# **Complete Summary**

### **GUIDELINE TITLE**

Treating tobacco use and dependence: 2008 update.

# **BIBLIOGRAPHIC SOURCE(S)**

Treating tobacco use and dependence: 2008 update. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2008 May. 257 p.

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: U.S. Department of Health and Human Services, Public Health Service. Fiore MC, Bailey WC, Cohen SJ, et al. Treating tobacco use and dependence. Clinical practice guideline. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2000 Jun. 197 p. [311 references].

# \*\* REGULATORY ALERT \*\*

## FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse**: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

• <u>February 1, 2008, Chantix (varenicline)</u>: New information has been added to the WARNINGS and PRECAUTIONS sections in Chantix's prescribing information about serious neuropsychiatric symptoms experienced in patients taking this medication.

# **COMPLETE SUMMARY CONTENT**

\*\* REGULATORY ALERT \*\*

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

## SCOPE

## **DISEASE/CONDITION(S)**

Tobacco use and dependence

# **GUIDELINE CATEGORY**

Counseling Screening Treatment

## **CLINICAL SPECIALTY**

Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Pharmacology
Preventive Medicine
Pulmonary Medicine

# **INTENDED USERS**

Advanced Practice Nurses
Allied Health Personnel
Dentists
Health Plans
Hospitals
Managed Care Organizations
Nurses
Pharmacists
Physical Therapists
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Public Health Departments
Respiratory Care Practitioners

Substance Use Disorders Treatment Providers

# **GUIDELINE OBJECTIVE(S)**

 To provide evidence-based recommendations along with a simple and flexible set of strategies that ensure that all patients who use tobacco are offered motivational interventions and effective treatments to overcome tobacco addiction • To include new effective clinical treatments for tobacco dependence that have become available since the 2000 guideline was published

## **TARGET POPULATION**

Tobacco users

## INTERVENTIONS AND PRACTICES CONSIDERED

## Screening/Assessment

- 1. Screen for tobacco use
- 2. Assess willingness to quit
- 3. Assess for abstinence

#### Treatment

- 1. Brief clinical interventions, including patient education, motivational techniques to promote quitting, relapse prevention (minimal practice and prescriptive) for the patient who has recently quit
- 2. Counseling and behavioral therapy
  - Problem solving skills/skills training
  - Clinician-provided encouragement and assistance
- 3. Pharmacotherapy
  - First line
    - Bupropion SR (sustained released bupropion)
    - Nicotine replacement therapy (NRT), including nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, and nicotine patch (over-the-counter, prescribed)
    - Varenicline
  - Second line
    - Clonidine
    - Nortriptyline
    - Combination nicotine replacement therapy

NOTE: Medications considered but not recommended include:

- Antidepressants other than bupropion SR and nortriptyline
- Selective serotonin re-uptake inhibitors (SSRIs)
- Anxiolytics/benzodiazepines/beta-blockers
- Opioid antagonists/naltrexone
- Silver acetate
- Mecamylamine
- Extended use of medications
- 4. Clinician training and systems considerations
- 5. Consideration of special populations and situations
  - Children/adolescents
  - Light smokers
  - Noncigarette users

- Pregnant
- Weight gain after smoking cessation

## **MAJOR OUTCOMES CONSIDERED**

- Ouit rates after at least 5 months
- Morbidity and mortality due to tobacco use
- Societal cost of tobacco use

### **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

# DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Guideline update is based on three systematic reviews of the available scientific literature. The first review occurred during the creation of the original Guideline published in 1996 and included literature published from 1975 through 1994. The second review was conducted for the 2000 Guideline and included literature from 1995 through January 1999. The third review was conducted on literature published from 1999 to June 2007. The three data sets were combined into a single database that was used for the 2008 analyses.

# **Literature Review and Inclusion Criteria**

Approximately 8,700 articles were screened to identify evaluable literature. This figure includes approximately 2,700 articles added to the literature since publication of the 2000 Guideline. These 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. These criteria were that the article: (a) reported the results of a randomized, placebo/comparison controlled trial of a tobacco use treatment intervention randomized on the patient level (except as noted in the original guideline document); (b) provided followup results at least 5 months after the quit date (except in the case of studies evaluating tobacco dependence treatments for pregnant smokers); (c) was published in a peerreviewed journal; (d) was published between January 1975 and June 2007; (e) was published in English; and (f) was one of the 11 topics chosen to be included in the 2008 update (see Table 1.1 in the original guideline document). It is important to note that the article-screening criteria were updated for the 2008 Guideline update. Additionally, articles were screened for relevance to safety, economic, or health systems issues. As a result of the original and update literature reviews, more than 300 articles were identified for possible inclusion in a meta-analysis, and more than 600 additional articles were examined in detail by the Panel. These latter articles were used in the formulation of Panel recommendations that were not supported by meta-analyses. The literature search for the update project was validated by comparing the results against a

search conducted by the Centers for Disease Control and Prevention (CDC) and through review by the expert Panel.

When individual authors published multiple articles meeting the meta-analytic inclusion criteria, the articles were screened to determine whether they contained unique data. When two articles reported data from the same group of subjects, both articles were reviewed to ensure that complete data were obtained. The data were treated as arising from a single study in meta-analyses.

## NUMBER OF SOURCE DOCUMENTS

As a result of the original and update literature reviews, more than 300 articles were identified for possible inclusion in a meta-analysis, and more than 600 additional articles were examined in detail by the Panel.

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The quality and quantity of empirical support for the recommendation was rated by the following scheme:

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

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 findings across different studies. In some areas, the highest quality evidence does not depend on randomized trials (e.g., cost-effectiveness). 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.

## METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials Systematic Review with Evidence Tables

# **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

# **Preparation of Evidence Tables**

Two Guideline staff reviewers independently read and coded each article that met inclusion criteria. The reviewers coded the treatment characteristics that were used in data analyses (see Tables 6.1 and 6.2 in Chapter 6 of the original guideline document). The same general coding procedure employed during the 2000 Guideline process was employed during the update. When adjustments to the coding process were made, articles coded with the original process were recoded to reflect the changed coding (e.g., more refined coding criteria were used for the coding of treatment intensity).

A third reviewer then examined the coding of both reviewers and adjudicated any differences. Discrepancies that could not be resolved through this process were adjudicated by the project manager, Panel chair, and/or the Panel's senior scientist. Finally, each article accepted for a meta-analysis had key fields reviewed by the project manager as a final quality check. The data then were compiled and used in relevant analyses and/or Panel deliberations. Analyses done for the 2000 Guideline revealed that intervention coding categories could be used reliably by independent raters.

See the original guideline document for a discussion of outcome data.

# **Meta-Analytic Techniques**

The principal analytic technique used in this Guideline update was meta-analysis. This statistical technique estimates the impact of a treatment or variable across a set of related investigations. The primary meta-analytic model used in this and the previous two Guidelines was logistic regression using random effects modeling. The modeling was performed at the level of the treatment arm, and study effects were treated as fixed. The panel methodologist chose to employ random effects modeling, assuming that both the subject populations and the treatment elements analyzed would vary from study to study (e.g., counseling might be done somewhat differently at two different sites). Random effects modeling is well suited to accommodate such variation among studies. The statistician used the EGRET Logistic Normal Model. A complete and detailed review of the meta-analytic methods used in the Guideline can be found in the Smoking Cessation Guideline Technical Report No. 18, available from the Agency for Healthcare Research and Quality (AHRQ) as AHCPR Publication No. 97-N004. The specific articles used in each meta-analysis included in the 2008 Guideline can be found at <a href="https://www.surgeongeneral.gov/tobacco/qdlnrefs.htm">www.surgeongeneral.gov/tobacco/qdlnrefs.htm</a>.

In general, meta-analysis was used only with studies with randomization at the level of subject. In some areas (health systems changes, adolescents), however, studies often involved randomization at another level (e.g., clinician, clinic, etc.). Such studies were used in meta-analyses of a small number of topics when such studies occurred in sufficient numbers to permit inferences. Screening of such articles considered factors such as data nonindependence, the evaluation of pre-intervention or baseline status, and the number and types of higher level units.

The initial step in meta-analysis was the selection of studies that were relevant to the treatment characteristic being evaluated. After relevant studies were identified (i.e., those that contained a self-help intervention if self-help treatments were being evaluated), Panel staff reviewed the studies to ensure that they passed screening criteria. Some screening criteria were general (e.g., study presents greater than 5 months of follow-up data), whereas other criteria were specific to the type of treatment characteristic evaluated (i.e., in the analysis of quit lines, screening ensured that treatment arms were not confounded with differing intensities of in-person counseling).

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

See the original guideline document for a discussion of the limitations of metaanalytic techniques and interpretation of meta-analysis results.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This Guideline, Treating Tobacco Use and Dependence: 2008 Update, a Public Health Service-sponsored Clinical Practice Guideline, is the product of the Treating Tobacco Use and Dependence Guideline Panel ("the Panel"), government liaisons, consultants, and staff. These individuals were charged with the responsibility of identifying effective, experimentally validated tobacco dependence clinical treatments and practices. This Guideline update is the third Public Health Service Clinical Practice Guideline published on tobacco use. The first 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). That Guideline reflected scientific literature published between 1975 and 1994. The 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). That Guideline reflected the scientific

literature published from 1975 to 1999. The current 2008 update addresses literature published from 1975 to 2007.

The updated Guideline was written in response to new, effective clinical treatments for tobacco dependence that have been identified since 1999. These treatments promise to enhance the rates of successful tobacco cessation. The original 1996 Guideline was based on some 3,000 articles on tobacco treatment published between 1975 and 1994. The 2000 Guideline required the collection and screening of an additional 3,000 articles published between 1995 and 1999. The 2008 Guideline update screened an additional 2,700 articles; thus, the present Guideline update reflects the distillation of a literature base of more than 8,700 research articles. This 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.

The 2008 updated Guideline was sponsored by a consortium of eight Federal Government and private nonprofit 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.

# **Topics Included in the Guideline**

The Panel identified tobacco use as the targeted behavior and tobacco users as the clinical population of interest. Tobacco dependence treatments were evaluated for effectiveness, as were interventions aimed at modifying both clinician and health care delivery system behavior. At the start of the 2008 update process, Guideline Panel members, outside experts, and consortium representatives were consulted to determine those aspects of the 2000 Guideline that required updating. These consultations resulted in the following chief recommendations that guided the update efforts: (1) to conduct new literature reviews and metaanalyses on topics distinguished by their public health importance and for which significant new evidence is available; (2) to review previous recommendations and to identify a subset of recommendations for which to review new data; special attention was paid to clinical situations for which the Panel had previously achieved consensus in the absence of relevant controlled trials ("C"-level recommendations) to ensure that these still warranted Guideline Panel support; (3) to consider anew the strategies that might be used in clinical settings to deliver brief tobacco dependence interventions (see Chapter 3 in the original guideline document); and (4) to identify important topics for future research. Eleven topics out of 64 considered were chosen by the Panel for updated metaanalysis (see Table 1.1 in the original guideline document).

# RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## **COST ANALYSIS**

## **Cost-Effectiveness of Tobacco Use Treatments**

Tobacco use treatments are not only clinically effective, but are cost-effective as well. Tobacco use treatments, ranging from clinician advice to medication to specialist-delivered intensive programs, are cost-effective in relation to other medical interventions such as treatment of hypertension and hyperlipidemia and to other preventive interventions such as periodic mammography. In fact, tobacco use treatment has been referred to as the "gold standard" of health care cost-effectiveness. Tobacco use treatment remains highly cost-effective, even though a single application of any effective treatment for tobacco dependence may produce sustained abstinence in only a minority of smokers. 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. The cost-effectiveness of Guideline recommendations for tobacco use treatment is addressed in detail in Chapter 6 in the original guideline document.

### **METHOD OF GUIDELINE VALIDATION**

External Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

For the present update, the Panel and consortium members invited 106 reviewers to make comments. In addition, a draft of the Guideline was published in the *Federal Register* in September 2007 for public comment. A total of 81 invited reviewers and 15 members of the public supplied written comments. Peer reviewers included clinicians, health care administrators, social workers, counselors, health educators, researchers, consumers, key personnel at selected Federal agencies and State tobacco control programs, and others. All peer reviewers made financial disclosure statements, which were provided to the Panel. Reviewers were asked to evaluate the Guideline based on five criteria: validity, reliability, clarity, clinical applicability, and utility. Comments from the peer reviewers and public were incorporated into the Guideline when appropriate. Two individuals made oral presentations to the Guideline Panel during an advertised open presentation period.

# **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

The strength of evidence ratings (A-C) are defined at the end of the "Major Recommendations" field.

# **Guideline Update: Advances**

A comparison of the findings 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:

 The updated Guideline has produced even stronger evidence that counseling is an effective tobacco use treatment strategy. Of particular note are findings

- that counseling adds significantly to the effectiveness of tobacco cessation medications, quitline counseling is an effective intervention with a broad reach, and counseling increases abstinence among adolescent smokers.
- The updated Guideline offers the clinician a greater number of effective medications than were identified in the previous Guideline. Seven different effective first-line smoking cessation medications are now approved by the U.S. Food and Drug Administration (FDA) for treating tobacco use and dependence. In addition, multiple combinations of medications have been shown to be effective. Thus, the clinician and patient have many more medication options than in the past. The Guideline also now provides evidence regarding the effectiveness of medications relative to one another.
- The updated Guideline contains new evidence that health care policies significantly affect the likelihood that smokers will receive effective tobacco dependence treatment and successfully stop tobacco use. For instance, making tobacco dependence a benefit covered by insurance plans increases the likelihood that a tobacco user will receive treatment and guit successfully.

See Appendix D in the original guideline document for key recommendation changes from the 2000 guideline.

# **Ten Key Guideline Recommendations**

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

- 1. Tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit. Effective treatments exist, however, that can significantly 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 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. Numerous effective medications are available 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 (5 nicotine and 2 non-nicotine) reliably increase long-term smoking abstinence rates:
  - Bupropion SR
  - Nicotine gum
  - Nicotine inhaler
  - Nicotine lozenge
  - Nicotine nasal spray
  - Nicotine patch
  - Varenicline
- Clinicians also should 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. The combination of counseling and medication, however, 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 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 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.

# **Counseling and Psychosocial Recommendations**

## Screening and Assessment

Screen for Tobacco Use.

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, significantly increase rates of clinician intervention. (Strength of Evidence = A)

# Specialized Assessment

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

- If the patient is willing to make a quit attempt at this time, interventions identified as effective in this Guideline should be initiated. (see Chapter 3A and 4 in the original guideline document)
- If the patient is unwilling to quit at this time, an intervention designed to increase future quit attempts should be provided. (see Chapter 3B in the original guideline document)

Tobacco dependence treatment is effective and should be delivered even if specialized assessments are not used or available. (Strength of Evidence = A)

# **Treatment Structure and Intensity**

Advice to Quit Smoking

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)

Intensity of Clinical Interventions

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

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

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

# Type of Clinician

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

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

# Formats of Psychosocial Treatments

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

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

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

# Follow-up Assessment and Procedures

All patients who receive a tobacco dependence intervention should be assessed for abstinence at the completion of treatment and during subsequent clinic contacts. (1) Abstinent patients should have their quitting success acknowledged, and the clinician should offer to assist the patient with problems associated with quitting (see Chapter 3C, For the Patient Who Has Recently Quit, in the original guideline document). (2) Patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt. (Strength of Evidence = C):

- If the patient is willing to make another quit attempt, provide or arrange additional treatment (see Chapter 3A, For the Patient Willing To Quit, in the original guideline document.)
- If the patient is not willing to try to quit, provide or arrange an intervention designed to increase future quit attempts (see Chapter 3B, For the Patient Unwilling To Quit, in the original guideline document).

## **Treatment Elements**

Types of Counseling and Behavioral Therapies

Two types of counseling and behavioral therapies result in higher abstinence rates: (1) providing smokers with practical counseling (problem solving skills/skills training), and (2) providing support and encouragement as part of treatment. These types of counseling elements should be included in smoking cessation interventions. (Strength of Evidence = B)

Combining Counseling and Medication

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)

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)

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

Motivational intervention techniques appear to be effective in increasing a patient's likelihood of making a future quit attempt. Therefore, 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)

## **Medication Evidence**

Clinicians should encourage all patients attempting to quit to use effective medications for tobacco dependence treatment, 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). (Strength of Evidence = A)

# Recommendations Regarding Individual Medications: First-Line Medications

First-line medications are those that have been found to be safe and effective for tobacco dependence treatment and that have been approved by the FDA for this use, except in the presence of contraindications or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). These first-line medications have an established empirical record of effectiveness, and clinicians should consider these agents first in choosing a medication. For the 2008 update, the first-line medications are listed in Table 6.26 in the original guideline document by size of the odds ratio and in the text alphabetically by generic name.

Bupropion SR (Sustained Release)

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

Nicotine Replacement Therapies (NRTs)

## Nicotine Gum

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

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

# Nicotine Inhaler

The nicotine inhaler is an effective smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

## Nicotine Lozenge

The nicotine lozenge is an effective smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = B)

# Nicotine Nasal Spray

Nicotine nasal spray is an effective smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

## Nicotine Patch

The nicotine patch is an effective smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

### Varenicline

Varenicline is an effective smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

# **Recommendations Regarding Second-Line Medications**

Second-line medications are medications for which there is evidence of effectiveness for treating tobacco dependence, but they have a more limited role than first-line medications because: (1) the FDA has not approved them for a tobacco dependence treatment indication; and (2) there are more concerns about potential side effects than exist with first-line medications. Second-line medications should be considered for use on a case-by-case basis after first line treatments (either alone or in combination) have been used without success or are contraindicated. The listing of the second-line medications is alphabetical by generic name.

### Clonidine

Clonidine is an effective 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)

# Nortriptyline

Nortriptyline is an effective 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)

### **Combination Medications**

Certain combinations of first-line medications have been shown to be effective smoking cessation treatments. Therefore, clinicians should consider using these combinations of medications with their patients who are willing to quit. Effective combination medications are:

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

The number and variety of analyzable articles was sufficient to assess the effectiveness of five combinations of medications relative to placebo. Only the patch + bupropion combination has been approved by the FDA for smoking cessation. See the original guideline document for evidence regarding the following combinations:

- Nicotine patch + bupropion SR
- Nicotine patch + nicotine inhaler

- Long-term nicotine patch use + ad libitum NRT
- Nicotine patch + nortriptyline
- Nicotine patch + second generation antidepressants

# **Medications Not Recommended by the Guideline Panel**

- Antidepressants other than bupropion SR and nortriptyline
- Selective serotonin re-uptake inhibitors (SSRIs)
- Anxiolytics/benzodiazepines/beta-blockers
- Opioid antagonists/naltrexone
- Silver acetate
- Mecamylamine
- Extended use of medications
- Use of NRT in cardiovascular patients

### **Use of Over-the-Counter Medications**

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

# **Systems Evidence**

# **Clinician Training and Reminder Systems**

All clinicians and clinicians-in-training should be trained in effective strategies to assist tobacco users willing to make a quit attempt and to motivate those unwilling to quit. Training appears to be more effective when coupled with systems changes. (Strength of Evidence = B)

## **Cost-Effectiveness of Tobacco Dependence Interventions**

The tobacco dependence treatments shown to be effective in this Guideline (both counseling and medication) are highly cost-effective relative to other reimbursed treatments and should be provided to all smokers. (Strength of Evidence = A)

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

# Tobacco Dependence Treatment as a Part of Assessing Health Care Quality

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., National Committee for Quality Assurance [NCQA] Healthcare Effectiveness Data and Information Set [HEDIS]). These 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)

# Providing Treatment for Tobacco Use and Dependence as a Covered Benefit

Providing tobacco dependence treatments (both medication and counseling) as a paid or covered benefit by health insurance plans has been shown to increase the proportion of smokers who use cessation treatment, attempt to quit, and successfully quit. Therefore, treatments shown to be effective in the Guideline should be included as covered services in public and private health benefit plans. (Strength of Evidence = A)

# **Special Populations and Other Topics**

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

See the original guideline document for a discussion of clinical issues for specific populations, including human immunodeficiency virus (HIV)-positive smokers; hospitalized smokers; lesbian/gay/bisexual/transgender (LGBT) smokers; smokers with low socioeconomic status (SES)/limited formal education; smokers with comorbid conditions, including cancer, cardiac disease, chronic obstructive pulmonary disease (COPD), diabetes, and asthma; older smokers; smokers with psychiatric disorders, including substance use disorders; racial and ethnic minority populations, and women.

## Other Specific Populations and Topics

Children and Adolescents

Clinicians should ask pediatric and adolescent patients about tobacco use and provide a strong message regarding the importance of totally abstaining from tobacco use. (Strength of Evidence = C)

Counseling has been shown to be effective in treatment of adolescent smokers. Therefore, adolescent smokers should be provided with counseling interventions to aid them in quitting smoking. (Strength of Evidence = B)

Secondhand smoke is harmful to children. Cessation counseling delivered in pediatric settings has been shown to be effective in increasing abstinence among parents who smoke. Therefore, to protect children from secondhand smoke, clinicians should ask parents about tobacco use and offer them cessation advice and assistance. (Strength of Evidence = B)

Light Smokers

Light smokers should be identified, strongly urged to quit, and provided counseling cessation interventions. (Strength of Evidence = B)

# Noncigarette Tobacco Users

Smokeless tobacco users should be identified, strongly urged to quit, and provided counseling cessation interventions. (Strength of Evidence = A)

Clinicians delivering dental health services should provide brief counseling interventions to all smokeless tobacco users. (Strength of Evidence = A)

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

# Pregnant Smokers

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

Although abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in pregnancy can yield benefits. Therefore, clinicians should offer effective tobacco dependence interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy. (Strength of Evidence = B)

## Weight Gain After Smoking Cessation

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)

## **Definitions:**

## **Strength of Evidence Grades**

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

# **CLINICAL ALGORITHM(S)**

Clinical algorithms are provided in the original guideline document for the following:

- Model for treatment of tobacco use and dependence
- Treating tobacco use

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

The Panel's recommendations primarily are based on published, evidence-based research. When the evidence was incomplete or inconsistent in a particular area, the recommendations reflect the professional judgment of Panel members.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### **POTENTIAL BENEFITS**

Appropriate assessment and treatment of tobacco use and dependence

## **POTENTIAL HARMS**

- Weight gain related to cessation of tobacco use
- Exacerbation of comorbid psychiatric conditions following cessation of tobaccouse
- Side effects of pharmacological agents approved by the U.S. Food and Drug Administration (FDA) for smoking cessation:

Bupropion SR: The most common side effects reported were insomnia (35% to 40%) and dry mouth (10%).

*Nicotine chewing gum*: Common side effects 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.

*Nicotine inhaler*: 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.

*Nicotine lozenge*: The most common side effects are nausea, hiccups, and heartburn. Individuals on the 4-mg lozenge also had increased rates of headache and coughing (less than 10% of participants).

Nicotine nasal spray:

- <u>Nasal/airway reactions</u>. Some 94% of users report moderate to severe nasal irritation in the first 2 days of use; 81% still reported nasal irritation after 3 weeks, although rated severity was mild to moderate. Nasal congestion and transient changes in sense of smell and taste were also reported. Nicotine nasal spray should not be used in persons with severe reactive airway disease.
- <u>Dependency</u>. Nicotine nasal spray has a dependence potential intermediate between other nicotine-based therapies and cigarettes. About 15% to 20% of patients report using the active spray for longer periods than recommended, and 5% used the spray at a higher dose than recommended.

Nicotine patch: Up to 50% of patients using the nicotine patch will have a local skin reaction. Skin reactions are usually mild and self-limiting, but occasionally worsen over the course of therapy. Local treatment with hydrocortisone cream (1%) or triamcinolone cream (0.5%) and rotating patch sites may ameliorate such local reactions. In fewer than 5% of patients, such reactions require the discontinuation of nicotine patch treatment. Other side effects include insomnia and/or vivid dreams.

Varenicline: Nausea, trouble sleeping, abnormal/vivid/strange dreams

• Side effects of pharmacologic agents not FDA approved for smoking cessation:

Clonidine: Most commonly reported side effects include dry mouth (40%), drowsiness (33%), dizziness (16%), sedation (10%), and constipation (10%). As an antihypertensive medication, clonidine can be expected to lower blood pressure in most patients. Therefore, clinicians may need to monitor blood pressure when using this medication. Rebound hypertension may occur if the dose is not gradually reduced over a period of 2 to 4 days (rapid increase in blood pressure, agitation, confusion, and/or tremor may occur).

Nortriptyline: Most commonly reported side effects include sedation, dry mouth (64% to 78%), blurred vision (16%), urinary retention, lightheadedness (49%), and shaky hands (23%).

See the tables in Chapter 3 of the original guideline documents for additional information, including precautions when using medications in pregnant smokers or those with cardiovascular disease. Also see Chapter 6 in the original guideline document for information about interactions of first-line tobacco use medications with other drugs.

# **CONTRAINDICATIONS**

## **CONTRAINDICATIONS**

Bupropion SR: This agent is contraindicated in individuals with a history of seizures or eating disorders, who are taking another form of bupropion, or who have used a monoamine oxidase (MAO) inhibitor in the past 14 days.

# **QUALIFYING STATEMENTS**

# **QUALIFYING STATEMENTS**

- The recommendations may not be appropriate for use in all circumstances and are designed particularly for clinical settings. Decisions to adopt any particular recommendation must be made by clinicians in light of available resources and circumstances presented by individual patients and in light of new clinical information such as that provided by the U.S. Food and Drug Administration (FDA).
- Most tobacco users in the United States are cigarette smokers. As a result, the majority of clinician attention and research in the field has focused on the treatment and assessment of smoking. 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 effort 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." The use of the term "smoker" means that all relevant evidence for a recommendation arises from studies of cigarette smokers.
- The Panel identified randomized placebo/comparison controlled trials as the strongest level of evidence for the evaluation of treatment effectiveness. Thus, evidence derived from randomized controlled trials serves as the basis for meta-analyses and for almost all of the recommendations contained in this Guideline. Questions have been raised about medication placebo controls because individuals sometimes guess their actual medication condition at greater than chance levels. It is possible, therefore, that the typical randomized control trial does not control completely for placebo effects. This should be borne in mind when appraising the results of the medication meta-analyses. Further, in studies of counseling, it often is not possible to control for a nonspecific placebo effect.

# **Caveats Regarding Recommendations**

- An absence of studies should not be confused with proven lack of
  effectiveness. In certain situations, there was little direct evidence regarding
  the effectiveness of some treatments, and in these cases the Panel usually
  rendered no opinion. Even when there were enough studies to perform a
  meta-analysis, a nonsignificant result does not prove ineffectiveness. Rather,
  nonsignificance merely indicates that effectiveness was not demonstrated
  given the data available.
- The primary emphasis of this Guideline update is to identify effective interventions, not to rank-order interventions in terms of effectiveness. The most important goal of the analytic process is to identify effective interventions. Selection or use of particular intervention techniques or strategies is usually a function of practical factors: patient preference, time available, training of the clinician, cost, and so on. The Panel believes clinicians should choose the most appropriate intervention from among the effective interventions identified in the Guideline update, given clinical circumstances. An excessive emphasis on relative effectiveness might discourage clinicians from using interventions that have small, but reliable, impact on quit rates. One meta-analysis that is new to the update does provide focused tests of the relative effectiveness of different interventions.

Specifically, the inclusive meta-analysis of the tobacco use medications involved *a priori* tests of medication effectiveness versus the nicotine patch. Finally, the Panel occasionally identified an intervention as superior to another in the absence of formal statistical contrasts; some interventions were so superior to control or no-treatment conditions that the Panel clearly identified them as superior to another intervention. For instance, although minimal person-to-person contact can increase smoking abstinence rates over no-treatment conditions, there is little doubt that longer person-to-person interventions have greater impact.

## **IMPLEMENTATION OF THE GUIDELINE**

### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

# Coordination of Care: Institutionalizing the Treatment of Tobacco Dependence

Increasing evidence shows that the success of any tobacco dependence treatment strategy cannot be divorced from the health care system in which it is embedded. Data strongly indicate that the consistent and effective delivery of tobacco interventions requires coordinated interventions. Just as a clinician must intervene with his or her patient, so must the health care administrator, insurer, and purchaser ensure the provision of tobacco dependence treatment as an integral element of health care delivery. Health care purchasers and insurers should ensure that evidence-based tobacco dependence counseling and medications are a covered and available health insurance benefit for all enrollees and that enrollees are aware of such benefits. Health care administrators also should provide clinicians with the training and institutional support and systems to ensure consistent identification of and intervention with patients who use tobacco. Therefore, insurers, purchasers, and health care organizations should promote the utilization of covered treatments and assess usage and outcomes in performance measurement systems. Finally, increasing evidence shows that, for maximum public health benefit, access to effective treatments should be increased during and following the implementation of population-level tobacco control policies (i.e., tobacco tax increases and clean indoor air laws), which boost motivation and support for quitting efforts.

# Recommendations for Health Care Administrators, Insurers, and Purchasers

Health care delivery administrators, insurers, and purchasers can promote the treatment of tobacco dependence through a systems approach. Purchasers (often business entities or other employers, State or Federal units of government, or other consortia that purchase health care benefits 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 and lower utilization of health care resources. 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 identification system in every clinic (Systems Strategy 1).
- Providing adequate training, resources, and feedback to ensure that providers consistently deliver effective treatments (Systems Strategy 2).
- Dedicating staff to provide tobacco dependence treatment and assessing the delivery of this treatment in staff performance evaluations (Systems Strategy 3).
- Promoting hospital policies that support and provide tobacco dependence services (Systems Strategy 4).
- Including tobacco dependence treatments (both counseling and medication) identified as effective in this Guideline, as paid or covered services for all subscribers or members of health insurance packages (Systems Strategy 5).

Strategy details can be found in the original guideline document. These strategies are based on the evidence presented in the guideline document as well as on panel opinion.

## **IMPLEMENTATION TOOLS**

Clinical Algorithm
Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides
Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### **IOM CARE NEED**

Living with Illness Staying Healthy

## **IOM DOMAIN**

Effectiveness Patient-centeredness

# **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

Treating tobacco use and dependence: 2008 update. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2008 May. 257 p.

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

# **DATE RELEASED**

1996 (revised 2008 May)

# **GUIDELINE DEVELOPER(S)**

Public Health Service (U.S.) - Federal Government Agency [U.S.]

### **GUIDELINE DEVELOPER COMMENT**

The updated guideline was sponsored by a consortium of eight Federal Government and nonprofit organizations.

# **SOURCE(S) OF FUNDING**

United States Government

## **GUIDELINE COMMITTEE**

Tobacco Use and Dependence Guideline Panel

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Michael C. Fiore, MD, MPH (Panel Chair); Carlos Roberto Jaén, MD, PhD, FAAFP (Panel Vice Chair); Timothy B. Baker, PhD (Senior Scientist); William C. Bailey, MD, FACP, FCCP; Neal L. Benowitz, MD; Susan J. Curry, PhD; Sally Faith Dorfman, MD, MSHSA; Erika S. Froelicher, PhD, RN, MA, MPH; Michael G. Goldstein, MD; Cheryl G. Healton, DrPH; Patricia Nez Henderson, MD, MPH; Richard B. Heyman, MD; Howard K. Koh, MD, MPH, FACP; Thomas E. Kottke, MD, MSPH; Harry A. Lando, PhD; Robert E. Mecklenburg, DDS, MPH; Robin J. Mermelstein, PhD; Patricia Dolan Mullen, DrPH; C. Tracy Orleans, PhD; Lawrence Robinson, MD, MPH; Maxine L. Stitzer, PhD; Anthony C. Tommasello, PhD, MS; Louise Villejo, MPH, CHES; Mary Ellen Wewers, PhD, MPH, RN

# FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The evaluation of conflict for the 2008 Guideline Update comprised a two-stage procedure designed to obtain increasingly detailed and informative data on potential conflicts over the course of the Guideline development process. See Appendix A in the original guideline document for a description of the procedure, including the criteria used to determine if a potential conflict is "significant."

Three Panel members whose disclosures exceeded the Public Health Service (PHS) criteria for significant financial interest were recused from Panel deliberations relating to their areas of conflict; one additional Panel member voluntarily recused himself.

## **Panel Members**

The following is a summary listing for any of the years 2005, 2006, and 2007 of all significant financial interests as defined above, as well as any additional disclosures Panel members chose to make.

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

Timothy B. 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 that were sponsored by four pharmaceutical companies.

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

Susan J. Curry reported no significant financial interests and no additional disclosures.

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 (UW) 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 UW appointed him to a named Chair, which was made possible by an unrestricted gift to the UW from GlaxoWellcome.

Erika S. Froehlicher reported no significant financial interests and no additional disclosures.

Michael G. Goldstein reported no significant financial interests. Under additional disclosures, he reported that his employer 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.

Cheryl Healton reported no significant financial interests and no additional disclosures.

Patricia Nez Henderson reported no significant financial interests and no additional disclosures.

Richard B. Heyman reported no significant financial interests and no additional disclosures.

Carlos Roberto Jaén reported no significant financial interests and no additional disclosures.

Howard K. Koh reported no significant financial interests and no additional disclosures.

Thomas E. Kottke reported no significant financial interests and no additional disclosures.

Harry A. 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 E. 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.

Robin Mermelstein reported no significant financial interests and no additional disclosures.

Patricia Dolan Mullen reported no significant financial interests and no additional disclosures.

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

Lawrence Robinson reported no significant financial interests and no additional disclosures.

Maxine L. 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.

Anthony C. Tommasello reported no significant financial interests and no additional disclosures.

Louise Villejo reported no significant financial interests and no additional disclosures.

Mary Ellen Wewers reported no significant financial interests and no additional disclosures.

## Liaisons

Liaisons followed the same process as Panel members in reporting significant financial interests. Their disclosures are summarized below:

Glen Bennett reported no significant financial interests and no additional disclosures.

Stephen Heishman reported no significant financial interests and no additional disclosures.

Corinne Husten reported no significant financial interests and no additional disclosures.

Glen Morgan reported no significant financial interests and no additional disclosures.

Ernestine W. Murray reported no significant financial interests and no additional disclosures.

Christine Williams reported no significant financial interests and no additional disclosures.

## **Peer Reviewers**

Peer reviewers were required to report significant financial interests at the time they submitted their peer reviews. The interests were reviewed prior to the adjudication of each reviewer's comments. Any significant financial interests are noted below their listing in the Contributors Section of the original guideline document.

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: U.S. Department of Health and Human Services, Public Health Service. Fiore MC, Bailey WC, Cohen SJ, et al. Treating tobacco use and dependence. Clinical practice guideline. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2000 Jun. 197 p. [311 references].

# **GUIDELINE AVAILABILITY**

Electronic copies: Available from the <u>United States Department of Health & Human Services Web site</u>.

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- Helping smokers quit. A guide for clinicians. Rockville (MD): U.S. Department of Health and Human Services. Public Health Services. 2008 May. 8 p. Electronic copies: Available from the <u>United States Department of Health &</u> Human Services Web site.
- A Smoking Cessation Web page is available from the <u>Public Health Service</u> Web site.

## **PATIENT RESOURCES**

The following are available:

- Help for smokers and other tobacco users. Rockville (MD): U.S. Department of Health and Human Services. Public Health Services. 2008 May. 12 p. Electronic copies: Available in English and Spanish from the <u>United States</u> <u>Department of Health & Human Services Web site</u>.
- You can quit smoking. Prenatal clinician tear sheet. Rockville (MD): U.S.
  Department of Health and Human Services. Public Health Services. 2007 Apr.
  2 p. Electronic copies: Available in English and Spanish from the <u>United States</u>
  Department of Health & Human Services Web site.
- You can quit smoking. Poster. Rockville (MD): U.S. Department of Health and Human Services. Public Health Services. 1 p. Electronic copies: Available in English and Spanish from the <u>United States Department of Health & Human</u> Services Web site.
- Quitting helps you heal faster. Hospital card. Rockville (MD): U.S. Department
  of Health and Human Services. Public Health Services. 1 p. Electronic copies:
  Available in English and Spanish from the <u>United States Department of Health</u>
  & Human Services Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## **NGC STATUS**

This NGC Summary was completed by ECRI on June 26, 2000. It was reviewed by the guideline developer as of June 27, 2000. This NGC summary was updated by ECRI Institute on May 12, 2008.

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