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A Clinical Practice Guideline for Treating Tobacco Use and Dependence: 2008 Update:

A U.S. Public Health Service Report

The Clinical Practice Guideline Treating Tobacco Use and Dependence 2008 Update Panel, Liaisons, and Staff

Abstract

Objective—To summarize the U.S. Public Health Service guideline *Treating Tobacco Use and Dependence: 2008 Update*, which provides recommendations for clinical interventions and system changes to promote the treatment of tobacco dependence.

Participants—An independent panel of 24 scientists and clinicians selected by the U.S. Agency for Healthcare Research and Quality on behalf of the U.S. Public Health Service. A consortium of eight governmental and nonprofit organizations sponsored the update.

Evidence—Approximately 8700 English-language, peer-reviewed articles and abstracts, published between 1975 and 2007, were reviewed for data that addressed assessment and treatment of tobacco dependence. This literature served as the basis for more than 35 meta-analyses.

Consensus Process—Two panel meetings and numerous conference calls and staff meetings were held to evaluate meta-analyses and relevant literature, to synthesize the results, and to develop recommendations. The updated guideline was then externally reviewed by more than 90 experts, made available for public comment, and revised.

Conclusions—This evidence-based, updated guideline provides specific recommendations regarding brief and intensive tobacco-cessation interventions as well as system-level changes designed to promote the assessment and treatment of tobacco use. Brief clinical approaches for patients willing and unwilling to quit are described.

Introduction

This report summarizes the 2008 U.S. Public Health Service (PHS) Clinical Practice Guideline, *Treating Tobacco Use and Dependence* (“2008 Update”) and provides an evidence-based blueprint for clinicians and healthcare systems to treat the deadly chronic disease of tobacco addiction effectively. The importance of such a blueprint is clear—clinicians and healthcare delivery systems have unparalleled access to American smokers;

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over 70% of smokers visit a clinician each year and most of them report wanting to quit. Half of all smokers alive today—more than 20 million Americans—will be killed prematurely by a disease directly caused by their tobacco use, making the treatment of tobacco dependence the chief medical and public health challenge of our time.

This guideline concludes that tobacco use presents a rare confluence of circumstances: (1) a highly significant health threat,¹ (2) a disinclination among clinicians to intervene consistently,² and (3) the presence of effective interventions. This last point is buttressed by evidence that tobacco-dependence interventions, if delivered in a timely and effective manner, significantly reduce the smoker's risk of suffering from smoking-related disease.^{3–10} Indeed, it is difficult to identify any other condition that presents such a mix of lethality, prevalence, and neglect, despite effective and readily available interventions.

Although tobacco use is still an enormous threat, the story of tobacco control efforts over the last half century is one of remarkable progress and promise. In 1965, current smokers outnumbered former smokers three-to-one.¹¹ Over the past 40 years, the rate of quitting has so outstripped the rate of initiation that, today, there are more former smokers than current smokers.¹² Moreover, 40 years ago, smoking was viewed as a habit rather than a chronic disease. No scientifically validated interventions were available for the treatment of tobacco use and dependence and it had little place in healthcare delivery. Today, numerous effective treatments exist, and tobacco-use assessment and intervention are considered to be requisite duties of clinicians and healthcare delivery entities. Finally, every state now has a telephone quitline, increasing access to effective treatment.

This 2008 Update builds substantially on prior findings published in the 1996 and 2000 guidelines.¹³ The scant dozen years since the first guideline was released yielded impressive improvements in the treatment of tobacco addiction. In 1997, only 25% of managed healthcare plans covered any tobacco-dependence treatment; this figure approached 90% by 2003,¹⁴ although coverage often includes provisions that serve as barriers to its use (e.g., large co-pays). Numerous states added Medicaid coverage for tobacco-dependence treatment since the publication of the first guideline so that by 2005, 72% offered coverage for at least one guideline-recommended treatment.^{14–16} In 2002, the Joint Commission (formerly, JCAHO), which accredits some 15,000 hospitals and healthcare 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. Finally, Medicare, the Veteran's Health Administration, and the U.S. military now provide coverage for tobacco-dependence treatment. Such policies and systems changes are paying off in terms of increased rates of clinical assessment and treatment of tobacco use.

This 2008 Update serves as a benchmark of the progress made and the challenges that remain. It should reassure clinicians, policymakers, funding agencies, and the public that tobacco use is amenable to both scientific analysis and to clinical interventions. This history of remarkable progress should encourage renewed efforts by clinicians, policymakers, and researchers to help those who remain dependent on tobacco. Adherence to the recommendations in this 2008 Update will provide such help, ensuring that every smoker

who visits a healthcare setting in America can receive an effective treatment for tobacco dependence.

Background

The Clinical Practice Guideline for Treating Tobacco Use and Dependence: 2008 Update (2008 Update) is the result of a collaboration among eight governmental and nonprofit organizations: Agency for Healthcare Research and Quality (AHRQ); CDC; National Cancer Institute (NCI); National Heart, Lung, and Blood Institute; National Institute on Drug Abuse; Robert Wood Johnson Foundation; the Legacy Foundation; and the Center for Tobacco Research and Intervention at the University of Wisconsin School of Medicine and Public Health. The 2008 Update was developed by a panel of 24 scientists and clinicians supported by liaisons from the sponsoring organizations, consultants, and staff. The goal of the guideline is to complete a comprehensive review and analysis of the extant scientific evidence and to identify evidence-based clinical treatments for tobacco dependence.

This article is intended to serve as a primer for effective clinic-based tobacco-intervention treatments. Readers interested in more details regarding the literature review, data-analytic methods, and the consensus process may refer to the updated guideline,¹⁷ which is also located on the AHRQ website (www.ahrq.gov). Both this article and the 2008 Update target two principal audiences: first, clinicians including clinicians for whom tobacco-dependence treatment is just one of many activities and second, healthcare administrators, insurers, and purchasers who have the capacity to implement systems changes that support and encourage tobacco-dependence treatments, including reimbursing for these cost-effective treatments.

The 2008 Update is generally consistent with the 2000 guideline. Its conclusions and recommendations are also consistent with those made by other organizations including: the American Psychiatric Association,^{18, 19} the American Medical Association,²⁰ the American Dental Association,²¹ the American Nurses Association,²² the American College of Obstetricians and Gynecologists, the Institute of Medicine,²³ the United Kingdom Guideline,²⁴ and the Cochrane Collaboration (www.cochrane.org/index.htm).

While generally consistent with the 2000 guideline, the 2008 Update reveals considerable progress made in tobacco research over the brief period separating these two publications. Tobacco dependence is increasingly recognized as a chronic disease, one that typically requires ongoing assessment and repeated intervention. In addition, the updated guideline offers the clinician many more effective treatment strategies than were identified in the original guideline. There are now seven different first-line effective medications in the smoking cessation pharmacopoeia, and some combinations of medications are highly effective, allowing the clinician and patient many different options. In addition, recent evidence provides even stronger support for counseling (both when used alone and with other treatments) as an effective tobacco-cessation strategy; counseling adds to the effectiveness of tobacco-cessation medications, quitline counseling is an effective intervention with a broad reach, and counseling increases tobacco cessation among adolescent smokers. There is also new evidence that motivational interventions increase quit attempts among smokers currently uninterested in making a quit attempt.

There is increasing evidence that the success of any tobacco-dependence treatment strategy cannot be divorced from the healthcare system in which it is embedded. The 2008 Update contains new evidence that healthcare policies significantly affect the likelihood that smokers will receive effective tobacco-dependence treatment and successfully stop tobacco use. For instance, making tobacco-dependence treatment a covered benefit of insurance plans increases the likelihood that a tobacco user will receive treatment and quit successfully. Data strongly indicate that effective tobacco interventions require *coordinated interventions*. Just as the clinician often must intervene with his or her patient as a member of a treatment team, so must the healthcare administrator, insurer, and purchaser foster and support tobacco intervention as an integral element of healthcare delivery. Insurers and healthcare administrators should ensure that clinicians have the support and training to deliver consistent, effective intervention to tobacco users.

The 2008 Update also casts into stark relief those areas in which more progress is needed. There is a need for innovative and more effective counseling strategies. In addition, although adolescents appear to benefit from counseling, there is also a clear need for more effective interventions and options for use with children, adolescents, and young adults. Smoking prevalence remains discouragingly high in certain populations such as in those with low SES/low educational attainment, some American Indian populations, and individuals with psychiatric disorders including substance use disorders.²⁵ New techniques and treatment delivery strategies may be required before the needs of these groups are adequately addressed. Also, much of the available data come from randomized clinical trials occurring in research settings. It is imperative that new research examines how effective treatments can be implemented in real-world clinical settings. Finally, new strategies are needed to create consumer demand among tobacco users for effective treatments; there has been little increase in the proportion of smokers who make quit attempts and too few smokers who do try to quit take advantage of evidence-based treatment that can double or triple their odds of success.²⁶ New research and communication efforts must impart greater hope, confidence, and increased access to treatments so that tobacco users in ever-greater numbers attempt tobacco cessation, use effective therapies, and achieve abstinence. To succeed, all of these areas require adequate funding if we are to reach the *Healthy People 2010* goals and objectives relative to tobacco.²⁷

Evidence Synthesis: Overview of the Guideline Development Procedures

Figure 1 provides an overview of the guideline development process. Since the panel was asked to update, rather than completely revise, the 2000 Treating Tobacco Use and Dependence Guideline, the panel's first task was to identify those topics that merited specific meta-analyses based on their importance and the availability of relevant literature, ideally, with some published since 1999. Consultations with panel members and outside experts generated a list of 64 topics from which the panel selected 11 to be meta-analyzed for the 2008 Update (see Table 1). For each of these topics, the literature since 1999 (approximately 2700 articles identified by electronic searches of 11 databases) was examined for relevance to each of the 11 topics to be addressed through meta-analyses. Articles that were relevant were coded for possible use in meta-analyses if they: (1) reported the results of a placebo/comparison-controlled trial evaluating a tobacco-use assessment or

treatment randomized on the patient level; (2) provided follow-up results at least 5 months after the quit date; (3) were published in a peer-reviewed journal; (4) were published between January 1, 1999, and December 31, 2007; and (5) were published in English. These criteria result in limitations including the exclusion of findings not published (publication bias) and the exclusion of non-English language findings.^{28,29} Exceptions were made for research about topics for which randomization at the patient level was not possible—such as systems interventions, which often randomized clinics or providers; and interventions for adolescents, which often randomized classrooms or schools.

For systems research, articles using such higher-level randomization were included only if the data analysis addressed this design feature. Two independent raters coded features of all articles accepted for possible use in the meta-analyses. A third reviewer compared the two independent reviews and adjudicated any discrepancies. A fourth independent review was conducted before final acceptance for meta-analysis. Where possible, efficacy analyses used point-prevalence abstinence data that reflected the intent-to-treat principle. Except for pregnancy studies, all follow-up data reflected smoking status at 6 months following the quit day (>5 months minimum) and included both biochemically confirmed and self-reported data when biochemically verified data were not available. Pregnancy analyses examined pre-natal and post-natal outcomes separately and included only biochemically confirmed data. Finally, all the randomized control trials identified for the 1996 and 2000 guidelines were examined anew and included in the new meta-analyses if they were relevant. Random-effects logistic regression was used for meta-analysis. A listing of the articles used in the meta-analyses can be found on the AHRQ website (www.ahrq.gov/).

The results of the new meta-analyses and other relevant data (e.g., meta-analyses from the original guideline, other published meta-analyses, background, and review articles) were presented to the guideline panel, which examined the findings and made requests for additional data and analyses as needed. The preponderance of the literature considered addressed smoking reflecting the fact that most tobacco users in the U.S. are smokers.³⁰ The guideline panel considered this as they reached consensus and made qualifications in recommendations for nonsmoker tobacco uses as appropriate with the result that the guideline applies to all tobacco users, not just smokers. The guideline panel generated consensus recommendations from the findings and assigned strength-of-evidence ratings to each recommendation. Ratings reflected the quality and amount of evidence supporting a recommendation and can be found in the 2008 Update.

A draft of the 2008 Update was reviewed by more than 90 external experts in the field of tobacco research and treatment and made available for public comment through a notice in the Federal Register. Over 1700 comments were received and considered; modifications were made accordingly.

Key Guideline Recommendations

Figure 2 presents a model for treating tobacco use and dependence. It underscores the chronic and often relapsing nature of tobacco dependence emphasizing the message that clinicians need to persist in efforts to provide evidence-based treatments.

Assessing Tobacco Use

The first step in treating tobacco use and dependence is to identify tobacco users. At least 70% of smokers see a physician each year, and almost one third see a dentist.^{31,32} Smokers also see physician assistants; nurse practitioners; nurses; respiratory, physical, and occupational therapists; pharmacists; counselors; and other clinicians. Therefore, virtually all clinicians are in a position to intervene with patients who use tobacco. Moreover, 70% of smokers report wanting to quit³³ and almost two thirds of smokers who relapse want to try quitting again within 30 days.³⁴ Finally, smokers cite a physician's advice to quit as an important motivator to stop smoking.³⁵⁻⁴⁰ These data suggest that most smokers are interested in quitting, clinicians and health systems are frequently in contact with smokers, and clinicians have high credibility with smokers. Further, effective identification of tobacco-use status not only opens the door for successful interventions (e.g., physician advice), but it guides clinicians to identify appropriate interventions based on patients' tobacco-use status and willingness to quit.

Brief Clinical Interventions

Brief interventions can be provided by any clinician but are most relevant to clinicians who treat a wide variety of patients and face severe time constraints. Interventions as brief as 3 minutes can increase cessation rates significantly.⁴¹ In addition, these interventions can be used with all populations, including adolescents, pregnant women, older smokers, smokers with medical co-morbidities, smokers with mental illness, and racial and ethnic minorities. Brief interventions are effective for three types of patients: current tobacco users now willing to make a quit attempt, current tobacco users unwilling to make a quit attempt at this time, and former tobacco users who have recently quit. The goal is to ensure that every patient who uses tobacco is identified and offered at least a brief intervention at each clinical visit.

For the patient willing to quit—Given that so many tobacco users visit a clinician each year, it is important that clinicians be prepared to intervene with tobacco users who are willing to quit. Meta-analyses in the 2008 Update clearly show that counseling and medication work best when used together: outcomes improve when counseling is added to medications and outcomes improve when medications are added to counseling. However, medication and counseling are each effective alone, and should be provided even if the tobacco user is not interested in combined therapy. Whenever possible, smokers who are willing to quit should be provided both. However, special considerations about using medications exist when they are medically contraindicated or with populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents).

The 5A's is a model that presents the five major steps in providing a brief intervention in the primary care setting (see Table 2). These steps are: (1) **ask** the patient if he or she uses tobacco, (2) **advise** him or her to quit, (3) **assess** willingness to make a quit attempt, (4) **assist** those who are willing to make a quit attempt, and (5) **arrange** for follow-up contact to prevent relapse. These strategies are designed to be brief, requiring 3 minutes or less of direct clinician time. Office systems that institutionalize tobacco-use assessment and intervention will foster the adoption of these strategies. While the 5A's are consistent with

those recommended by the NCI^{42,43} and the American Medical Association,²⁰ as well as others,^{18,44–47} the clinical situation may suggest delivering these intervention components in an order or format different from that presented.^{38,48–51}

Effective counseling interventions—Table 3 describes the common elements of practical counseling: problem solving/skills training and support during treatment (intra-treatment support). These elements can be used in brief interventions but also form the foundation for more intense interventions. In addition, the 2008 Update completed new meta-analyses of tobacco quitlines, finding them to be effective as a treatment for tobacco dependence.

Effective medication interventions—Table 4 describes general guidelines for using medications, and Table 5 provides prescribing instructions for the seven FDA-approved first-line medications. In addition, for the first time, the 2008 guideline panel conducted an inclusive meta-analysis of medication regimens that complements the inclusive meta-analysis of psychosocial interventions that was conducted for the 2000 guideline. Results of this inclusive meta-analysis are shown in Table 6. The 2008 guideline panel also conducted a meta-analysis that compared all medications with the nicotine patch (nicotine replacement therapy; NRT). The nicotine patch was selected as a comparison condition since a greater number of study arms were available for this condition than for any other, and because this condition was of representative, mid-range effectiveness relative to other conditions. For this meta-analysis, a conservative Hochberg⁷³ adjustment to the alpha level was used so that only treatments that were substantially different in effectiveness would be found to be significantly different. The a posteriori tests resulted in three treatment conditions being statistically more effective than the nicotine patch—2 mg/day varenicline and the combination of long-term patch + ad libitum NRT (gum or spray) (Table 7).

For the patient unwilling to make a quit attempt at this time—For patients not ready to make a quit attempt at this time, clinicians should use a brief intervention designed to promote the motivation to quit. Patients unwilling to make a quit attempt during a visit may lack information about the harmful effects of tobacco use and the benefits of quitting, may lack the required financial resources, may have fears or concerns about quitting, or may be demoralized because of previous relapse.^{73–77} Such patients may respond to brief motivational interventions consistent with motivational interviewing strategies,⁷⁸ which is a directive, patient-centered counseling intervention.⁷⁹ There is evidence that such strategies are effective in increasing future quit attempts^{80–84}; however, it is unclear that motivational interviewing strategies are successful in boosting abstinence among individuals motivated to quit smoking.^{84,85,86}

Clinicians employing motivational interviewing techniques focus on exploring a tobacco user's feelings, beliefs, ideas, and values regarding tobacco use in an effort to uncover any ambivalence about using tobacco.^{79,87,88} 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). Motivational interviewing researchers have found that having a patient use his or her own words to commit to change

is more effective than clinician exhortations, lectures, or arguments for quitting which tend to build, rather than lessen, patient resistance to change.⁸⁷

The four general principles that underlie motivational interviewing are: (1) express empathy, (2) develop discrepancy, (3) roll with resistance, and (4) support self efficacy.^{78,88,89} Since this is a specialized technique, it may be beneficial to have a member of the clinical staff receive training in motivational interviewing. The content areas that should be addressed in a motivational counseling intervention can be captured by the 5Rs: relevance, risks, rewards, roadblocks, and repetition (see Table 8). Research suggests that addressing the 5Rs enhances future quit attempts.^{79,90}

For the patient who has recently quit—Smokers who have recently quit face a high risk of relapse. Although most relapse occurs early in the quitting process,^{91–93} some relapse occurs months or even years after the quit date.^{92,94–96} Numerous studies have been conducted to identify treatments that can reduce the likelihood of future relapse. These studies attempt to reduce relapse either by including special counseling or therapy in the cessation treatment, or by providing additional treatment to smokers who have previously quit. In general, such studies have failed to identify either counseling or medication treatments that are effective in lessening the likelihood of relapse,⁹⁷ although there is some evidence that special mailings can reduce the likelihood of relapse.^{98,99} Thus, at present, the best strategy for producing high long-term abstinence rates appears to be use of the most effective cessation treatments available, that is, the use of evidence-based cessation medication during the quit attempt and relatively intense cessation counseling (e.g., four or more sessions that are 10 minutes or more in length).

If a clinician encounters a tobacco user who recently quit, the clinician might reinforce the patient's success at quitting, review the benefits of quitting, and assist the patient in resolving any residual problems arising from quitting. 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. The abstinent former smoker may also experience problems related to cessation that deserve treatment in their own right. Table 9 presents some of these common problems and possible responses.

Intensive Clinical Interventions

Intensive tobacco-dependence treatment can be provided by any suitably trained clinician. The evidence presented in the 2008 Update shows that intensive tobacco-dependence treatment is more effective than brief treatment. Intensive interventions (i.e., more-comprehensive treatments that may occur over multiple visits for longer periods of time and may be provided by more than one clinician) are appropriate for any tobacco user willing to participate in them; neither their effectiveness nor cost effectiveness is limited to a subpopulation of tobacco users (e.g., heavily dependent smokers).^{100–106} In addition, patients, even those not ready to quit, have reported increased satisfaction with their overall

health care as tobacco-counseling intensity increases.^{107,108} Table 10 presents the components of an intensive intervention.

The 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. The 2008 Update identified that telephone counseling such as that provided through a quitline is effective, as have other reviews.¹⁰⁹ In addition to providing their own clinical tobacco-dependence interventions, clinicians, and health systems can take advantage of this availability by implementing systems that regularly refer patients to quitlines either directly or via using fax referrals (e.g., “fax-to-quit” referral procedures).^{110–114}

Clinician Training

Training in tobacco-use interventions should not only transmit essential treatment skills but also inculcate the belief that tobacco-dependence treatment is a standard of good clinical practice.^{48,115,116} Such training has been shown to be cost effective.¹¹⁷ For clinicians-in-training, most clinical disciplines currently neither provide training, nor require competency, in tobacco-use interventions,¹¹⁸ although this is slowly improving.^{119,120} One survey of U.S. medical schools found that most medical schools (69%) did not require clinical training in tobacco-dependence treatment.¹²¹ The NCI’s Prevention and Cessation Education in Medical Schools (PACE) reported that, in 2004, about 36% of medical school courses offered about 10 hours of tobacco-related teaching over 4 years¹²² and that PACE has developed competencies for graduating medical students.¹²³ Similarly, the American Association of Dental Schools has guidelines recommending tobacco-use cessation clinical activities (TUCCA) education for dental and dental hygiene students; as many as 70% or more of dental schools reported some clinical training in this area.^{124,125}

A meta-analysis in the 2008 Update found that training clinicians increases the percentage of smokers who receive treatment, such as a discussion of benefits/obstacles to quitting, medication, and the provision of support. Further, combining clinician training with a charting system, such as chart reminder stickers or treatment algorithms attached to the chart, increases rates of tobacco-use assessment, setting a quit date, providing materials, and arranging for follow-up. Thus, clinician training, especially when coupled with other systems changes such as reminder systems, increases the rates at which clinicians engage in tobacco interventions that reliably boost tobacco cessation.

Economic Aspects of Tobacco and Health Systems Interventions

Smoking exacts a substantial financial burden on the U.S. A recent report of the U.S. CDC estimated that tobacco dependence costs the nation more than \$96 billion per year in direct medical expenses and \$97 billion in lost productivity.¹²⁶ Given these substantial costs, research has focused on the economic impact and cost effectiveness of tobacco-cessation interventions.

Cost effectiveness can be measured in a variety of ways, including cost per quality-adjusted-life-year saved (QALY); cost per quit; healthcare costs and utilization pre- and post-quit;

and return on investment (ROI) for coverage of tobacco-dependence treatment. Numerous analyses have estimated the cost per QALY saved resulting from use of effective tobacco-dependence interventions.^{99,127–134} In general, evidence-based tobacco-use interventions compare quite favorably with other prevention and chronic disease interventions such as treatment of hypertension and mammography screening when using this criterion. Specific analyses have estimated the costs of tobacco-use treatment to range from a few hundred to a few thousand dollars per QALY saved.^{129,135}

A substantial body of research has investigated the effect of tobacco-use treatment on healthcare costs.^{136–140} A synthesis of these findings suggest that: (1) among individuals who quit tobacco use, healthcare costs typically increase during the year in which smokers quit, and then decline progressively, falling below those of continuing smokers for one to 10 years after quitting; (2) in general, smokers' healthcare costs begin to rise in the time period immediately prior to quit attempts; and (3) higher healthcare utilization predicts smoking cessation among smokers with and without chronic diseases. These findings suggest that quitting smoking often occurs in response to serious and expensive health problems. Such research also suggests that increases in healthcare costs, including hospitalizations during the year of quitting, may be a cause rather than a consequence of successful smoking cessation.

Return on investment (ROI) is a frequently used tool to estimate the amount of time it takes for an expenditure to earn back some or all of its initial investment. 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 often produces substantial net financial savings through increased healthcare savings, increased productivity, reduced absenteeism, and reduced life insurance payouts.^{141–144}

Managed care organizations (MCOs) often assess the per-member per-month (PMPM) cost of a benefit; the PMPM for tobacco-use treatment has been assessed in a variety of settings. In general, the PMPM for tobacco-use treatments have been low relative to other covered benefits, ranging from about \$0.20 to about \$0.80 PMPM.^{135,145–147}

From both a health and economic perspective, health systems (healthcare administrators, insurers, and purchasers), should promote the treatment of tobacco dependence. Several institutional policies would facilitate these interventions such as:

- Implementing a tobacco-user identification system in every clinic.
- Providing adequate training, resources, and feedback to ensure that providers consistently deliver effective treatments.
- Dedicating staff to provide tobacco-dependence treatment and to assess the delivery of this treatment in staff performance evaluations.
- Promoting hospital policies that support and provide tobacco-dependence services.
- Including 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. Meta-analyses in the 2008 Update found that compared to not having tobacco-use treatment as a covered benefit, individuals with the benefit were more likely to receive treatment, make a quit attempt, and attain abstinence from smoking.

- Including measures of outcome (e.g., use of cessation treatment, short- and long-term abstinence rates) in addition to measures of treatment provision in standard ratings and measures of overall health quality (e.g., National Committee for Quality Assurance [NCQA], Health Plan Employer Data and Information Set [HEDIS]).

Guideline Recommendations Regarding Special Populations and Special Topics

Because specific populations have higher tobacco-use prevalence rates, reaching these populations is a key challenge for effectively treating tobacco dependence. The 2008 Update panel concluded that the interventions found to be effective in this guideline are effective in a variety of populations including those with health disparities. In addition, many of the studies supporting these interventions comprised diverse samples of tobacco users. As a result, the panel concluded that the interventions identified as effective in the 2008 Update should be recommended for use by all individuals who use tobacco except when medication use is contraindicated or with specific populations in which medication use has not been shown to be effective (pregnant women, smokeless tobacco users, light smokers, and adolescents). This recommendation applies to a broad population of smokers including HIV-positive smokers, hospitalized smokers, lesbian/gay/bisexual/transgender smokers, those with low SES/limited formal education, smokers with medical co-morbidities, older smokers, smokers with psychiatric disorders including substance use disorders, racial and ethnic minorities, and women smokers. The 2008 Update contains detailed discussion about treatments for these populations as well as discussion of special topics such as addressing weight gain after quitting.

Conclusions

In summary, the 2008 tobacco guideline update panel's major conclusions and recommendations are:

1. Tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit. However, effective treatments exist that can significantly increase rates of long-term abstinence.
2. It is essential that clinicians and healthcare delivery systems consistently identify and document tobacco-use status and treat every tobacco user seen in a healthcare setting.
3. Tobacco dependence treatments are effective 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 effective. Clinicians should offer every patient who uses tobacco at least the brief treatments shown to be effective in this guideline.
5. Individual, group, and telephone counseling are effective and their effectiveness increases with treatment intensity. Two components of counseling are especially effective and clinicians should use these when counseling patients making a quit attempt:
 - Practical counseling (problem-solving/skills training)
 - Social support delivered as part of treatment
6. There are numerous effective medications for tobacco dependence, and clinicians should encourage their use by all patients attempting to quit smoking, except when medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents).
 - Seven first-line medications (five nicotine and two non-nicotine) reliably increase long-term smoking abstinence rates:
 - Bupropion SR
 - Nicotine gum
 - Nicotine inhaler
 - Nicotine lozenge
 - Nicotine nasal spray
 - Nicotine patch
 - Varenicline
 - Clinicians should also consider the use of certain combinations of medications identified as effective in this guideline.
7. Counseling and medication are effective when used by themselves for treating tobacco dependence. However, the combination of counseling and medication is more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.
8. Telephone quitline counseling is effective with diverse populations and has broad reach. Therefore, clinicians and healthcare delivery systems should both ensure patient access to quitlines and promote quitline use.
9. If a tobacco user is currently unwilling to make a quit attempt, clinicians should use the motivational treatments shown in this guideline to be effective in increasing future quit attempts.
10. Tobacco dependence treatments are both clinically effective and highly cost effective 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 identified as effective in this guideline as covered benefits.

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Appendix

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William Bailey reported significant financial interests in the form of compensation for speaking from three different pharmaceutical companies in 2006 and two in 2007.

Timothy Baker reported no significant financial interests. Under additional disclosures, he reported that he has served as a co-investigator on research studies at the University of Wisconsin sponsored by four pharmaceutical companies.

Neal Benowitz reported significant financial interest in the form of compensation from one pharmaceutical company for each of the years 2005–2007, as well as ownership of one pharmaceutical company stock. Under additional disclosures, he reported providing expert testimony in lawsuits against tobacco companies.

Sally Faith Dorfman reported no significant financial interests. Under additional disclosures, she reported her employment by Ferring Pharmaceuticals, Inc., a company whose business does not relate to treating tobacco dependence.

Michael C. Fiore reported no significant financial interests. Under additional disclosures, he reported that he served as an investigator on research studies at the University of Wisconsin that were supported wholly or in part by four pharmaceutical companies and in 2005 received compensation from one pharmaceutical company. In addition, he reported that, in 1998, the University of Wisconsin appointed him to a named Chair, made possible by an unrestricted gift to the university from GlaxoWellcome.

Michael Goldstein reported no significant financial interests. Under additional disclosures, he reported that the organization that employs him received support from Bayer Pharmaceutical prior to 2005 and that he was employed by Bayer Pharmaceutical Corporation prior to January 1, 2005. His organization received payments for his professional services from two pharmaceutical companies and one commercial Internet smoking cessation site during the period 2005–2007.

Harry Lando reported no significant financial interests. Under additional disclosures, he reported serving on an advisory panel for a new tobacco-use cessation medication and attending 2-day meetings in 2005 and 2006 as a member of this panel.

Robert Mecklenburg reported no significant financial interests. Under additional disclosures, he reported assisting Clinical Tools, Inc. through a governmental contract to develop a PHS 2000 guideline-based Internet continuing education course.

C. Tracy Orleans reported significant financial interests in the form of a dependent child who owns pharmaceutical stock and no additional disclosures.

Maxine Stitzer reported no significant financial interests. Under additional disclosures, she reported participation on a pharmaceutical scientific advisory panel for a new tobacco-use cessation medication.

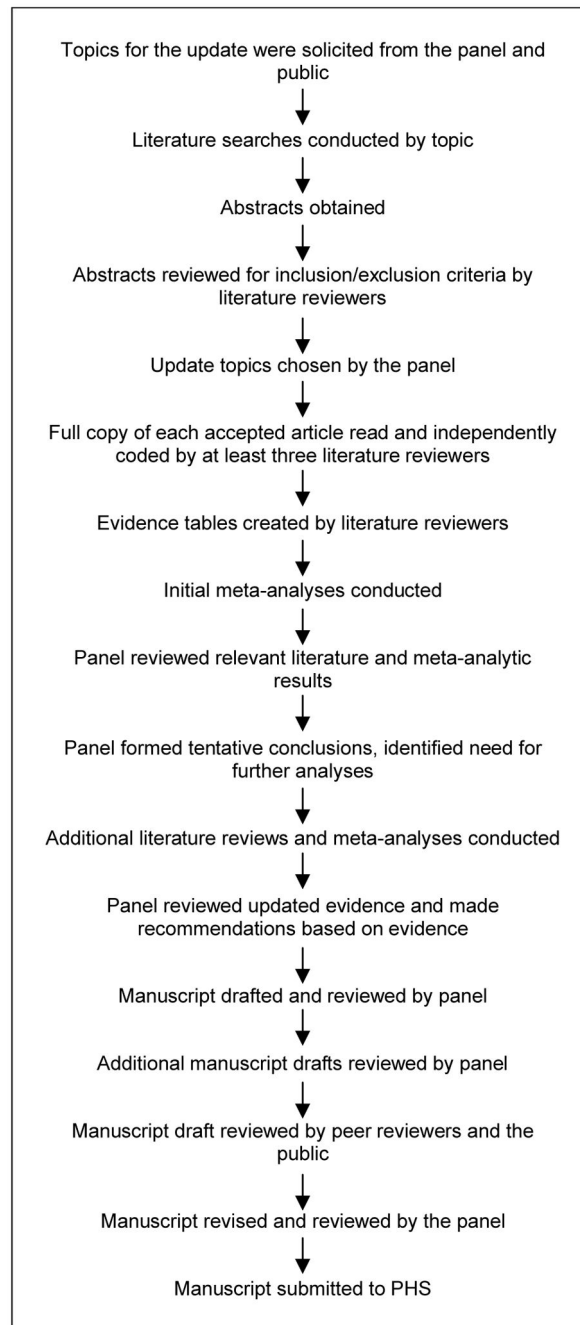


Figure 1.
2008 Update development process

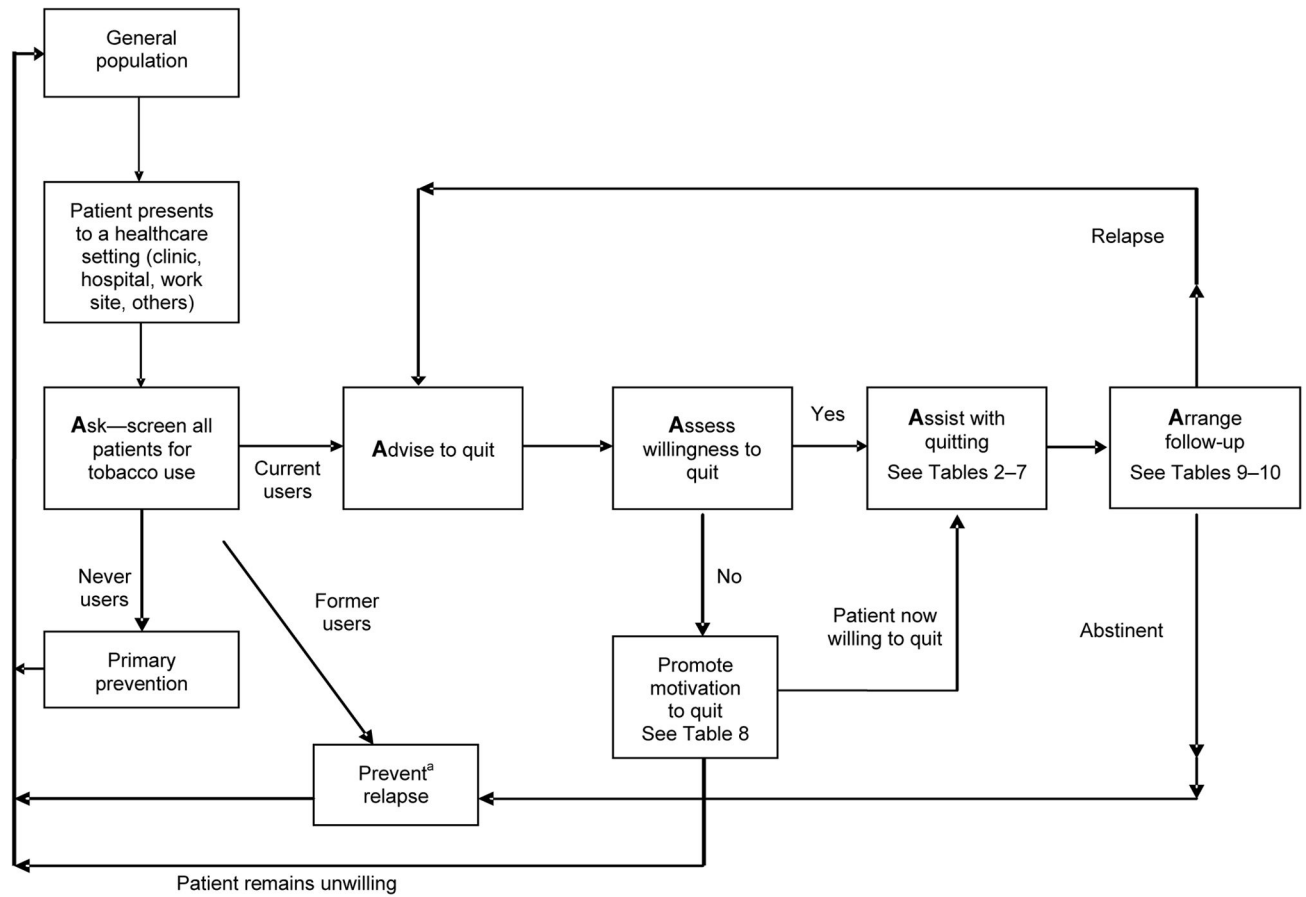


Figure 2.

Model for treatment of tobacco use and dependence.

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

Table 1

Topics chosen by the 2008 Update panel for updated meta-analyses

Effectiveness of proactive quitlines
Effectiveness of combining counseling and medication relative to either counseling or medication alone
Effectiveness of varenicline
Effectiveness of various medication combinations
Effectiveness of long-term medication use
Effectiveness of tobacco use interventions for individuals with low socioeconomic status/limited formal education
Effectiveness of tobacco use interventions for adolescent smokers
Effectiveness of tobacco use interventions for pregnant smokers
Effectiveness of tobacco use interventions for individuals with psychiatric disorders including substance use disorders
Effectiveness of providing tobacco use interventions as a health benefit
Effectiveness of systems interventions, including provider training and the combination of training and systems interventions

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Table 2

Brief strategies to help the Patient Willing to Quit Tobacco Use – The “5 A’s”

Strategy A1. <i>Ask</i> —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: Current Former Never (circle one)
Strategy A2. <i>Advise</i> —Strongly urge all tobacco users to quit	
Action	Strategies for implementation
In a <i>clear, strong, and personalized</i> manner, urge every tobacco user to quit.	Advice should be: <ul style="list-style-type: none"> • <i>Clear</i>—“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.” • <i>Strong</i>—“As your clinician, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you.” • <i>Personalized</i>—Tie tobacco use to current 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. <i>Assess</i> —Determine willingness to make a quit attempt	
Action	Strategies for implementation
Assess every tobacco user’s willingness to make a quit attempt at this time.	Assess patient’s willingness to quit: “Are you willing to give quitting a try?” <ul style="list-style-type: none"> • If the patient is willing to make a quit attempt at this time, provide assistance. <ul style="list-style-type: none"> – If the patient will participate in an intensive treatment, deliver such a treatment or link/refer to an intensive intervention. – If the patient is a member of a special population (e.g., adolescent, pregnant smoker, racial/ethnic minority), consider providing additional information. • If the patient clearly states he or she is unwilling to make a quit attempt at this time, provide an intervention shown to increase future quit attempts (see “For the Patient Unwilling to Make a Quit Attempt at This Time” and Table 7)
Strategy A4. <i>Assist</i> —Aid the patient in quitting (provide counseling and medication)	
Action	Strategies for implementation
Help the patient with a quit plan.	<i>A patient’s preparations for quitting:</i> <ul style="list-style-type: none"> • <i>Set a quit date.</i> Ideally, the quit date should be within 2 weeks. • <i>Tell</i> family, friends, and coworkers about quitting and request understanding and support • <i>Anticipate</i> challenges to the upcoming quit attempt, particularly during the critical first few weeks. These include nicotine withdrawal symptoms. • <i>Remove</i> tobacco products from your environment. Prior to quitting, avoid smoking in places where you spend a lot of time (e.g., work, home, car). Make your home smoke-free.
Recommend the use of approved medication, except where contraindicated or with specific populations for which there is	Recommend the use of medications found to be effective in this guideline Explain how these medications increase quitting success and reduce withdrawal symptoms. The first-line medications include: bupropion SR, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, nicotine patch and varenicline and second-line medications include: clonidine and nortriptyline.

Strategy A4. Assist—Aid the patient in quitting (provide counseling and medication)	
Action	Strategies for implementation
insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers and adolescents). (See Tables 4–6)	
Provide practical counseling (problem-solving/skills training). (See Table 3)	<p><i>Abstinence.</i> Striving for total abstinence is essential. Not even a single puff after the quit date.</p> <p><i>Past quit experience.</i> Identify what helped and what hurt in previous quit attempts. Build on past success.</p> <p><i>Anticipate triggers or challenges in upcoming attempt.</i> Discuss challenges/triggers and how patient will successfully overcome them (e.g., avoid triggers, alter routines).</p> <p><i>Alcohol.</i> Since alcohol is associated with relapse, the patient should consider limiting/abstaining from alcohol while quitting. (Note that reducing alcohol intake could precipitate withdrawal in alcohol-dependent individuals.)</p> <p><i>Other smokers in the household.</i> Quitting is more difficult when there is another smoker in the household. Patients should encourage housemates to quit with them or not smoke in their presence.</p>
Provide intra-treatment social support. (See Table 3)	Provide a supportive clinical environment while encouraging the patient in his or her quit attempt. “ <i>My office staff and I are available to assist you.</i> ” “ <i>I’m recommending treatment that can provide ongoing support.</i> ”
Provide supplementary materials, including information on quitlines.	<p><i>Sources:</i> Federal agencies, nonprofit agencies, national quitline network (1-800-QUIT-NOW), or local/state/tribal health departments/quitlines</p> <p><i>Type:</i> Culturally/racially/educationally/age appropriate for the patient.</p> <p><i>Location:</i> Readily available at every clinician’s workstation.</p>

Strategy A5. Arrange—Ensure follow-up contact	
Action	Strategies for implementation
Arrange for follow-up contacts, either in person or via telephone	<p><i>Timing.</i> Follow-up contact should begin soon after the quit date, preferably during the first week. A second follow-up contact is recommended within the first month. Schedule further follow-up contacts as indicated.</p> <p><i>Actions during follow-up contact.</i> For all patients, identify problems already encountered and anticipate challenges in the immediate future. Assess medication use and problems. Remind patients of quitline support (1-800-QUIT-NOW). Address tobacco use at next clinical visit (treat tobacco use as a chronic disease) (see Table 8). For patients who are abstinent, congratulate them on their success.</p> <p>If tobacco use has occurred, review circumstances and elicit recommitment to total abstinence. Consider use of or link to more intensive treatment (see “For the Patient Who Has Recently Quit” and Table 9).</p>

^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 are tobacco-use status stickers on all patient charts or to indicate tobacco use status using electronic medical records or computer reminder systems.

Table 3

Common elements of practical counseling

Component	Examples
Problem solving/skills training	
<i>Recognize danger situations</i> – Identify events, internal states, or activities that increase the risk of smoking or relapse.	<ul style="list-style-type: none"> • Negative affect and stress. • Being around other tobacco users. • Drinking alcohol. • Experiencing urges. • Smoking cues and availability of cigarettes
<i>Develop coping skills</i> – Identify and practice coping or problem-solving skills. Typically, these skills are intended to cope with danger situations.	<ul style="list-style-type: none"> • Learning to anticipate and avoid temptation 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).
<i>Provide basic information</i> – provide basic information about smoking and successful quitting.	<ul style="list-style-type: none"> • The fact that any smoking (even a single puff) increases the likelihood of a full relapse. • Withdrawal 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.
Supportive treatment	
Encourage the patient in the quit attempt.	<ul style="list-style-type: none"> • Note that effective tobacco-dependence treatments are now available. • Note that one half of all people who have ever smoked have now quit. • Communicate belief in patient's ability to quit.
Communicate caring and concern.	<ul style="list-style-type: none"> • Ask how patient feels about quitting. • Directly express concern and willingness to help as often as needed. • Ask about the patient's fears and ambivalence regarding quitting.
Encourage the patient to talk about the quitting process.	<p>Ask about:</p> <ul style="list-style-type: none"> • Reasons the patient wants to quit. • Concerns or worries about quitting. • Success the patient has achieved. • Difficulties encountered while quitting.

Table 4

General 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 where contraindicated or for specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers and adolescents)
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, the 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 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. Please refer to FDA package inserts for this complete information and FDA updates and to the individual drug tables in the 2008 Update and Table 5. (See information below regarding second-line medications.)
What other factors may influence medication selection?	Pragmatic factors may also influence selection such as insurance coverage or out-of-pocket patient costs, likelihood of adherence, dentures when considering the gum, or dermatitis when considering the patch.
Is a patient's prior experience with a medication relevant?	Prior successful experience (sustained abstinence with the medication) suggests that the medication may be helpful to the patient in a subsequent quit attempt, especially if the patient found the medication to be tolerable and/or easy to use. However, it is difficult to draw firm conclusions from prior failure with a medication. Some evidence suggests that retreating relapsed smokers with the same medication produces small or no benefit ^{52,53} while other evidence suggests that it may be of substantial benefit. ⁵⁴
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. ⁵⁵⁻⁵⁷ Also, there is evidence that combination NRT therapy may be particularly effective in suppressing tobacco withdrawal symptoms. ^{58,59} Thus it may be that NRT combinations are especially helpful to 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 genders ⁶⁰⁻⁶² ; however, evidence is mixed as to whether NRT is less effective in women than men. ⁶³⁻⁶⁷ 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 extensively evaluated in 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. Please refer to FDA package inserts for this information and to the individual drug tables in the 2008 Update.
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 be especially considered in patients with a past history of depression?	Bupropion SR and nortriptyline appear to be effective with this population, ⁶⁸⁻⁷² 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 individual drug tables in 2008 Update 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 symptoms during the course of medications, who 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 risk and developing dependence on medications is uncommon. Additionally, the FDA has approved the use of bupropion SR, varenicline and some NRT medications for 6 month use.
Is medication adherence important?	Yes. Patients frequently do not use cessation medications as recommended (e.g., they don't use them at recommended doses or for recommended durations) and this may reduce their effectiveness.

May medications ever be combined? Yes. Among first-line medications, evidence exists that combining the nicotine patch long-term (> 14 weeks) with either nicotine gum or nicotine nasal spray, the nicotine patch with the nicotine inhaler, or the nicotine patch with bupropion SR, increases long-term abstinence rates relative to placebo treatments. Varenicline is not recommended in combination with NRT.

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Table 5

Suggestions for the clinical use of pharmacotherapies for smoking cessation *

Pharmacotherapy	Precautions, contraindications	Adverse effects	Dosage	Duration	Availability
<i>First-line</i>					
Sustained release bupropion hydrochloride	History of seizure	Insomnia	150 mg every morning for 3 days, then 150 mg twice daily (begin treatment 1–2 weeks pre-quit)	7–12 weeks Maintenance up to 6 months	Prescription only
Nicotine gum	History of eating disorders	Dry mouth Seizures Mouth soreness Dyspepsia	1–24 cigarettes/day: 2mg gum (up to 24 pieces/day) 25 cigarettes/day: 4 mg gum (up to 24 pieces/day)	Up to 12 weeks	OTC only
Nicotine inhaler		Local irritation of mouth and throat	6–16 cartridges/day	Up to 6 months	Prescription only
Nicotine lozenge		Nausea Heartburn	Time to 1 st cigarette > 30 min: 2 mg lozenge Time to 1 st cigarette 30 min: 4 mg lozenge Between 4–20 lozenges/day	Up to 12 weeks	OTC only
Nicotine nasal spray		Nasal irritation	8–40 doses/day	3–6 months	Prescription only
Nicotine patch		Local skin reaction Insomnia	Ex. 21 mg/24 hrs 14 mg/24 hrs 7 mg/24 hrs	4 weeks then 2 weeks then 2 weeks 8 weeks	Prescription and OTC
Varenicline	Significant kidney disease Patients on dialysis	Nausea Trouble sleeping Abnormal or vivid/strange dreams	Ex. 15 mg/16 hrs 0.5 mg/day for 3 days 0.5 mg twice/day for 4 days	3–6 months	Prescription only
		Depressed mood and other psychiatric symptoms	Then, 1 mg twice/day (Begin treatment one week pre-quit)		

* The information contained in this table is not comprehensive. See package inserts for additional information including safety information.

Table 6

Effectiveness and abstinence rates for various medications and medication combinations compared to placebo at 6-months post-quit ($n=86$ studies)

Medication	Number of arms*	Estimated OR (95% CI)	Estimated abstinence rate (95% CI)
Placebo	80	1.0	13.8
Monotherapies			
Varenicline (2 mg/day)	5	3.1 (2.5, 3.8)	33.2 (28.9, 37.8)
Nicotine nasal spray	4	2.3 (1.7, 3.0)	26.7 (21.5, 32.7)
High dose nicotine patch (>25 mg) (these included both standard or long-term duration)	4	2.3 (1.7, 3.0)	26.5 (21.3, 32.5)
Long-term nicotine gum (>14 weeks)	6	2.2 (1.5, 3.2)	26.1 (19.7, 33.6)
Varenicline (1 mg/day)	3	2.1 (1.5, 3.0)	25.4 (19.6, 32.2)
Nicotine inhaler	6	2.1 (1.5, 2.9)	24.8 (19.1, 31.6)
Clonidine	3	2.1 (1.2, 3.7)	25.0 (15.7, 37.3)
Bupropion SR	26	2.0 (1.8, 2.2)	24.2 (22.2, 26.4)
Nicotine patch (6–14 weeks)	32	1.9 (1.7, 2.2)	23.4 (21.3, 25.8)
Long-term nicotine patch (>14 weeks)	10	1.9 (1.7, 2.3)	23.7 (21.0, 26.6)
Nortriptyline	5	1.8 (1.3, 2.6)	22.5 (16.8, 29.4)
Nicotine gum (6–14 weeks)	15	1.5 (1.2, 1.7)	19.0 (16.5, 21.9)
Combination therapies			
Patch (long-term; >14 weeks) + ad lib NRT (gum or spray)	3	3.6 (2.5, 5.2)	36.5 (28.6, 45.3)
Patch + bupropion SR	3	2.5 (1.9, 3.4)	28.9 (23.5, 35.1)
Patch + nortriptyline	2	2.3 (1.3, 4.2)	27.3 (17.2, 40.4)
Patch + inhaler	2	2.2 (1.3, 3.6)	25.8 (17.4, 36.5)
Patch + second generation antidepressants (paroxetine, venlafaxine)	3	2.0 (1.2, 3.4)	24.3 (16.1, 35.0)
Medications not shown to be effective			
Selective serotonin reuptake inhibitors (SSRIs)	3	1.0 (0.7, 1.4)	13.7 (10.2, 18.0)
Naltrexone	2	0.5 (0.2, 1.2)	7.3 (3.1, 16.2)

* The term “arms” refers to the separate treatment or control groups comprised by the analyzed studies.

Table 7Effectiveness and abstinence rates of medications relative to the nicotine patch ($n=86$ studies)

Medication	Number of arms*	Estimated odds ratio (95% CI)
Nicotine patch (reference group)	32	1.0
Monotherapies		
Varenicline (2 mg/day)	5	1.6 (1.3, 2.0)
Nicotine nasal spray	4	1.2 (0.9, 1.6)
High dose nicotine patch (>25 mg; standard or long-term)	4	1.2 (0.9, 1.6)
Long-term nicotine gum (>14 weeks)	6	1.2 (0.8, 1.7)
Varenicline (1 mg/day)	3	1.1 (0.8, 1.6)
Nicotine Inhaler	6	1.1 (0.8, 1.5)
Clonidine	3	1.1 (0.6, 2.0)
bupropion SR	26	1.0 (0.9, 1.2)
Long-term nicotine patch (>14 weeks)	10	1.0 (0.9, 1.2)
Nortriptyline	5	0.9 (0.6, 1.4)
Nicotine Gum	15	0.8 (0.6, 1.0)
Combination therapies		
Patch (long-term; >14 weeks) + NRT (gum or spray)	3	1.9 (1.3, 2.7)
Patch + bupropion SR	3	1.3 (1.0, 1.8)
Patch + nortriptyline	2	0.9 (0.6, 1.4)
Patch + inhaler	2	1.1 (0.7, 1.9)
Second-generation antidepressants & Patch	3	1.0 (0.6, 1.7)
Medications not shown to be effective		
Selective serotonin reuptake inhibitors (SSRIs)	3	0.5 (0.4, 0.7)
Naltrexone	2	0.3 (0.1, 0.6)

*The term "arms" refers to the separate treatment or control groups comprised by the analyzed studies.

Table 8

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).
Risks	<p>The clinician should ask the patient to identify potential negative consequences of tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient. The clinician should emphasize that smoking low-tar/low-nicotine cigarettes or use of other forms of tobacco (e.g., smokeless tobacco, cigars, and pipes) will not eliminate these risks. Examples of risks are:</p> <ul style="list-style-type: none"> • <i>Acute risks:</i> Shortness of breath, exacerbation of asthma, increased risk of respiratory infections, harm to pregnancy, impotence, infertility. • <i>Long-term risks:</i> Heart attacks and strokes, lung and other cancers (e.g., larynx, oral cavity, pharynx, esophagus, pancreas, stomach, kidney, bladder, cervix and acute myelocytic leukemia), chronic obstructive pulmonary diseases (chronic bronchitis and emphysema), osteoporosis, long-term disability and need for extended care. • <i>Environmental risks:</i> Increased risk of lung cancer and heart disease in spouses; increased risk for low birth weight, sudden infant death syndrome (SIDS), asthma, middle ear disease, and respiratory infections in children of smokers.
Rewards	<p>The clinician should ask the patient to identify potential benefits of stopping tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient. Examples of rewards follow:</p> <ul style="list-style-type: none"> • Improved health. • Food will taste better. • Improved sense of smell. • Saving money. • Feeling better about yourself. • Home, car, clothing, breath will smell better. • Setting a good example for children and decrease the likelihood that they will smoke. • Having healthier babies and children. • Feeling better physically. • Performing better in physical activities. • Improved appearance including reduced wrinkling/aging of skin and whiter teeth.
Roadblocks	<p>The clinician should ask the patient to identify barriers or impediments to quitting and provide treatment (problem-solving counseling, medication) that could address barriers. Typical barriers might include:</p> <ul style="list-style-type: none"> • Withdrawal symptoms. • Fear of failure. • Weight gain. • Lack of support. • Depression. • Enjoyment of tobacco. • 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.

Table 9

Addressing problems encountered by former smokers.

A patient who previously smoked might identify a problem that negatively affects health or quality of life. Specific problems likely to be reported by former smokers and potential responses follow:

Problems	Responses
Lack of support for cessation	<ul style="list-style-type: none"> • Schedule follow-up visits or telephone calls with the patient. • Urge the patient to call the national quitline network (1-800-QUIT-NOW) or other local quitline. • Help the patient identify sources of support within his or her environment. • Refer the patient to an appropriate organization that offers counseling or support.
Negative mood or depression	<ul style="list-style-type: none"> • If significant, provide counseling, prescribe appropriate medication, or refer the patient to a specialist.
Strong or prolonged withdrawal symptoms	<ul style="list-style-type: none"> • If the patient reports prolonged craving or other withdrawal symptoms, consider extending the use of an approved medication or adding/combining medications to reduce strong withdrawal symptoms.
Weight gain	<ul style="list-style-type: none"> • Recommend starting or increasing physical activity. • Reassure the patient that some weight gain after quitting is common and is usually self-limiting. • Emphasize the health benefits of quitting relative to the health risks of modest weight gain. • Emphasize the importance of a healthy diet and active lifestyle. • Suggest low-calorie substitutes such as sugarless chewing gum, vegetables, or mints. • Maintain the patient on medication known to delay weight gain (e.g., bupropion SR, NRTs, particularly 4 mg nicotine gum,¹³² and lozenge). • Refer the patient to a nutritional counselor or program.
Smoking lapses	<ul style="list-style-type: none"> • Suggest continued use of tobacco use medications, which can reduce the likelihood that a lapse will lead to a full relapse. • Encourage another quit attempt or a recommitment to total abstinence. • Reassure that quitting may take multiple attempts and use the lapse as a learning experience. • Provide or refer for intensive counseling.

Table 10

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)
Program clinicians	Multiple types of clinicians are effective and should be used. One counseling strategy would be to have a medical/healthcare clinician deliver a strong message to quit, information about health risks and benefits, 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 relationship; therefore, when possible, the intensity of the program should be: <ul style="list-style-type: none"> • <i>Session length:</i> longer than 10 minutes. • <i>Number of sessions:</i> 4 or more sessions.
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 websites is optional. Follow-up interventions should be scheduled.
Type of counseling and behavioral therapies	Counseling should include practical counseling (problem-solving/skills-training) and intra-treatment social support (see Table 3).
Medication	Combining counseling and medication increases abstinence rates. See Tables 4–6.
Population	Intensive intervention programs may be used with all tobacco users willing to participate in such efforts.