identify smoking status	9	3.1 (2.2–4.2)	65.6 (58.3–72.6)

[a] Go to *www.surgeongeneral.gov/tobacco/gdlnrefs.htm* for the articles used in this meta-analysis.

Identifying Tobacco Users: Impact on Tobacco Cessation. ree studies met

that these results are generalizable to all tobacco users. is approach is designed to produce consistent assessment and documentation of tobacco use. Evidence from controlled trials shows that this approach increases the probability that tobacco use is assessed and documented consistently.[54,232] However, documenting smoking status is not by itself su cient to promote treatment by clinicians.[233] Systems changes beyond smoker identi cation strategies are likely to be needed to increase rates of cessation advice and intervention.[139,234-237]

Table 6.5. Meta-

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

e clinician also may want to perform specialized assessments of individual and environmental attributes that provide information for tailoring treatment and that predict quitting success. Specialized assessments refer to the use of formal instruments (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 (in addition, the reader may nd other assessments relevant to medication use and speci c populations when selecting treatment). Some of the variables targeted by specialized assessments that predict quitting success are listed in Table 6.6.

Several considerations should be kept in mind regarding the use of specialized assessments. First, there is little consistent evidence that a smoker's status on a specialized assessment is useful for treatment matching. e one exception is that persons who are highly nicotine dependent may bene t more from higher nicotine gum or lozenge doses (see Medication Evidence; Section B of Chapter 6). More importantly, the Panel found that, regardless of their standing on specialized assessments, all smokers have the potential to bene t from tobacco dependence treatments. erefore, delivery of tobacco dependence treatments should not depend on the use of specialized assessments. Finally, tailored interventions based on specialized assessments do not consistently produce higher long-term quit rates than do nontailored interventions of equal intensity. Some promising studies exist, however, that suggest that individualizing self-help materials may be bene cial (see Individually Tailored and Stepped-Care Interventions, page 92).[238-245] In addition, the Panel recognizes that some e ective interventions, such as general problemsolving (see Types of Counseling and Behavioral erapies, on page 96), entail treatment tailoring based on a systematic assessment that occurs as an integral part of treatment.

Table 6.6. Variables associated with higher or lower abstinence rates

- Whether working to change the social network can improve abstinence rates (e.g., intervening with other smokers in the household to change their smoking patterns, teaching quitting support, or encouraging a smokefree home)

- Disparities in screening and assessment in specific populations

2. Treatment Structure and Intensity

Advice To Quit Smoking

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

For these recommendations, the 2008 Guideline Panel relied on meta-analyses performed for the 1996 Guideline. Seven studies were included in the 1996 meta-analysis of the effectiveness of physician advice to quit smoking. In the studies used in this analysis, the modal length of clinician intervention was 3 minutes or less. Two studies in this analysis used interventions lasting about 5 minutes. Results of the meta-analysis on physician advice are shown in Table 6.7. This analysis shows that brief physician advice significantly increases long-term smoking abstinence rates. These results were also supported by a more recent, independent meta-analysis.[56]

Advice by physicians was examined in the Table 6.7 meta-analysis from the 1996 Guideline; there were too few studies to examine advice delivered by any other type of clinician, although one study found that advice to quit from health care providers in general did significantly increase quit rates.[249] The analysis for total amount of contact time (see Table 6.9) indicates that minimal counseling (advice) delivered by a variety of clinician types increases long-term abstinence rates. Also, studies have shown that dentists and dental hygienists can be effective in assessing and advising smokeless/spit tobacco users to quit[250] (see Chapter 7). Given the large number of smokers who visit a clinician each year, the potential public health impact of universal advice to quit is substantial.[56]

Table 6.7. Meta-analysis (1996): Effectiveness of and estimated abstinence rates for advice to quit by a physician (n = 7 studies)[a]

Advice	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
No advice to quit (reference group)	9	1.0	7.9
Physician advice to quit	10	1.3 (1.1–1.6)	10.2 (8.5–12.0)

[a] Go to *www.surgeongeneral.gov/tobacco/gdlnrefs.htm* for the articles used in this meta-analysis.

Future Research

e following topics regarding advice to quit require additional research:

- E fectiveness of advice to quit smoking given by

ese recommendations are supported by three separate meta-analyses conducted for the 2000 Guideline: one involving session length, one involving total amount of contact time, and one involving the number of sessions.

Total Amount of Contact Time. irty- ve studies met the selection criteria for the analysis assessing the impact of total contact time. e amount of contact time was calculated from the text as the total time accumulated (the number of sessions multiplied by the session length). When the exact time was not known for minimal and low-intensity interventions, they were assigned median lengths of 2 and 6.5 minutes, respectively. e total amount of contact time was then categorized as no-contact, 1–3 minutes, 4–30 minutes, 31–90 minutes, 91–300 minutes, and greater than 300 minutes. As Table 6.9 shows, any contact time signi cantly increased abstinence rates over those produced by no contact. However, there was a clear trend for abstinence rates to increase across contact time, up to the 90-minute mark. ere was no evidence that more than 90 minutes of total contact time substantially increases abstinence rates.

Table 6.9. Meta-analysis (2000): Effectiveness of and estimated abstinence rates for total amount of contact time (n = 35 studies)[a]

Total amount of contact time	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
No minutes	16	1.0	11.0
1–3 minutes	12	1.4 (1.1–1.8)	14.4 (11.3–17.5)
4–30 minutes	20	1.9 (1.5–2.3)	18.8 (15.6–22.0)
31–90 minutes	16	3.0 (2.3–3.8)	26.5 (21.5–31.4)
91–300 minutes	16	3.2 (2.3–4.6)	28.4 (21.3–35.5)
> 300 minutes	15	2.8 (2.0–3.9)	25并乘틹酚孺繁02 31.4腰

Table 6.11. Meta-analysis (2000): Effectiveness of and estimated abstinence rates for interventions delivered by different types of clinicians (n = 29 studies)[a]

Type of clinician	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
No clinician	16	1.0	10.2
Self-help	47	1.1 (0.9–1.3)	10.9 (9.1–12.7)
Nonphysician clinician	39	1.7 (1.3–2.1)	15.8 (12.8–18.8)
Physician clinician	11	2.2 (1.5–3.2)	19.9 (13.7–26.2)

[a] Go to *www.surgeongeneral.gov/tobacco/gdlnrefs.htm* for the articles used in this meta-analysis.

Table 6.12. Meta-analysis (2000): Effectiveness of and estimated abstinence rates for interventions delivered by various numbers of clinician types (n = 37 studies)[a]

Number of clinician types	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
No clinician	30	1.0	10.8
One clinician type	50	1.8 (1.5–2.2)	18.3 (15.4–21.1)
Two clinician types	16	2.5 (1.9–3.4)	23.6 (18.4–28.7)
Three or more clinician types	7	2.4 (2.1–2.9)	23.0 (20.0–25.9)

[a] Go to *www.surgeongeneral.gov/tobacco/gdlnrefs.htm* for the articles used in this meta-analysis.

Future Research

e following topics rega4(e0T Qf(in)8(g t)-3yp) 0 14 68.25 277.9172 Tm <0001002

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

Recommendation: Tailored materials, both print and Web-based, appear to be e ective in helping people quit. erefore, clinicians may choose to provide tailored self-help materials to their patients who want to quit. (Strength of Evidence = B)

Format Types. Ovencf 1t(e)5((d s)-9(e)4TTj /T5(t)12(e)5(ri)-4(a)a(p)-110 1 61 Tl)5(

als constituted the sole di erence in treatment arms. In the main format analysis, some treatment arms di ered on factors other than self-help *per se* (e.g., intensity of counseling). e treatments that accompanied self-help material in the focused analysis ranged from no advice or counseling to intensive counseling. e results of this analysis were comparable to those in the larger format analysis (i.e., self-help was of marginal e ectiveness).

For the 2000 Guideline analysis, 21 studies met selection criteria to evaluate the e ectiveness of providing multiple types of self-help interventions (e.g., pamphlets, videotapes, audiotapes, and reactive hotlines/helplines). e results provide little evidence that the provision of multiple types of self-help, when o ered without any person-to-person intervention, signi cantly enhances treatment outcomes (see Table 6.15).

Two nal 2000 meta-analyses addressed the impact of self-help brochures *per se*. In one analysis, brochures were used as the only intervention. In the other analysis, self-help brochures were used in addition to counseling. In neither analysis did self-help signi cantly boost abstinence rates.

Table 6.13. Meta-analysis (2000): Effectiveness of and estimated abstinence rates for various types of formats (n = 58 studies)[a]

Format Number	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
No format	20	1.0	10.8
Self-help	93	1.2 (1.02–1.3)	12.3 (10.9–13.6)
Proactive telephone counseling	26	1.2 (1.1–1.4)	13.1 (11.4–14.8)
Group counseling	52	1.3 (1.1–1.6)	13.9 (11.6–16.1)
Individual counseling	67	1.7 (1.4–2.0)	16.8 (14.7–19.1)

Table 6.14. Meta-analysis (2000): Effectiveness of and estimated abstinence rates for number of formats (n = 54 studies)[a]

Number of formats[b]	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
No format	20	1.0	10.8
One format	51	1.5 (1.2–1.8)	15.1 (12.8–17.4)
Two formats	55	1.9 (1.6–2.2)	18.5 (15.8–21.1)
Three or four formats	19	2.5 (2.1–3.0)	23.2 (19.9–26.6)

[a] Go to *www.surgeongeneral.gov/tobacco/gdlnrefs.htm* for the articles used in this meta-analysis.
[b] Formats included self-help, proactive telephone counseling, group, or individual counseling.

Table 6.15. Meta-analysis (2000): Effectiveness of and estimated abstinence rates for number of types of self-help (n = 21 studies)[a]

Factor	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
No self-help	17	1.0	14.3
One type of self-help	27	1.0 (0.9–1.1)	14.4 (12.9–15.9)
Two or more types	10	1.1 (0.9–1.5)	15.7 (12.3–19.2)

[a] Go to *www.surgeongeneral.gov/tobacco/gdlnrefs.htm* for the articles used in this meta-analysis.

Quitlines. Both the substantial growth in quitline research and the implementation of a national network of tobacco quitlines (available through 1-800-QUIT-NOW) led the 2008 Guideline Panel to identify quitline e ectiveness as a topic deserving focused meta-analyses. Nine studies met selection criteria and were analyzed for the 2008 Guideline update comparing the e ectiveness of a quitline intervention versus minimal or no contact or self-help materials. is di ers from the 2000 meta-analysis (Table 6.13) in that the current analysis focused on study arms that used quitline intervention alone rather than telephone counseling that may have occurred with other types of interventions. For the purpose of this analysis, quitlines are de ned as telephone counseling in which at least some of the contacts are initiated by the quitline counselor to deliver tobacco use interventions, including call-back counseling. Quitlines signi cantly increase abstinence rates compared to minimal or no counseling interventions (Table 6.16).[254] In a second 2008 meta-analysis of quitlines, six studies were analyzed comparing the e ect of adding quitline counseling to medication versus medication alone. e addition of quitline counseling to medication signi cantly improves abstinence rates

compared to medication alone (see Table 6.17). ese analyses suggest a robust e ect of quitline counseling and are consistent with a recent independent analysis[254] and with the recently released Centers for Disease Control and Prevention's *Guide to Community Preventive Services.*[92]

element of a complex intervention, or is considerably more intense than the comparison intervention. Given the potential reach and low costs of such interventions, however, they remain a highly promising delivery system for tobacco dependence.

Future Research

Future Research

e following topics regarding followup assessment and treatments require additional research:

- Optimal timing and types of relapse prevention interventions
- E fectiveness of various formats for relapse prevention treatments (e.g., e ectiveness of telephone contacts in reducing the likeliho

Table 6.18. Meta-analysis (2000): Effectiveness of and estimated abstinence rates for various types of counseling and behavioral therapies (n = 64 studies)[a]

ing or behavioral therapy in isolation. Second, various types of counseling and behavioral therapies tended to be correlated with other treatment characteristics. For instance, some types of counseling and behavioral therapies were more likely to be delivered using a greater number of sessions across longer time periods. ird, all of these types of counseling and behavioral therapies were compared with no-contact/control conditions. erefore, the control conditions in this meta-analysis did not control for nonspeci c or placebo e ects of treatment. is further restricted the ability to attribute e ectiveness to particular types of counseling and behavioral therapies *per se*. Fourth, the studies used in this analysis o en tailored the types of counseling and behavioral therapies to the needs of speci c populations being studied, thereby a ecting the generalizability of the study results. Fi h, there was considerable heterogeneity within each type of counseling and behavioral therapy.

Tables 6.19 and 6.20 outline elements of practical counseling (problemsolving/skills training) and intratreatment social support, respectively. ese tables are designed to help clinicians using these counseling and behavioral therapies. It must be noted, however, that these treatment labels are nonspeci c and include heterogeneous treatment elements. e e ectiveness of encouragement and support as part of treatment is consistent with the literature regarding the importance of providing a caring, empathic, and understanding context in making other health behavior changes.[278-280]

Table 6.19. Common elements of practical counseling (problemsolving/skills training)

Practical counseling (problemsolving/ skills training) treatment component	Examples
Recognize danger situations – Identify events, internal states, or activities that increase the risk of smoking or relapse.	• **Negative affect and stress** • **Being around other tobacco users** • **Drinking alcohol** • **Experiencing urges** • **Smoking cues and availability of cigarettes**
Develop coping skills – Identify and practice coping or problemsolving skills. Typically, these skills are intended to cope with danger situations.	• **Learning to anticipate and avoid temptation and trigger situations** • **Learning cognitive strategies that will reduce negative moods** • **Accomplishing lifestyle changes that reduce stress, improve quality of life, and reduce exposure to smoking cues** • **Learning cognitive and behavioral activities to cope with smoking urges (e.g., distracting attention; changing routines)**

Practical counseling (problemsolving/ skills training) treatment component	Examples
Provide basic information – Provide basic information about smoking and successful quitting.	• **The fact that any smoking (even a single puff) increases the likelihood of a full relapse** • **Withdrawal symptoms typically peak within 1–2 weeks after quitting but may persist for months. These symptoms include negative mood, urges to smoke, and difficulty concentrating.** • **The addictive nature of smoking**

Table 6.20. Common elements of intratreatment supportive interventions

Hypnosis. e 1996 Guideline did not conduct a separate meta-analysis on hypnosis because few studies met inclusion criteria, and those that did used very heterogeneous hypnotic procedures. ere was no common or standard intervention technique to analyze. Literature screening for the 2000 Guideline revealed no new published studies on the treatment of tobacco dependence by hypnosis that met the inclusion criteria; therefore, this topic was not reexamined. Moreover, an independent review of nine

- Effectiveness of smokefree policies, particularly smokefree homes and worksites, on increasing interest in, and the effectiveness of, tobacco dependence treatment[286]

- Effectiveness of family systems interventions as a means to increase support

Combining Counseling and Medication

Recommendation: The combination of counseling and medication is more effective for smoking cessation than either medication or counseling alone. Therefore, whenever feasible and appropriate, both counseling and medication should be provided to patients trying to quit smoking. (Strength of Evidence = A)

Recommendation: There is a strong relation between the number of sessions of counseling, when it is combined with medication, and the likelihood of successful smoking cessation. Therefore, to the extent possible, clinicians should provide multiple counseling sessions, in addition to medication, to their patients who are trying to quit smoking. (Strength of Evidence = A)

Evidence in this Guideline update supports the independent effectiveness of both counseling interventions and medication interventions. In the 2008 Guideline update, the Panel evaluated whether combining counseling and medication improved cessation rates relative to using either of these treatments alone.

Providing Counseling in Addition to Medication. Eighteen studies met selection criteria to evaluate the effectiveness of providing counseling in addition to medication versus medication alone. The results of this 2008 meta-analysis indicate that providing counseling in addition to medication significantly enhances treatment outcomes (see Table 6.22). These same 18 studies also were analyzed to examine the relation of counseling intensity when it was used in combination with a medication. Results revealed that two or more sessions significantly enhance treatment outcomes, and more than eight sessions produced the highest abstinence rates (see Table 6.23).

The counseling provided in these studies was delivered either in person or via telephone.

For Smokers Not Willing To Make a Quit Attempt At This Time

Recommendation: Motivational intervention techniques appear to be e ective in increasing a patient's likelihood of making a future quit attempt. erefore, clinicians should use motivational techniques to encourage smokers who are not currently willing to quit to consider making a quit attempt in the future. (Strength of Evidence = B)

Evidence suggests that a variety of motivational interventions can increase the motivation for behavior change. ese interventions have varied contents and labels (e.g., individualized motivational intervention, motivational consulting, and motivational interviewing; see e.g., Chan et al.,[170] Butler et al.,[171] and Brown et al.[173]). e motivational intervention that has perhaps the greatest level of support and content speci city is motivational interviewing.

Motivational interviewing (MI) is a speci c counseling strategy that is intended to increase a person's motivation for behavior change.[168] MI comprises a variety of strategies that are designed to help individuals resolve ambivalence about such change.[175] e technique has been used successfully to help individuals attempt and achieve many types of behavior change, including reduced drinking and illicit drug use, and reduction of HIV risk behaviors.[175,287,288]

Several studies have shown that MI techniques appear to be e ective in motivating smokers to make quit attempts. A randomized controlled trial of an MI-based intervention among 137 smokers with cancer found that MI signi cantly increased quit attempts compared to an advice condition.[289] Another study found that a single session of MI, versus either brief psychoeducational counseling or advice, signi cantly increased the proportion of patients with schizophrenia who contacted a tobacco dependence treatment provider and attended an initial treatment session.[174] A third study showed that two 45-minute individual counseling sessions based on MI principles yielded higher levels of intention to quit smoking among adolescents than did a brief advice condition.[173] No di erences in quitting attempts or quitting success were seen in that study, however. Studies that used motivational approaches that shared features of MI (but that were not

MI) yielded a mixed pattern of results, with some studies showing signi - cant increases in quit attempts (see, e.g., Butler et al.[171]); others showed only trends in that direction.[170] Finally, one study that targeted unmotivated smokers showed that counseling based on the "5 R's" (see Chapter 3, Strategy B2) signi cantly increased the odds of making a quit attempt that lasted at least 24 hours.[169]

e available evidence shows that the reviewed motivational interventions such as MI increase quit attempts when used with individuals not already interested in quitting. e evidence does not show that such interventions are reliably e ective as cessation treatments,[173,175,290] nor is there consistent evidence that MI-induced quit attempts translate into higher long-term abstinence rates. Evidence also shows that such interventions are more e ective in smokers with little pre-existing motivation to quit.[171,173] Finally, some evidence suggests that extensive training is needed before competence is achieved in the MI technique.[175,291]

Physiological Monitoring/Biological Marker Feedback To Motivate Smokers To Quit

Investigators have sought to determine whether feedback regarding either smoking e ects or disease risk motivates quit attempts. Modest evidence indicates that such feedback motivates quit attempts.[292] One small study found that multifaceted feedback involving CO level, vital capacity measurement, and discussion of pulmonary symptoms led to more quit attempts among smokers identi ed during routine medical screening.[293] In a second study, feedback regarding CO level and genetic susceptibility to cancer was associated with a greater likelihood of quit attempts 1 year later.[294] Although these results are encouraging, there is too little information to evaluate de nitively the e ects of physiological feedback.[284] In addition, there is insu cient information as to how this feedback a ects those at di erent levels of readiness to quit. It also is unclear whether feedback that a person is *not* at high risk would encourage continued smoking. Finally, data are mixed regarding the e ectiveness of feedback as a cessation versus motivational intervention. at is, data are mixed as to whether or not feedback increases abstinence rates.[284,295,296]

Future Research

e following topics require additional research:

- E ectiveness of motivational interviewing and related techniques, including the impact of brief motivational interviewing strategies delivered in primary care settings

- E ectiveness of physiological monitoring and biological marker feedback to motivate smokers to quit and increase abstinence rates

B. Medication Evidence

Recommendation: Clinicians should encourage all patients attempting to quit to use e ective medications for tobacco dependence treatment, except where contraindicated or for speci c populations for which there is insu cient evidence of e ectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). (Strength of Evidence = A)

As with other chronic diseases, the most e ective treatment of tobacco

at an appropriate dose and duration, were entered into one analysis. is inclusive medication meta-analysis allows for the comparison of particular medications to both placebo controls and other active medications (Table

12-month analyses were very similar to the 6-month results shown in Table 6.26.

Table 6.25. Coding rules for medication duration and dose

Medication	Coding	Meaning
Nicotine Patch	Usual duration	6–14 weeks
	Long duration	> 14 weeks
	Usual dose/day	15 mg/16 hours/day 21 mg/24 hours/day
	High dose喀埃Us　ｱ丿幎禅瓶枸梯瓶嵫濩け嵩＃暑㈰酧	
	Long duration	> 14 weeks
	へ覬舒詼過籠_古火ь位	U＃濩醼眥胺乘汸i咎疥唇膺Usual duratio

Table 6.26. Meta-analysis (2008): Effectiveness and abstinence rates for various medications and medication combinations compared to placebo at 6-months postquit (n = 83 studies)[a]

Bupropion SR (Sustained Release)

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

Bupropion SR was the rst non-nicotine medication shown to be e ective for smoking cessation and was approved by the FDA for that use in 1997. Its possible mechanisms of action include blockade of neuronal re-uptake of dopamine and norepinephrine and blockade of nicotinic acetylcholinergic receptors. It is contraindicated in patients with a seizure disorder, a current or prior diagnosis of bulimia or anorexia nervosa, use of a monoamine oxidase (MAO) inhibitor within the previous 14 days, or in patients taking another medication that contains bupropion. Bupropion SR is available exclusively as a prescription medication and can be used in combination with nicotine replacement therapies. Suggestions regarding the clinical use of bupropion SR are provided in Table 3.3.

Twenty-four studies generated the 26 arms that served as the basis for estimating the bupropion SR e ect. e bupropion SR dose was 150 mg for 3 of these study arms, and 300 mg for the other 22 of these arms (one study did not report dose). As Table 6.26 reveals, bupropion SR approximately doubles the likelihood of long-term (> 5 month) abstinence from tobacco use as compared to placebo treatment. ese results are consistent with other independent reviews.[299]

Nicotine Replacement Therapies (NRTs)

Nicotine replacement therapy (NRT) medications deliver nicotine with the

Nicotine gum currently is available exclusively as an OTC medication and is packaged with important instructions on correct usage, including chewing (see Table 3.4 for information on the clinical use of nicotine gum). Nine studies generated the 15 study arms that served as the basis for estimating the e ect of nicotine gum. In addition, another four studies generated the six arms that served as the basis for the estimation of e ects of long-term gum use (directed use beyond 14 weeks). Two arms used gum for 52 weeks, and the other four arms used gum for 24–26 weeks. Table 6.26 reveals that regular course and long-term nicotine gum use increased the likelihood of long-term abstinence by about 50 percent compared to placebo treatment. ese results are consistent with other independent reviews.

a rst cigarette 30 minutes or more a er waking) approximately doubled and the 4-mg lozenge for highly dependent smokers (smoke a rst cigarette within 30 minutes of waking) approximately tripled the odds of abstinence at 6 months postquit as compared to placebo treatment. See Table 6.27 for the study results. ese results are consistent with other independent reviews.[300]

Table 6.27. Effectiveness of the nicotine lozenge: Results from the single randomized controlled trial

Twenty- ve studies generated the 32 study arms that served as the basis for

Evidence indicates that varenicline is well-tolerated for periods up to 1 year[306] and that extended treatment may prove useful in reducing the likelihood of relapse.[307] More research is needed, however, to evaluate varenicline as a relapse prevention medication, to assess its long-term e ects, and to evaluate its e ectiveness in speci c populations.

e metabolism of bupropion is mediated primarily by CYP2B6. ree categories of drugs could have clinically signi cant interactions with bupropion: drugs a ecting CYP2B6, drugs metabolized by CYP2D6, and general enzyme inducers/inhibitors.[310] Drugs that a ect CYP2B6 metabolism, such as cyclophosphamide and orphenadrine, potentially could alter bupropion metabolism. Bupropion and its metabolites inhibit CYP2D6[311,312] and could a ect the impact of agents metabolized by this enzyme (e.g., tricyclic antidepressants, antipsychotics, type 1C anitarrhythmics, or certain beta-blockers). Due to the extensive metabolism of bupropion, enzyme inducers (e.g., carbamazepine, phenobarbital, phenytoin) and inhibitors (e.g., valproate, cimetidine) may alter its plasma concentration. Bupropion can lower seizure threshold. It should be used with caution with medications that can also lower seizure threshold.[310,313] Speci cally, use of bupropion within 14 days of discontinuation of therapy with any MAO inhibitor is contraindicated.

Varenicline is eliminated unchanged by kidney excretion and thus is

ree studies generated three analyzable study arms that served as the basis for estimating clonidine's e ects on long-term abstinence. ese studies all were conducted prior to 1997. Table 6.26 reveals that the use of clonidine approximately doubles abstinence rates when compared to a placebo. ese studies varied the clonidine dose from 0.1 to 0.75 mg per day. e drug was delivered either transdermally or orally. It should be noted that abrupt discontinuation of clonidine can result in symptoms such as nervousness, agitation, headache, and tremor, accompanied or followed by a rapid rise in blood pressure and elevated catecholamine levels.

Clonidine is used primarily as an antihypertensive medication and has not been approved by the FDA as a medication for treating tobacco use and dependence. erefore, clinicians need to be aware of the speci c warnings regarding this medication as well as its side-e ect pro le. Additionally, a speci c dosing regimen for the use of clonidine in smoking cessation has not been established. e Guideline Panel chose to recommend clonidine as a second-line as opposed to rst-line agent because of the warnings associated with clonidine discontinuation, variability in dosages used to test this medication, and lack of FDA approval. As such, clonidine should be considered for treating tobacco use under a physician's monitoring with patients unable to use rst-line medications because of contraindications or with patients who were unable to quit when using rst-line medications. An independent review[298] indicated that clonidine is e ective in promoting smoking abstinence, but prominent side e ects limit its usefulness. Suggestions regarding clinical use of clonidine are provided in Table 3.10.

Nortriptyline

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

Four studies generated the ve analyzable study arms that served as the basis for estimating the e ect of nortriptyline on long-term abstinence. Nortriptyline dosages were 75 mg per day (3 arms) and 100 mg per day (2 arms), with treatment lasting from 6 to 13 weeks across the ve arms. As Table 6.26 shows, nortriptyline almost doubles a smoker's likelihood of achieving long-term abstinence from tobacco as compared to placebo treatment. A recent independent review[158] also indicated that nortriptyline is e ective in treating tobacco dependence. Suggestions regarding the

clinical use of nortriptyline are provided in Table 3.11. Nortriptyline is used primarily as an antidepressant and has not been evaluated or approved by the FDA as a medication for treating tobacco use and dependence. Clinicians need to be aware of the speci c warnings regarding this medication as well as its side-e ect pro le. Because of the side-e ect pro le and the lack of FDA approval for tobacco dependence treatment, nortriptyline is recommended as a second-line rather than a rst-line agent. As such, nortriptyline should be considered for treating tobacco use under a physician's direction with patients unable to use rst-line medications because of contraindications or with patients who were unable to quit using rst-line medications.

Combination Medications

Recommendation: Certain combinations of rst-line medications have been shown to be e ective smoking cessation treatments. erefore, clinicians should consider using these combinations of medications with their patients who are willing to quit. E ective combination medications are:

- **Long-term (> 14 weeks) nicotine patch + other NRT (gum and spray)**
- **e nicotine patch + the nicotine inhaler**
- **e nicotine patch + bupropion SR (Strength of Evidence = A)**

e number and variety of analyzable articles was su cient to assess the e ectiveness of ve combinations of medications relative to placebo. Only the patch + bupropion combination has been approved by the FDA for smoking cessation.

Nicotine Patch + Bupropion SR

ree studies yielded three analyzable study arms that served as the basis for estimating the e ect of the nicotine patch + bupropion SR on long-term abstinence. Both the patch and bupropion SR were used at standard durations and doses (see Table 6.25).

Nicotine Patch + Nicotine Inhaler

Two studies generated two arms that served as the basis for estimating the

Effectiveness of Medication Combinations

Table 6.26 displays the 2008 meta-analytic results describing the e ectiveness data for the ve medication combinations. e data reveal that the nicotine patch + bupropion SR, the nicotine patch + inhaler, the long-term nicotine patch + *ad libitum* NRT, the nicotine patch + nortriptyline, and the nicotine patch + second generation antidepressants all signi cantly increased a smoker's likelihood of abstinence relative to placebo treatment. A meta-analysis using 12-month abstinence rates had similar results. e rst three medication combinations involve only rst-line medications and therefore are recommended for use as rst-line treatments.

Decisions about use of a medication combination may be based on considerations other than abstinence. Evidence indicates, for instance, that a combination of medication may result in greater suppression of tobacco withdrawal symptoms than does the use of a single medication.[148,315,316] Patient preferences also may play a role, because some combinations of medications may produce more side e ects and cost more than individual medications.[315,317,318]

Relative Effectiveness of Medications

Information on the relative e ectiveness of medications may help the clinician and patient select an appropriate medication intervention. To this end, all medication conditions in Table 6.26 were compared with the nicotine patch. e nicotine patch was selected as a comparison condition because more study arms were available for this condition than for any other, and because this condition was of moderate e ectiveness relative to other conditions (see Table 6.26; OR = 1.9). Contrasts between all treatments were not conducted because of concerns about Type I error due to multiple testing. Also, a conservative Hochberg[319] adjustment to

Finally, a small pilot study found that prequit patch use was well tolerated by smokers wanting to quit.[322] Given the limited data on this strategy, the Panel declined to recommend precessation use of NRT among patients making a quit attempt. However, this topic warrants further research.

decided not to recommend medication use as a standard intervention for smokers unwilling to quit. A recent Cochrane analysis[323] found that NRT signi cantly increased quit rates among smokers not initially motivated to quit. e authors concluded, however, that there was insu cient evidence to recommend this as a standard treatment approach with this population.

e Panel believes that this topic warrants further research.

Selective Serotonin Re-Uptake Inhibitors (SSRIs)

Two studies yielded three analyzable arms that served as the basis for estimating the e ects of SSRIs. Sertraline (200 mg per day) served as the medication in one arm, and uoxetine (30 to 60 mg per day) served as the medication in the other two arms. e treatment duration was 10 weeks in all arms. Results showed that treatment with SSRIs did not signi cantly increase the likelihood of abstinence relative to placebo treatment. ese results are consistent with other independent reviews[299] (see Table 6.26).

Anxiolytics/Benzodiazepines/Beta-Blockers

A few trials have evaluated anxiolytics and other agents that reduce the somatic signs or the symptoms of anxiety. Early individual trials of propranolol, a beta-blocker,[329] and diazepam, an anxiolytic,[330] did not reveal a bene cial e ect for these drugs compared with control interventions. Likewise, of the early studies assessing the anxiolytic buspirone that met inclusion criteria, only one revealed evidence of e ectiveness relative to placebo.[331] Further studies of buspirone have failed to replicate this e ect.[332-334] ese results are consistent with other independent reviews.[333] Because of a lack of data, no meta-analyses were conducted, and no conclusions were drawn regarding the e ectiveness of anxiolytics in smoking cessation.

Opioid Antagonists/Naltrexone

Two studies yielded the analyzable study arms that served as the basis for estimating the e ects of the opiate antagonist naltrexone. Table 6.26 reveals that naltrexone treatment did not increase the likelihood of abstinence relative to placebo treatment. ese results are consistent with other independent reviews.[335] Two studies[336,337] also examined whether naltrexone added to the e ectiveness of the nicotine patch. e studies used di erent

Silver Acetate

Due to limitations of the literature available regarding silver acetate, this agent was not included in the inclusive meta-analysis. Several randomized clinical trials[338-340] of silver acetate, however, revealed no bene cial e ects for smoking cessation; a Cochrane review concurs with this nding.[341]

Mecamylamine

In the single study that compared mecamylamine alone to placebo, no e ectiveness was noted.[342] Another early study compared a combination of mecamylamine plus the nicotine patch to placebo and found a signi cant e ect for this combination.[343] A more recent study comparing nicotine patch alone to nicotine patch plus mecamylamine found no signi cant di erences.[344] ese ndings are consistent with other independent reviews.[345] Because of these ndings, the Panel drew no conclusions regarding mecamylamine as a monotherapy.

Extended Use of Medications

For some patients, it may be appropriate to continue medication treatment for periods longer than is usually recommended. Results of the inclusive meta-analysis indicated that long-term patch and gum use are e ective. Evidence indicates that the long-term use of gum may be more e ective than a shorter course of gum therapy (Table 6.26). e Lung Health Study, of almost 4,000 smokers with evidence of early COPD, reported that approximately one-third of long-term quitters still were using nicotine gum at 12 months,[346] and some for as long as 5 years, with no serious side e ects.[347] Other studies also have found that, among patients given free access to nicotine gum, 15 to 20 percent of successful abstainers continue to use the gum for a year or longer.[348] us, it may be that certain groups of smokers may bene t from long-term medication use. Although weaning should be encouraged for all patients using medications, continued use of such medication clearly is preferable to a return to smoking with respect to health consequences. is is because, unlike smoking, these medications do not (a) contain non-nicotine toxic substances (e.g., "tar," carbon monoxide, formaldehyde, benzene); (b) produce sharp surges in blood nicotine levels; and/or (c) produce strong dependence.[349,350] Finally, it should be noted that the medication treatment that produced the largest e ects on abstinence rates, of those analyzed, involved long-term nicotine patch therapy + *ad libitum* NRT (Table 6.26).

Use of NRT in Cardiovascular Patients

Soon a er the nicotine patch was released, the media reported a possible link between the use of this medication and cardiovascular risk. is question has been studied systematically since that time. Separate analyses now have documented the lack of an association between the nicotine patch and acute cardiovascular events,[351-356] even in patients who continued to smoke while on the nicotine patch,[357] although a recent study raised questions regarding NRT use in intensive care units.[358] Because of inaccurate media coverage in the past, it may be important to inform patients who are reluctant to use NRTs that there is no evidence of increased cardiovascular risk with these medications. Note that package inserts recommend caution in patients with acute cardiovascular diseases (see Tables 3.3–3.11).

Future Research

e following pharmacotherapeutic topics require additional research:

- Relative e fectiveness and safety of the seven FDA-approved medications, in general and for speci c subpopulations (e.g., women; adolescents; older smokers; smokeless tobacco users; individuals with psychiatric disorders, including substance use disorders; postmyocardial infarction patients) and for long-term treatment

- Use of combined tobacco dependenc] D iveness and andmdic

Use of Over-the-Counter Medications

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

No new studies were identified for the 2008 update that examined the effectiveness of nicotine patch versus placebo patch in an OTC setting. Based on the 2000 Guideline, there were three placebo-controlled studies with six arms that met selection criteria for the meta-analysis of medication interventions in OTC settings. These three studies specifically examined the effect of patch versus placebo. The only additional treatments in these studies were a self-help manual, instructions contained in the package, or written directions for using the patch. As shown in Table 6.30, the use of the nicotine patch in OTC settings nearly doubles abstinence rates when compared to a placebo. These results are consistent with a more recent (2003) meta-analysis of active versus placebo patch in an OTC setting that found an odds ratio of 2.5 (95% C.I. = 1.8–3.6) for active nicotine patch.[359] A study that did not meet inclusion criteria for meta-analysis reported low abstinence rates when the nicotine patch was used in the OTC setting.[360] Too few studies were done in the OTC setting to permit meta-analysis of the OTC effect of any other medication. The "B" strength of evidence rating reflects the Panel's concern about the external validity of the studies designed to reflect the OTC context.

The FDA has approved nicotine gum, the nicotine lozenge, and the nicotine patch for OTC use. The patches and gum are identical to those previously available only via prescription. Although the OTC status of these medications has increased their availability and use,[361] this does not reduce the clinician's responsibility to intervene with smokers or insurers/managed care organizations/payers to cover the costs of such treatment. Moreover, OTC availability may enhance the capacity of a broad array of clinicians to intervene comprehensively when treating tobacco dependence.

All clinicians have specific responsibilities regarding these products, such as encouraging their use when appropriate, identifying patients with specific contraindications, providing counseling and followup, encouraging total abstinence during a quit attempt, offering instruction on appropriate use, addressing common patient misconceptions, and providing prescriptions

when needed for select populations to ensure reimbursement (e.g., Medicaid patients). Additionally, patients should be urged to read the package insert and consult with their pharmacist. Finally, the clinician should advise patients regarding the selection and use of medications, whether purchased OTC or by prescription. Debate has arisen in the eld regarding the e ec-

C. Systems Evidence

outcomes such as clinician assessment of smoking status (“Ask”), provision

Table 6.34. Meta-analysis (2008): Effectiveness of training combined with charting on setting a quit date ("Assist") (n = 2 studies)[a]

provide training nor require competency in tobacco use interventions,[370] although this is improving slowly.[371,372] One survey of U.S. medical schools found that most medical schools (69%) did not require clinical training in tobacco dependence treatment.[373] The National Cancer Institute's Prevention and Cessation Education in Medical Schools (PACE) reported that, in

Future Research

e following topics regarding clinician training require additional research:

- E fectiveness of training programs for other health disciplines, such as nursing, psychology, dentistry (including hygienists), social work, and pharmacy

- E fective elements in successful training programs (e.g., continuing medical education, interactive components)

- Combined e fect of multiple systems changes, such as clinician training, reminder systems, clinician feedback, incentive payments, and recruitment of opinion leaders

Cost-Effectiveness of Tobacco Dependence Interventions

Recommendation: e tobacco dependence treatments shown to be e ective in this Guideline (both counseling and mediEMC 5 j EMC [7encica e ecFF4FEFFtivdelinep05A0r]TJ /4(crin t(nd me)-13(d0>>> e)G)3(ui)7(v)004E

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medical treatments. Cost-e ectiveness analyses have shown that tobacco dependence treatment compares favorably with routinely reimbursed medical interventions such as the treatment of hypertension and hypercholesterolemia, as well as preventive screening interventions such as periodic mammography or Papanicolaou smears.[222,224,379-382]

Health Care Costs and Utilization Pre- and Postquit

A substantial body of research has investigated the e ect of tobacco use treatment on health care costs.[395-399] A synthesis of these ndings suggests that: (1) among individuals who quit tobacco use, health care costs typically increase during the year in which smokers quit then decline progressively, falling below those of continuing smokers for 1 to 10 years a er quitting; (2) in general, smokers' health care costs begin to rise in the time period immediately prior to quit attempts; and (3) higher health care utilization predicts smoking cessation among smokers with and without chronic diseases. ese ndings suggest that quitting smoking o en occurs in response to serious and expensive health problems. Such research also suggests that increases in health care costs, including hospitalizations, during the year of quitting may be a cause rather than a consequence of successful smoking cessation.

Return on Investment for Coverage of Tobacco Dependence Treatment

e ROI tool is used frequently to estimate the amount of time it takes for an expenditure to earn back some or all of its initial investment. e economic arguments supporting the decision to provide insurance coverage for tobacco use treatments would be enhanced if the costs of such coverage are modest compared to economic bene ts resulting from successful cessation (reductions in health care expenditures, increased productivity, and/or other costs).

Studies have documented that tobacco dependence treatments provide a timely return on investment when considered by the employer. Such analyses have concluded that providing coverage for tobacco use treatment for employees o en produces substantial net nancial savings through increased health care savings, increased productivity, reduced absenteeism, and reduced life insurance payouts.[229,400-402]

Financial savings are more di cult to attain for a health plan given factors such as member turnover, the di culty of attributing reduced health care expenditures to tobacco dependence, and the absence of economic bene ts resulting from productivity gains. Although most analyses have

Tobacco Dependence Treatment as a Part of Assessing Health Care Quality

Recommendation: Provision of Guideline-based interventions to treat tobacco use and dependence should remain in standard ratings and measures of overall health care quality (e.g., NCQA HEDIS). ese standard measures should also include measures of outcomes (e.g., use of cessation treatment, short- and long-term abstinence rates) that result from providing tobacco dependence interventions. (Strength of Evidence = C)

e provision of tobacco dependence treatment should be increased by: (1) attention to health organization "report cards" (e.g., HEDIS, e Joint Commission, Physician Consortium for Performance Improvement, National Quality Forum, Ambulatory Quality Alliance),[89,412-414] which support smoker identi cation and treatment; (2) accreditation criteria used by e Joint Commission and other accrediting bodies that include the presence of e ective tobacco assessment and intervention policies; and (3) increasing the use of tobacco-related measures in pay-for-performance initiatives.

Future Research

e following topics regarding cost-e ectiveness and health systems require additional research:

- Cost-e fectiveness of the various tobacco dependence treatments, both short- and long-term
- Optimal ways to remove systemic barriers that prevent clinicians from e ectively delivering tobacco dependence treatments
- Systemic interventions to encourage provider and patient utilization of e ective tobacco dependence treatments
- Relative costs and economic impacts of di ferent formats of e fective treatments (e.g., proactive telephone counseling, face-to-face contact, medication)

- Impact of using tobacco

Table 6.37. Meta-analysis (2008): Estimated rates of intervention for individuals who received tobacco use interventions as a covered health insurance benefit (n = 3 studies)[a]

Treatment	Number of arms	Estimated odds ratio (95% C.I.)	Estimated intervention rate (95% C.I.)
Individuals with no covered health insurance benefit	3	1.0	8.9
Individuals with the benefit	3	2.3 (1.8–2.9)	18.2 (14.8–22.3)

[a] Go to *www.surgeongeneral.gov/tobacco/gdlnrefs.htm* for the articles used in this meta-analysis.

Table 6.38. Meta-analysis (2008): Estimated rates of quit attempts for individuals who received tobacco use interventions as a covered health insurance benefit (n = 3 studies)[a]

Future Research

- Impact of promotion or communication of tobacco dependence treatment bene ts on utilization and resulting population health and economic e ects
- Cost-e fectiveness of speci fc elements of tobacco dependence treatment
- Appropriate level of payment needed to optimize clinician delivery of tobacco dependence treatment

Chapter 7 Specific Populations and Other Topics

Background

Many factors could a ect the acceptability, use, and e ectiveness of tobacco dependence treatments. is raises the question of whether interventions should be tailored or modi ed on the basis of personal characteristics or contextual factors such as gender, race/ethnicity, age, comorbidity, or hospitalization status. Should pregnant smokers receive tobacco dependence medication? Do tobacco dependence interventions interfere with nontobacco chemical dependency treatments? ese and other speci c populations and issues are considered in this chapter. e answers to these questions are relevant to a range of clinicians who routinely deal with speci c populations of smokers (e.g., obstetricians, gynecologists, pediatricians, psychiatrists, internists, cardiologists, nurses, pharmacists, dentists, and dental hygienists).

Recommendation: e interventions found to be e ective in this Guideline have been shown to be e ective in a variety of populations. In addition, many of the studies supporting these interventions comprised diverse samples of tobacco users. erefore, interventions identi ed as e ective in this Guideline are recommended for all individuals who use tobacco, except when medication use is contraindicated or with speci c populations in which medication has not been shown to be e ective (pregnant women, smokeless tobacco users, light smokers, and adolescents). (Strength of Evidence = B)

Effective Treatments for Specific Populations

e above recommendation applies to the broad population of smokers, including HIV-positive smokers; hospitalized smokers; lesbian/gay/bisexual/transgender smokers; those with low socioeconomic status (SES)/limited formal education; smokers with medical comorbidities; older smokers; smokers with psychiatric disorders, including substance use disorders; racial and ethnic minorities; and women smokers. It does not apply to adolescents, pregnant smokers, light smokers, and smokeless tobacco users (see below).

e recommendation that tobacco dependence treatments be used with broad populations of tobacco users arises from several considerations. One is that many of the randomized trials that generated the treatment recommendations comprised diverse samples. A second consideration is that the studies that tested interventions in homogeneous, speci c populations show that interventions that are e ective in one population tend to be e ective in other populations. Finally, the relative safety of the tobacco dependence treatments versus the hazards of continued tobacco use supports some extrapolation from extant data. Table 7.1 reviews the randomized clinical trial (RCT) evidence of e ectiveness of various treatments in di erent populations. Unless speci cally stated, this table presents evidence from individual, screened RCTs rather than from meta-analyses. It is not intended to provide a comprehensive review of the relevant literature, but rather to provide some key ndings from that review. Importantly, adolescents, pregnant smokers, light smokers, and smokeless tobacco users each have their own sections of this Guideline update, given that they usually are excluded from the RCTs used to evaluate the e ectiveness of interventions presented in this Guideline and may have other special issues (e.g., safety).

Table 7.1. Evidence of effectiveness of tobacco dependence interventions in specific populations

Population of Smokers	Review of Evidence
HIV-positive	No long-term RCTs have examined the effectiveness of interventions in this population. More research is needed. • One study with 3-month followup indicated that telephone counseling is promising.[418] • Pilot data indicate that effective treatments work with this population.[419]
Hospitalized patients	2007 Cochrane analyses[420] revealed that intensive intervention (inpatient contact plus followup for at least 1 month) was associated with a significantly higher quit rate compared to control conditions (OR = 1.65; 95% CI = 1.44–1.90, 17 trials). Specific additional Cochrane findings: • Posthospitalization followup appears to be a key component of effective interventions. • No significant effect of medication was seen in this population. However, the effect sizes were comparable to those obtained in other clinical trials, suggesting that nicotine replacement therapy (NRT) and bupropion SR may be effective in this population.

Population of Smokers	Review of Evidence
Older smokers	•

Clinical Issues for Specific Populations

ere are population-speci c concerns and clinical issues regarding prevalence and treatment of tobacco dependence (see Table 7.2).

Table 7.2. Clinical issues for treating specific populations

Issue	Approach
Language	• **Ensure that interventions are provided in a language the patient understands. Most quitlines provide counseling in Spanish, and some provide counseling in other languages.[503]** • **All textual materials used (e.g., self-help brochures) should be written at an appropriate reading level. This is particularly important t # ㈜暑酚濩툉㈜暄pro旨穀亟ы穎烜含褻毋暑滋垌ゼ簪**

they will not live long enough for the health e ects of smoking to matter.[507,522] In addition, some HIV-positive smokers report that smoking is an e ective way to cope with the stress of their illness.[522]

Future Research

e following topics regarding HIV-positive smokers require additional research:

- E ectiveness of medications and counseling/behavioral interventions, including tailored interventions
- E ectiveness of motivational interviewing and educational approaches in increasing motivation to quit
- E ectiveness of community and social support networks in bolstering quitting motivation and improving treatment outcomes

Hospitalized Smokers

It is vital that hospitalized patients attempt to quit using tobacco because tobacco use may interfere with their recovery and overall health. Among cardiac patients, second heart attacks are more common in those who continue to smoke.[9,523] Lung, head, and neck cancer patients who are successfully treated for their cancer but who continue to smoke are at elevated risk for a second cancer.[524-531] Additionally, smoking negatively a ects COPD as well as bone and wound healing.[531-538]

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 tobacco use, highlighting the patient's perceived vulnerability to the health risks of smoking[539] and making the hospitalization a "teachable moment." Second, every hospital in the United States must now be smoke-free if it is to be accredited by e Joint Commission. As a result, every hospitalized smoker is temporarily housed in a smoke-free environment. In addition, more hospitals are adopting policies establishing tobacco-free campuses, thus extending smoke-free space from indoor facilities to surrounding outdoor environments.[540-542] For these reasons, clinicians should use hospitalization as an opportunity to promote smoking cessation.[11,543,544] is also is an opportunity for clinicians to

Lesbian/Gay/Bisexual/Transgender (LGBT) Smokers

LGBT individuals, both adolescents and adults, are more likely to smoke than the general population,[548-550] and tobacco marketing is targeted at these communities.[551-554] LGBT individuals are more likely to have other risk factors for smoking, including daily stress related to prejudice and stigma.[555-558]

Future Research

e following topics regarding LGBT smokers require additional research:

- Accessibility and acceptability of tobacco dependence

Future Research

e following topics regarding low SES/limited formal education smokers require additional research:

- E fectiveness of and compliance with medications shown to be e fective with general populations of smokers

- E fectiveness and utilization z s

- Impact and effectiveness of specialized assessment and tailored interventions in these populations

Older Smokers

It is estimated that more than 18 million Americans age 45 and older smoke cigarettes, accounting for 41 percent of all adult smokers in the United States;[589] 4.5 million adults over age 65 smoke cigarettes.[590] Even smokers over the age of 65 can benefit greatly from abstinence.[9,405,523,591] Older smokers who quit can reduce their risk of death from coronary hear/TT0 1(i)3/lioa(0)12(uce t)12(ucen0100.4510(ui)(ucP4(eD)40045)7(lder)]6(v)8u)1

tobacco dependence treatment may have a past history of depression,[599,600] and 20 percent or more may have a past history of alcohol abuse or de-

- Relative effectiveness and reach of different tobacco dependence medications and counseling strategies in patients with psychiatric comorbidity, including depression

- Effectiveness and impact of tobacco dependence treatments within the context of nontobacco chemical dependency treatments

- Importance and effectiveness of specialized assessment and tailored interventions in these populations

- Impact of stopping tobacco use on psychiatric disorders and their management

Racial and Ethnic Minority Populations

Some racial and ethnic minority populations in the United States—African Americans, American Indians and Alaska Natives, Asians and Pacific Islanders, Hispanics—experience higher mortality in a number of disease categories compared with others. For example, African Americans experience substantial excess mortality from cancer, cardiovascular disease, and infant death, all of which are directly affected by tobacco use.[622-626] Moreover, they experience greater exposure to tobacco advertising.[627-629] American Indian and Alaska Natives have some of the highest documented rates of infant mortality caused by SIDS,[630,631] which also is affected by tobacco use and exposure to secondhand smoke. Therefore, the need to deliver effective tobacco dependence interventions to ethnic and racial minority smokers is critical. Unfortunately, evidence indicates that large proportions of some racial/ethnic groups lack adequate access to primary care providers and are more likely to have low SES.[632,633] These populations may be less aware of Medicaid or other available benefits[564,633-635] and more likely to harbor misconceptions about tobacco dependence treatments.[636-639] Finally, these populations may be less likely to receive advice to stop smoking[640,641] or ore8125 dv4057p4ec [(o)1n4 182nce t5atave lo

within minority subgroups (e.g., gender, level of acculturation, tribal communities).[636,657-663] Racial and ethnic minority groups also di er from whites in awareness of the health e ects of smoking[636,664-667] and awareness of the bene ts of proven treatments, and some racial and ethnic minority populations report a greater sense of fatalism that may a ect disease prevention e orts.[637,660] On the other hand, both tobacco dependence and desire to quit appear to be prevalent across varied racial and ethnic groups.[642,667-671] In fact, smokers in several racial and ethnic groups attempt to quit as o en as or more o en than nonminority smokers, but use e ective treatments less o en and have lower success rates.[642,672]

Future Research

e following topics regarding racial and ethnic minorities require additional research:

- E fectiveness of speci fc tobacco dependence interventions, including medications and quitlines, in these populations (e.g., American Indian and Alaska Native smokers)
- E fectiveness of culturally adapted versus generic interventions for different racial and ethnic minority populations
- Identi fcation and development of interventions to address the speci fc barriers or impediments to treatment delivery, use, or success (e.g., SES, inadequate access to medical care, treatment misconceptions, not viewing tobacco use as problematic)
- Identi fcation of motivators of cessation that are especially e fective with members of racial and ethnic minority populations (e.g., fear of illness requiring long-term care and disability)

Women

Data suggest that women are more likely to seek assistance in their quit attempts than are men.[673] Research suggests that women bene t from the same interventions as do men, although the data are mixed on whether they bene t as much as men.[156,157] Women may face di erent stressors and barriers to quitting that may be addressed in treatment. ese include greater likelihood of depression, greater weight control concerns, hormon-

al cycles, greater nonpharmacologic motives for smoking (e.g., for socialization), educational di erences, and others.[248] is suggests that women may bene t from tobacco dependence treatments that address these issues, although few studies have examined programs targeted at one gender.

Future Research

e following topics regarding gender di erences require additional research:

- Gender di f erences in the e f ectiveness of tobacco dependence treatments found to be e ective in this Guideline, including counseling and the e ectiveness of varenicline and combination medications

- Impact of gender-speci f c motives that may increase quit attempts and

Background

Tobacco use is a pediatric concern. In the United States, about 4,000 children and adolescents under age 18 smoke their first cigarette each day, and an estimated 1,200 children and adolescents become daily cigarette smokers each day.[44,674] Among adults who ever smoked daily, 90 percent tried their first cigarette before age 21.[675] It is estimated that in 2006, 3.3 million U.S. adolescents aged 12 to 17 were current (past month) users of tobacco products and 2.6 million were current cigarette smokers.[43] Although use of cigarettes and cigars declined slightly from 2005 among this age group, the use of smokeless tobacco increased.[43] If current patterns persist, an estimated 6.4 million youth will die prematurely from a smoking-related disease.[675] Young people experiment with or begin regular use of tobacco for a variety of reasons, including social and parental norms, advertising, movies and popular media, peer influence, parental smoking, weight control, and curiosity.[676-685] Nicotine dependence, however, is established rapidly even among adolescents.[686-689] Because of the importance of primary prevention, clinicians should ensure that they deliver tobacco prevention and cessation messages to pediatric patients and their parents. Because tobacco use often begins during preadolescence,[690] clinicians should routinely assess and intervene with this population. Intervention research remains a priority for this population. Current reviews of smoking prevention and cessation interventions for adolescents have, so far, demonstrated limited evidence of effectiveness.[691,692] A 2007 national survey of youth tobacco cessation programs showed a lack of such programs in communities most in need—those in which youth smoking prevalence is increasing.[693] Prevention strategies useful in more general settings can be found in the Institute of Medicine report *Growing Up Tobacco Free*[694] and in the 2000 Surgeon General's Report *Reducing Tobacco Use*[6] and recently have been addressed by several authors.[695,696]

Young people vastly underestimate the addictive potential of nicotine. Adolescent smokers, both occasional and daily smokers, are more likely than nonsmokers to think they can quit at any time.[697] However, only about 4 percent of smokers aged 12 to 19 successfully quit smoking each year,[698,699] and the rate of failed adolescent quit attempts exceeds that of adult smokers.[32] Adolescents are very interested in quitting; 82 percent of 11- to 19-year-olds who smoke are thinking about quitting,[700] and 77 percent have made a serious quit attempt in the past year.[701,702] Adolescent quit attempts are rarely planned, and adolescents tend to choose unassisted

rather than assisted quit methods,[32] even though young people who enroll in a tobacco cessation program are twice as likely to succeed in their quit attempt.[703,704]

Questions have been raised about whether and how clinicians caring for children and adolescents might o er treatment for tobacco dependence to their parents who smoke. Would such treatment interfere with the doctor-patient relationship that parents might have with their physicians? In response to this concern, the American Medical Association adopted a policy statement in 2005 supporting the practice of pediatricians addressing parental smoking.[726]

Tobacco Use Medications. Although nicotine replacement has been shown to be safe in adolescents, there is little evidence that these medications and bupropion SR are e ective in promoting long-term smoking abstinence among adolescent smokers.[727-731] As a result, they are not recommended as a component of pediatric tobacco use interventions. One small pilot study (N = 22) found some positive initial e ects for bupropion SR.[730] However, other studies have found no di erence between placebo and patch at 10 or 12 weeks postquit[727] or between placebo versus gum or patch at 6 months postquit.[729,732] e majority of these studies also included an intensive counseling component (6 or more sessions).

Future Research

e following topics regarding adolescents and children require additional research:

- E fectiveness of using the 5 A's in pediatric clinics to treat both adolescents and parents
- Safety and e fectiveness of medications in adolescents, including bupropion SR, NRT, varenicline, and a nicotine vaccine
- E fectiveness of counseling interventions designeddesigneddesd erventio]

ers (≤ 15 cigarettes per day) compared to placebo.[741] Another study found no di erence in e ectiveness of 2-mg gum versus placebo.[176]

Future Research

e following topic regarding light smokers requires additional research:

in the treatment of smokeless tobacco use. For instance, a large majority of moist snu users have identi able oral lesions, and emphasizing this information during an oral exam may be useful in motivating a quit attempt. A close review of the literature showed that dental health clinicians (e.g., dental hygienists) delivering brief advice to quit using smokeless tobacco, in the context of oral hygiene feedback, can increase abstinence rates.[250,751]

Cigar smokers are at increased risk for coronary heart disease; COPD; periodontitis; and oral, esophageal, laryngeal, lung, and other cancers; with evidence of dose-response e ects.[752-756] e prevalence of cigar smoking was 5 percent for men and less than 1 percent for women.[590] Although cigarette sales have declined over the last decade, cigar sales have increased in the United States, increasing 15.3 percent in 2005,[757] and sales of "little cigars" were at an all-time high in 2006.[758] Cigar smokers are known to discount the health e ects of cigar smoking, believing it to be less detrimental than cigarettes.[752,759]

Clinicians should be aware of and address the use of other noncigarette

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o ers more options to the clinician, including medication options, as fetal health concerns are not present.

Even women who have maintained total abstinence from tobacco for 6 or more months during pregnancy have a high rate of relapse in the postpartum period.[787,791,792] Postpartum relapse may be decreased by continued emphasis on the relationship between maternal smoking and poor health outcomes in infants and children (e.g., SIDS, respiratory infections, asthma, and middle ear disease).[793-798] One pilot study found that a relapse prevention intervention was e ective;[799] however, two reviews of relapse prevention trials (both pre- and postdelivery) found no signi cant reduction in relapse.[185,770] ere is a great need for research on the prevention of postpartum relapse. Table 7.7 outlines clinical factors to address when counseling pregnant women about smoking.

Meta-analytic results support the e ectiveness of self-help materials compared to either basic information sheets or no intervention in assisting women to quit during pregnancy (see Table 7.8). Pamphlets and quitting guides were used as the self-help intervention in both studies analyzed. Other studies document favorable outcomes when self-help materials, with or without brief discussion/counseling, are added to standard advice to quit smoking.[774,800]

Table 7.8. Meta-analysis (2008): Effectiveness of and estimated preparturition abstinence rates for self-help interventions with pregnant smokers (n = 2 studies)[a]

ally less than those seen with cigarette smoking.[822] e three clinical trials of NRT in pregnant women have yielded information relative to safety.

e Wisborg trial of 250 women randomized to nicotine patch (15 mg) or placebo for 11 weeks found no evidence of serious adverse e ects of nicotine.[801] To the contrary, birth weight was signi cantly higher in the NRT group, possibly due to reduced cigarette smoking in the NRT group. e Kapur study included 30 women randomized to nicotine patches (15 mg) or placebo, and reported no serious adverse e ects of NRT.[802] One placebo-treated woman experienced extreme nicotine withdrawal, associated with increased fetal movements, prompting discontinuation of the trial. e Pollack study included 181 women, 122 randomized to CBT plus NRT, and 59 to CBT alone.[803] e NRT group could select nicotine patches, gum, or lozenge, or no NRT. More than half the women selected nicotine patches, the dose of which was adjusted according to the number of cigarettes smoked per day on study entry. As described in the "e ectiveness" section above, women treated with NRT had signi cantly higher quit rates during pregnancy than did women receiving CBT alone. However, the study was terminated early by the Data Safety Monitoring Board (DSMB) due to a higher incidence of adverse events. Serious adverse events occurred in 30 percent of the NRT group compared to 17 percent of the CBT-alone group.

e most frequent cause of serious adverse events was preterm labor. ere was evidence that this di erence in preterm labor was due to a di erence between groups in history of preterm labor that predated study entry. e DSMB indicated that the study had to be terminated due to *a priori* stopping rules; however, they did not believe that the serious adverse events were related to NRT use. e authors concluded that this study cannot support or negate published literature about the harm of NRT during pregnancy.

Morales-Suarez-Varela et al. reported data from a retrospective cohort study suggesting that the use of NRT in women who quit smoking but who used nicotine substitutes during the rst 12 weeks of pregnancy was associated with a small but signi cant increase in congenital malformations compared to mothers who smoked during the rst trimester.[823] is study su ers from multiple, substantial methodological problems, however, making its ndings di cult to interpret. Also, the number of malformation cases in the NRT group was quite small, and the relative prevalence rate ratios for malformations in cases compared to controls were of borderline signi cance. Further, concerns exist about possible undetected spontaneous abortion among continuing smokers. In addition, most women who

use NRT do so in the second or third trimester, and no adverse event data were reported in these women.

Safety is not categorical. A designation of "safe" re ects a conclusion that a drug's bene ts outweigh its risks. Nicotine most likely does have adverse e ects on the fetus during pregnancy. Although the use of NRT exposes pregnant women to nicotine, smoking exposes them to nicotine plus numerous other chemicals that are injurious to the woman and fetus. ese concerns must be considered in the context of inconclusive evidence that

- Effects of reporting smoking status and the provision of cessation interventions as part of the national database for assisted reproductive technology treatments (the Center for Disease Control and Prevention's Assisted Reproductive Technology [ART] database, *www.cdc.gov/art*)

- Effectiveness of relapse prevention programs for spontaneous "self-quitters amongst pregnant women"

- Effectiveness of different types of counseling, behavioral therapies, and motivational interventions (e.g., physiological feedback of adverse impacts, quitting benefits) for pregnant women in general and in high-prevalence populations (e.g., American Indian and Alaska Native women, especially)

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

Weight Gain After Stopping Smoking

Recommendation: For smokers who are greatly concerned about weight gain, it may be most appropriate to prescribe or recommend bupropion SR or NRT (in particular, nicotine gum and nicotine lozenge), which have been shown to delay weight gain after quitting. (Strength of Evidence = B)

The majority of smokers who quit smoking gain weight. Most will gain fewer than 10 pounds, but there is a broad range of weight gain, with as many as 10 percent of quitters gaining as much as 30 pounds.[824-827] How-

Adolescents, even as young as middle-school age, who are concerned about their weight initiate smoking more o en than do other adolescents.[683,837-838]

Concern about weight varies substantially by ethnicity. For example, adolescent African-American females are much less likely to report that they smoke to control weight than are white European Americans.[683,839] is is an important area for further study, as little tobacco research focuses on women in racial/ethnic minority groups.[683]

ere is no convincing evidence that counseling interventions speci cally designed to mitigate weight gain during attempts to stop smoking result in reduced weight gain.[165,499,840] It also is unclear that such interventions a ect cessation success; speci cally, these interventions do not appear to adversely a ect cessation.[499,840-842]

Nicotine replacement—in particular, 4-mg nicotine gum and 4-mg nicotine lozenge—appears to be e ective 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). Bupropion SR also appears to be e ective in delaying postcessation weight gain.[484,843-845] Once either nicotine gum or bupropion SR therapy is stopped, however, the quitting smoker, on average, gains an amount of weight that is about the same as if she or he had not used these medications.[843,846-848]

Postcessation weight gain appears to be caused both by increased intake (e.g., eating, including high-caloric foods, and alcohol consumption) and by decreased metabolism. e involvement of metabolic mechanisms suggests that even if smokers do not increase their caloric intake upon quitting, they will, on average, gain some weight.[849-852] Once an individual relapses and begins smoking at precessation levels, he or she usually will lose some or all of the weight gained during the quit attempt.

e research evidence reviewed above shows why concerns about weight gain can be barriers to smoking abstinence. Many smokers (especially women) are concerned about their weight and fear that quitting will produce weight gain. Many also believe that they can do little to prevent postcessation weight gain except return to smoking. ese beliefs are di cult to address clinically because smoking does appear to a ect weight.

Recommendations to Clinicians When Addressing Weight Gain

How should the clinician deal with concerns about weight gain? First, the clinician should neither deny the likelihood of weight gain nor minimize its signi cance to the patient. Rather, the clinician should inform the patient about the likelihood of weight gain and prepare the patient for its occurrence. e clinician also should counter exaggerated fears about weight gain given the relatively moderate weight gain that typically occurs. Certain types of information may help prepare the patient for postcessation weight gain (see Table 7.9). Clinicians also should inform the patient that smoking presents a much greater health risk than the negligible health risk involved in the modest weight gain associated with smoking abstinence.

Second, during the quit attempt, the clinician should o er to help the patient address weight gain (either personally or via referral) once the patient has successfully quit smoking. e 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.[502,853]

Exercise

Available research does not show that interventions to increase exercise reliably boost smoking abstinence rates.[842,854] One recent study, however, showed that an exercise program occurring in three 45-minute sessions per week increases long-term smoking abstinence in women and delays weight gain when it is combined with a cognitive-behavioral smoking cessation program.[853] As was the case for weight loss interventions, there is no evidence that exercise interventions undermine success in stopping smoking. Some evidence suggests that weight gain is reduced if smoking abstinence is accompanied by a moderate increase in physical activity.[855] Vigorous exercise programs should not be implemented without consulting a physician. Although it may be di cult to get smokers to adhere to a vigorous exercise program, smokers should be encouraged to engage in moderate exercise and physical activity as part of a healthy lifestyle.[856]

Table 7.9. Clinician statements to help a patient prepare for and cope with post-cessation weight gain

Clinician statements
The great majority of smokers gain weight once they quit smoking. However, even without special attempts at dieting or exercise, weight gain is usually 10 lbs. or less.
Some medications, including bupropion SR and nicotine replacement medicines, may delay weight gain.
There is evidence that smokers often gain weight once they quit smoking, even if they do not eat more. However, there are medications that will help you quit smoking and limit or delay weight gain. I can recommend one for you.
The amount of weight you will likely gain from quitting will be a minor health risk compared with the risks of continued smoking.
I know that you don't want to gain a lot of weight. However, let's focus on strategies to get you healthy rather than on weight. Think about eating plenty of fruits and vegetables, getting regular exercise, getting enough sleep, and avoiding high-calorie foods and beverages. Right now, this is probably the best thing you can do for both your weight and your health.
Although you may gain some weight after quitting smoking, compare the importance of this with the added years of healthy living you will gain, your better appearance (less wrinkled skin, whiter teeth, fresher breath), and good feelings about quitting.

Future Research

Glossary

Abstinence percentage. e percentage of smokers who achieve long-term abstinence from smoking. e most frequently used abstinence 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 a er treatment.

Acupuncture. A treatment involving the placement of needles in speci c areas of the body with the intent to promote abstinence from tobacco use. Acupuncture also can be accomplished using electrostimulation or laser.

Addiction. Compulsive drug use, with loss of control, the development of dependence, continued use despite negative consequences, and speci c withdrawal symptoms when the drug is removed.

All-comers. Individuals included in a tobacco treatment study regardless of whether they sought to participate. For example, if 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 tobacco treatment studies ("want-to-quit" smokers) likely are more motivated to quit, and studies limited to these individuals may produce higher quit rates. All-comers can be contrasted with "want-to-quit" or self-selected populations.

Agonist. A drug action that generally mimics or enhances the e ect of another drug at a neural receptor site. Nicotine is a che in. Ner6022ym <0uitor

Aversive smoking. Several types of therapeutic techniques that involve smoking in an unpleasant or concentrated manner. ese techniques pair

Chronic disease model. Recognizes the long-term nature of tobacco dependence, with an expectation that patients may have periods of relapse and remission. e chronic disease model emphasizes the importance of continued patient education, counseling, and advice over time.

Cigarette fading/smoking reduction prequit. An intervention strategy designed to reduce the number of cigarettes smoked or nicotine intake prior to a patient's quit date. is may be accomplished through advice to cut down or to systematically restrict access to cigarettes. ese interventions use computers and/or strategies to accomplish prequitting reductions in cigarette consumption or nicotine intake.

Clinician. A professional directly providing health care services.

Clinic screening system. e strategies used in clinics and medical practices for the delivery of clinical services. Clinic screening system interventions involve changes in protocols designed to enhance the identi cation of and intervention with patients who smoke. Examples include a xing tobacco use status stickers to patients' charts, expanding the capture of vital signs to include tobacco use, incorporating tobacco use status items into patient questionnaires, and including prompts for tobacco use monitoring in electronic medical records.

Clonidine. An alpha-2-adrenergic agonist typically used as an antihypertensive medication, but also documented in this Guideline as an e ective medication for smoking cessation.

Cochrane Review. A service of the Cochrane Collaboration, an international nonpro t and independent organization (*www.cochrane.org/index.htm*) that regularly publishes evidence-based reviews about health care interventions.

Cognitive behavioral therapy (CBT). A psychotherapeutic approach aimed at identifying and modifying faulty or distorted negative thinking styles and the maladaptive behaviors associated with those thinking styles.

Combination medications. Treatment that combines two or more nicotine-containing medications or a nicotine-containing medication with another tobacco treatment medication such as bupropion SR.

Formats. Refers to tobacco dependence intervention delivery strategies that include self-help, proactive telephone counseling, computerized or e-health services, individual counseling, and group counseling.

Healthcare Effectiveness Data and Information Set (HEDIS). Serves as a "report card" for providing information on quality, utilization, enrollee access and satisfaction, and nances for managed care organizations and other health care delivery entities.

Higher intensity counseling. Refers to interventions that involve extended contact between clinicians and patients. It is coded based on the length of contact between clinicians and patients (greater than 10 minutes). If that information is unavailable, it is coded based on the content of the contact between clinicians and patients.

Hookah. A smoking pipe designed with a long tube passing through an urn of water that cools the smoke as it is drawn through. Also called "waterpipe," "hubble-bubble," "narghile," "shisha."

Hotline/helpline. A reactive telephone line dedicated to over-the-phone smoking intervention. Hotline/helpline treatment occurs when a hotline/helpline number is provided to a patient, or a referral to a hotline/helpline is made. e key distinction between a hotline/helpline and proactive telephone counseling is that, in the former, the patient must initiate each clinical contact.

Hypnosis. A treatment by which a clinician induces an altered attention

Intensive interventions. Comprehensive treatments that may occur over multiple visits for long periods of time and may be provided by more than one clinician.

Internet (Web-based) interventions.

Mecamylamine. A nicotine antagonist used as an antihypertensive agent. Mecamylamine does not have an FDA indication for treating tobacco use and dependence.

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

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

Motivation. Refers to a patient's intent or resolve to quit. Motivation can be bolstered through actions, such as setting a quit date, using a contract with a speci ed quit date, reinforcing correspondence (letters mailed from clinical/study sta congratulating the patient on his or her decision to quit or on early success), and providing information about the health risks of smoking.

Motivational intervention. An intervention designed to increase the smoker's motivation to quit.

Motivational interviewing (MI). A directive and patient-centered counseling method used to increase motivation and facilitate change.

Naltrexone. An opioid receptor antagonist used in substance abuse treatment. Naltrexone does not have an FDA indication for treating tobacco use and dependence.

National Committee for Quality Assurance (NCQA). Reviews and accredits managed care organizations, develops processes for measuring health plan performance, and disseminates information about quality so consumers can make informed choices (e.g., through "report cards," such as HEDIS).

Negative affect/depression intervention. A type of intervention designed to train patients to cope with negative a ect a er smoking cessation. e intensity of the interventions in this category may vary from prolonged counseling to the provision of information about coping with negative

moods. To receive this code, interventions target depressed mood, not simply stress. Interventions aimed at teaching subjects to cope with stressors are coded as problemsolving. When it is unclear whether an intervention is directed at negative a ect/depression or at psychosocial stress, problemsolving is used as the default code.

Neuroteratogenic. e capability of some substances to cause abnormal development of the nervous system in the fetus.

Neurotoxicity. e capablility of some substances to cause damage to the nervous system.

Quitline. A telephone counseling service that can provide both proactive telephone counseling and reactive telephone counseling (see Proactive Telephone Counseling and Reactive Telephone Counseling).

Randomized controlled trial. 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 comparison condition.

Random effects modeling. A model in which both study sampling errors (variance) and between-study variation are included in the assessment of

Restricted environmental stimulation therapy (REST). A treatment involving the use of sensory deprivation to promote abstinence from tobacco use.

Return on investment (ROI). Amount of money gained or lost, including money that would have been spent for health care, in relation to the amount of money needed to provide the treatment.

Screening. See Clinic Screening System.

Secondhand smoke.

Self-reported abstinence. Abstinence based on the patient's claim, which may or may not be veri ed clinically by biochemical con rmation.

Sertraline. A selective serotonin re-uptake inhibitor. Sertraline does not have an FDA indication for treating tobacco use and dependence.

Serum nicotine. Level of nicotine in the blood. is o en is used to assess a patient's tobacco/nicotine self-administration prior to quitting, and to con rm abstinence self-reports during followup. Nicotine commonly is measured in urine and saliva.

Serum nicotine/cotinine levels. Level of nicotine/cotinine in the blood. Cotinine is nicotine's major metabolite, which has a signi cantly longer half-life than nicotine. is o en is used to estimate a patient's tobacco/nicotine self-administration prior to quitting, and to con rm abstinence self-reports during followup. Cotinine commonly is measured in urine and saliva.

Side effects. Undesired actions or e ects of a drug used in tobacco use treatment, such as insomnia or dry mouth.

Silver acetate. Silver acetate reacts with cigarette smoke to produce an unpleasant taste and has been investigated as a smoking deterrent. It is not approved by the FDA for this use.

Skills training. Refers to a tobacco use treatment in which tobacco users are trained to identify and cope with events or problems that may increase the risk of tobacco use. 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 interventions are practical counseling, relapse prevention, and stress management.

Slip. A brief or reduced return to smoking a er quitting. Also referred to as a "lapse" (see Relapse).

Smokeless tobacco. Any form of unburned tobacco, including chewing tobacco, snus, and snu . Use of smokeless tobacco is as addictive as smoking and can cause cancer of the gum, cheek, lip, mouth, tongue, throat, and pancreas.

Social support. Nonmedicinal support for the smoking cessation patient that provides personal encouragement and empathetic listening. Tobacco

Tobacco treatment specialists. ese specialists typically provide intensive tobacco interventions. Specialists are not de ned by their professional af- liation or by the eld in which they trained. Rather, specialists view tobacco dependence treatment as a primary professional role. Specialists possess the skills, knowledge, and training to provide e ective interventions across a range of intensities, and o en are a liated with programs o ering intensive treatment interventions or services.

Tobacco user. A person addicted to one or more forms of tobacco products.

Transdermal. Refers to delivery of a substance by absorption through the skin. Transdermal nicotine o en is used as a synonym for "nicotine patch."

Treatment matching. Di erential assignment of a patient to treatment based on the patient's pretreatment characteristics. Treatment matching is based on the notion that particular types of tobacco users are most likely to bene t from particular types of treatments.

Treatment. An action or program that aims to bring about identi able outcomes. For tobacco dependence, the treatment generally is clinical in nature and may consist of counseling and the use of medications. Also may be referred to as "intervention."

Unaided quit attempts. Quit attempts made by patients, without the assistance of any clinical intervention or medications. Also known as "quitting cold turkey."

Varenicline. FDA-approved, non-nicotine recommended smoking cessation medication. Its mechanism of action is thought to be a function of its ability to serve both as a partial nicotine receptor agonist and a nicotine receptor antagonist. Available by prescription only.

Vital signs. Standard patient measurements to assess the critical body functions, including blood pressure, pulse, weight, temperature, and respiratory rate. e rst step (i.e., the rst "A") to providing smoking cessation interventions is identifying smokers. Vital signs should be expanded to include tobacco use status (current, former, never) or an alternative universal identi cation system in patient records.

Web-based interventions. See Internet Interventions.

Weight/diet/nutrition. An intervention strategy designed to address weight gain or concerns about weight gain. Interventions that teach weight/diet/nutrition 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.

Withdrawal symptoms. A variety of u(d/o)ietf u(d5(d)12(uc)-7t6/r)13(e-7(h)16td1.m

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Appendixes

Appendix A. Financial Disclosure for Panel Members, Liaisons, and Peer Reviewers

Panel Members

e evaluation of con ict for the 2008 Guideline Update comprised a two-stage procedure designed to obtain increasingly detailed and informative data on potential con icts over the course of the Guideline development process.

1. In July 2006 and prior to the initial meeting in October 2006, Panel members completed a general screen, reporting any potential con icts over the previous 5 years. Where potential con icts existed, Panel members provided a narrative listing of the relevant organizations and types of con ict. Panel members were asked to update this screen as new information or potential con icts became known.

2. Prior to the second in-person Panel meeting in June 2007, and before any decisions regarding Panel recommendations were made, Panel members were required to complete a more exhaustive disclosure process for calendar years 2005, 2006, and 2007, based on the United States Department of Health and Human Services, PHS Title 42, Chapter 1, Part 50 guidelines for the conduct of research (*ori.hhs.gov/policies/fedreg42cfr50.shtml*). Moreover, Panel members were asked to update this report as new information or potential con icts became known. In keeping with the PHS-based guidelines, a potential con ict was designated as "signi cant" if one or more of three criteria were met:

A. Net reportable compensation in excess of $10,000 in any reporting year to the Panel member, spouse, or dependent child for outside activities from any entity whose interests may be a ected by the recommendations in the Guideline (excluding public or nonpro t entities).

B. Leadership as an o cer, director, or trustee in any reporting year by the Panel member, spouse, or dependent child -10(t)-5(in)8(g y)8(D)ustive disc calendar yee recommendations in the Guideline (ing public or nonpro t (r y)8(e)-entities).

C. Ownership interests either in excess of $10,000 or 5 percent of the business in any reporting year by the Panel member, spouse, or

Carlos Roberto Jaén reported no signi cant nancial interests and no additional disclosures.

Howard K. Koh reported no signi cant nancial interests and no additional disclosures.

omas E. Kottke reported no signi cant nancial interests and no additional disclosures.

Harry A. Lando reported no signi cant nancial interests. Under additional disclosures, he reported serving on an advisory panel for a new tobacco

Louise Villejo reported no signi cant nancial interests and no additional disclosures.

Mary Ellen Wewers reported no signi cant nancial interests and no additional disclosures.

Liaisons

Liaisons followed the same process as Panel members in reporting signi cant nancial interests. eir disclosures are summarized below:

Glen Bennett reported no signi cant nancial interests and no additional disclosures.

Stephen Heishman reported no signi cant nancial interests and no additional disclosures.

Corinne Husten reported no signi cant nancial interests and no additional disclosures.

Glen Morgan reported no signi cant nancial interests and no additional disclosures.

Ernestine W. Murray reported no signi cant nancial interests and no additional disclosures.

Christine Williams reported no signi cant nancial interests and no additional disclosures.

Peer Reviewers

Peer reviewers were required to report signi cant nancial interests at the time they submitted their peer reviews. e interests were reviewed prior to the adjudication of each reviewer's comments. Any signi cant nancial interests are noted below their listing in the Contributors Section of this Guideline.

National Guideline Clearinghouse: *www.guideline.gov*

National Heart, Lung, and Blood Institute: *www.nhlbi.nih.gov*

National Institute on Drug Abuse: *www.nida.nih.gov*

O ce on Smoking and Health at the Centers for Disease Control and Prevention: *www.cdc.gov/tobacco*

Robert Wood Johnson Foundation: *www.rwjf.org*

Society for Research on Nicotine and Tobacco: *www.srnt.org*

TobaccoFree Nurses: *www.tobaccofreenurses.org*

Tobacco Technical Assistance Consortium: *www.ttac.org*

University of Wisconsin Center for Tobacco Research and Intervention: *www.ctri.wisc.edu*

World Health Organization: *www.who.int*

World Health Organization – Tobacco Atlas: *www.who.int/tobacco/statistics/tobacco_atlas/en*

Mental Disorders (290-319)

305.1 Tobacco Use Disorder (Tobacco Dependence).

Codes 99383–99397 include counseling/anticipatory guidance/risk factor reduction interventions, which are provided at the time of the initial or periodic comprehensive preventive medicine examination. (Refer to codes 99401–99412 for reporting those counseling/anticipatory guidance/risk factor reduction interventions that are provided at an encounter separate from the preventive medicine examination.)

Preventive Medicine, Group Counseling

99411 Preventive medicine counseling and/or intervention to treat the risk

B1. Office or Other Outpatient Facility

Insight-oriented, behavior modifying, and/or supportive psychotherapy.

90804 Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an o ce or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient.

90805 With medical evaluation and management services.

90806 Individual psychotherapy, insight-oriented, behavior modifying, and/or supportive, in an o ce or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient.

90807 With medical evaluation and management services.

90808 Individual psychotherapy, insight-oriented, behavior modifying, and/or supportive, in an o ce or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient.

90809 With medical evaluation and management services.

B2. Inpatient Hospital, Partial Hospital, or Residential Care Facility

Insight-oriented, behavior modifying, and/or supportive psychotherapy.

90816 Individual psychotherapy, insight-oriented, behavior modifying, and/or supportive, in an inpatient hospital, partial hospital, or residential care setting, approximately 20 to 30 minutes face-to-face with the patient.

90817 With medical evaluation and management services.

90818 Individual psychotherapy, insight-oriented, behavior modifying, and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient.

90819 With medical evaluation and management services.

90821 Individual psychotherapy, insight-oriented, behavior modifying, and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient.

F17.21	Nicotine dependence, cigarettes
F17.210	Nicotine dependence, cigarettes, uncomplicated
F17.211	Nicotine dependence, cigarettes, in remission
F17.213	Nicotine dependence, cigarettes, with withdrawal
F17.218	Nicotine dependence, cigarettes, with other nicotine-induced disorders
F17.219	Nicotine dependence, cigarettes, with unspeci ed nicotine-induced disorders
F17.22	Nicotine dependence, chewing tobacco
F17.220	Nicotine dependence, chewing tobacco, uncomplicated
F17.221	Nicotine dependence, chewing tobacco, in remission
F17.223	nicotine-induced dis h( )T35eci ed nicotine-induced dis h( )T35eci ed

O99.332 Smoking (tobacco) complicating pregnancy, second trimester
O99.333 Smoking (tobacco) complicating pregnancy, third trimester
O99.334 Smoking (tobacco) complicating childbirth
O99.335 Smoking (tobacco) complicating the puerperium

T65 Toxic effect of other and unspecified substances

T65.2 Toxic effect of tobacco and nicotine

Excludes2: nicotine dependence (F17.-).

T65.21 Toxic e ect of chewing tobacco
T65.211 Toxic e ect of chewing tobacco, accidental (unintentional)
Toxic e ect of chewing tobacco NOS
T65.212 Toxic e ect of chewing tobacco, intentional self-harm
T65.213 Toxic e ect of chewing tobacco, assault
T65.214 Toxic e ect of chewing tobacco, undetermined

T65.22 Toxic e ect of tobacco cigarettes
Toxic e ect of tobacco smoke
Use additional code for exposure to secondhand tobacco smoke (Z57.31, Z58.7).
T65.221 Toxic e ect of tobacco cigarettes, accidental (unintentional)
Toxic e ect of tobacco cigarettes NOS
T65.222 Toxic e ect of tobacco cigarettes, intentional self-harm
T65.223 Toxic e ect of tobacco cigarettes, assault
T65.224 Toxic e ect of tobacco cigarettes, undetermined

T65.29 Toxic e ect of other tobacco and nicotine
T65.291 Toxic e ect of other tobacco and nicotine, accidental (unintentional)
Toxic e ect of other tobacco and nicotine NOS
T65.292 Toxic e ect of other tobacco and nicotine, intentional self-harm
T65.293 Toxic e ect of other tobacco and nicotine, assault
T65.294 Toxic e ect of other tobacco and nicotine, undetermined

Z71 Persons encountering health services for other counseling and medical advice, not elsewhere classified

Z71.6 Tobacco abuse counseling
Use additional code for nicotine dependence (F17.-).

Z72 Problems related to lifestyle

Z72.0 Tobacco use
Tobacco use NOS
Excludes1: history of tobacco dependence (Z87.82), nicotine dependence (F17.2-), tobacco dependence (F17.2-), tobacco use during

Appendix D. Key Recommendation Changes From the 2000 PHS-Sponsored Clinical Practice Guideline: Treating Tobacco Use and Dependence

Below is a summary of the substantive changes in recommendations from the 2000 Guideline to the 2008 Guideline Update. ese changes include new 2008 update recommendations as well as recommendations that were deleted or changed substantially from the 2000 Guideline.

NEW RECOMMENDATIONS IN THE 2008 UPDATE

Most, but not all, of the new recommendations appearing in the 2008 Treating Tobacco Use and Dependence Update resulted from new meta-analyses of the topics chosen by the Guideline Panel.

1. Formats of Psychosocial Treatments

Recommendation: Tailored materials, both print and Web-based, appear to be e ective in helping people quit. erefore, clinicians may choose

3. For Smokers Not Willing To Make a Quit Attempt at This Time

Recommendation: Motivational intervention techniques appear to be ef-

with its potential bene ts, outweighs the risks of the medications and potential continued smoking. (Strength of Evidence = C)

6. Racial and Ethnic Minority Populations

Recommendation: Smoking cessation treatments have been shown to be e ective across di erent racial and ethnic minorities. erefore, members of racial and ethnic minorities should be provided treatments shown to be e ective in this Guideline. (Strength of Evidence = A)

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

7. Hospitalized Smokers

Recommendation: Smoking cessation treatments have been shown to be e ective for hospitalized patients. erefore, hospitalized patients should be provided smoking cessation treatments shown to be e ective in this Guideline. (Strength of Evidence = B)

8. Psychiatric Illness and/or Nontobacco Chemical Dependency

Recommendation: Smokers with comorbid psychiatric conditions should be provided smoking cessation treatments identi ed as e ective in this Guideline. (Strength of Evidence = C)

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

Recommendation: Evidence indicates that smoking cessation interventions do not interfere with recovery from chemical dependency. erefore, smokers receiving treatment for chemical dependency should be provided smoking cessation treatments shown to be e ective in this Guideline, including both counseling and medications. (Strength of Evidence = C)

9. Children and Adolescents

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

10. Older Smokers

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

11. Weight Gain After Stopping Smoking

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

12. Cost-Effectiveness of Tobacco Interventions

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

Note: e tobacco dependence treatments shown to be e ective in this Guideline still are recommended as highly cost-e ective with Strength of Evidence = A. e above recommendation, number 12, was deleted be-

RECOMMENDATIONS FROM THE 2000 GUIDELINE THAT WERE SUBSTANTIALLY CHANGED IN THE 2008 UPDATE:

The results of meta-analyses or consideration of literature not available for the 2000 Guideline led to substantive changes in some of the 2000 Guideline recommendations. Minor changes in wording are not listed here.

1. Screening and Assessment

2000 Guideline. Recommendation #1: All patients should be asked if they use tobacco and should have their tobacco-use status documented on a regular basis. Evidence has shown that this signi cantly increases rates of clinician intervention. (Strength of Evidence = A)

2000 Guideline. Recommendation #2: Clinic screening systems, such as expanding the vital signs to include tobacco use status, or the use of other reminder systems, such as chart stickers or computer prompts, are essential for the consistent assessment, documentation, and intervention with tobacco use. (Strength of Evidence = B)

2008 Guideline Update. Recommendation: All patients should be asked if they use tobacco and should have their tobacco use status documented on a regular basis. Evidence has shown that clinic screening systems, such as expanding the vital signs to include tobacco use status, or the use of other reminder systems, such as chart stickers or computer prompts, signi cantly increase rates of clinician intervention. (Strength of Evidence = A)

2. Types of Counseling and Behavioral Therapies

2000 Guideline. Recommendation: ree types of counseling and behavioral therapies result in higher abstinence rates: (1) providing smokers with practical counseling (problemsolving skills/skills training); (2) providing social support as part of treatment; and (3) helping smokers obtain social support outside the treatment environment. ese types of counseling and behavioral therapies should be included in smoking cessation interventions. (Strength of Evidence = B)

2008 Guideline Update. Recommendation: Two types of counseling and behavioral therapies result in higher abstinence rates: (1) providing smokers with practical counseling (problemsolving skills/skills training); and

2008 Guideline Update. Recommendation #1: Counseling has been shown to be e ective in treatment of adolescent smokers. erefore, adolescent smokers should be provided with counseling interventions to aid them in quitting smoking. (Strength of Evidence = B)

2000 Guideline. Recommendation #2: Clinicians in a pediatric setting should o er smoking cessation advice and interventions to parents to limit children's exposure to secondhand smoke. (Strength of Evidence = B)

2008 Guideline Update. Recommendation #2: Secondhand smoke is harmful to children. Cessation counseling delivered in pediatric settings has been shown to be e ective in increasing cessation among parents who smoke. erefore, to protect children from secondhand smoke, clinicians should ask parents about tobacco use and o er them cessation advice and assistance. (Strength of Evidence = B)

6. Noncigarette Tobacco Users

2000 Guideline. Recommendation: Smokeless/spit tobacco users should be identi ed, strongly urged to quit, and treated with the same counseling cessation interventions recommended for smokers. (Strength of Evidence = B)

2008 Guideline Update. Recommendation: Smokeless tobacco users should be identi ed, strongly urged to quit, and provided counseling cessation interventions. (Strength of Evidence = A)

7. Cost-Effectiveness of Tobacco Dependence Interventions

2000 Guideline. Recommendation: Su cient resources should be allocated for clinician reimbursement and systems support to ensure the delivery of e cacious tobacco use treatments. (Strength of Evidence = C)

2008 Guideline Update. Recommendation: Su cient resources should be allocated for systems support to ensure the delivery of e ective tobacco use treatments. (Strength of Evidence = C)

8. Tobacco Dependence Treatment as a Part of Assessing Health Care Quality

2000 Guideline. Recommendation: Provision of Guideline-based interventions to treat tobacco use and addiction should be included in standard

ratings and measures of overall health care quality (e.g., NCQA HEDIS, the Foundation for Accountability [FACCT]). (Strength of Evidence = C)

2008 Guideline Update. Recommendation: Provision of Guideline-based interventions to treat tobacco use and dependence should remain in standard ratings and measures of overall health care quality (e.g., NCQA, HEDIS). rat65es), th-3(a)19(d)]TJ T* [()-8(e)-5surlNtpitngttobr ap-145ettnt15ettiansatt()-8 v i d e n c e = C)

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Guideline Availability

is Guideline is available in several formats suitable for health care practitioners, the scienti c community, educators, and consumers.

e *Clinical Practice Guideline* presents recommendations for health care providers, with brief supporting information, tables and gures, and pertinent references.

e *Quick Reference Guide* is a distilled version of the clinical practice Guideline, with summary points for ready reference on a day-to-day basis.

e *Consumer Version* is an information booklet for the general public to increase consumer knowledge and involvement in health care decisionmaking.

e full text of the Guideline, with and without the text references and the meta-analyses references (listed by evidence table), is available by visiting the Surgeon General's Web site at: *www.ahrq.gov/path/tobacco.htm#Clinic*.

Single copies of these Guideline products and further information on the availability of other derivative products can be obtained by calling any of the following Public Health Service organizations' toll-free numbers:

Agency for Healthcare Research and Quality (AHRQ)
800-358-9295

Centers for Disease Control and Prevention (CDC)
800-311-3435

National Cancer Institute (NCI)
800-4-CANCER