



## Complete Summary

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### GUIDELINE TITLE

Smoking cessation.

### BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Smoking cessation. Ann Arbor (MI): University of Michigan Health System; 2006 Aug. 12 p. [1 reference]

### GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Smoking cessation. Guidelines for clinical care. Ann Arbor (MI): University of Michigan Health System; 2001 Feb. 9 p.

### \*\* 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.

- [February 1, 2008, Chantix \(varenicline\)](#): 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.
- [May 2, 2007, Antidepressant drugs](#): Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.

### COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

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## SCOPE

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

Tobacco dependence

### **GUIDELINE CATEGORY**

Counseling  
Screening  
Treatment

### **CLINICAL SPECIALTY**

Family Practice  
Internal Medicine  
Pediatrics

### **INTENDED USERS**

Health Care Providers  
Physicians

### **GUIDELINE OBJECTIVE(S)**

To provide a systematic framework for care providers to assist patients in smoking cessation

### **TARGET POPULATION**

Adult and adolescent smokers

### **INTERVENTIONS AND PRACTICES CONSIDERED**

#### **Screening**

1. Assessment and documentation of smoking status
2. Assessment of readiness to quit

#### **Treatment**

1. Advice and counseling:
  - Brief clinic intervention model known as "3-A's and Refer" model: Ask, Advise, Assess, and Refer

- Motivational intervention using "5 R's": Relevance, Risks, Rewards, Roadblocks, Repetition
2. Pharmacotherapy: First-Line:
    - Nicotine lozenge, such as Commit Lozenge
    - Transdermal nicotine patch, such as Nicoderm CQ, Nicotrol, or other generic nicotine transdermal patches
    - Nicotine gum (polacrilex), such as Nicorette, generic nicotine polacrilex
    - Nicotine nasal spray, such as Nicotrol NS
    - Nicotine inhaler, such as Nicotrol inhaler
    - Bupropion hydrochloride SR (Zyban®) or generic bupropion hydrochloride
    - Varenicline (Chantix®)
  3. Pharmacotherapy: Second-Line:
    - Clonidine
    - Nortriptyline
  4. Advice on weight gain after smoking cessation
  5. Follow-up to prevent relapse

## **MAJOR OUTCOMES CONSIDERED**

Efficacy of treatment as evidenced by smoking cessation rates

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

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

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

The update of literature beyond the search performed for the initial University of Michigan Health System (UMHS) Smoking Cessation Guideline began with a literature search performed to produce "Treating Tobacco Use and Dependence. A Clinical Practice Guideline," US Public Health Service, 2000 June. The guideline team updated the Public Health Service literature search through a Medline search of literature January 1999 – April 2005. This search used the major keywords of: smoking [prevention & control], smoking cessation, tobacco use [prevention & control, rehabilitation]. The search was restricted to literature that was also referenced as either guidelines or controlled trials, as studies of humans, and as published in English. Specific searches were performed for the topics: counseling (includes assessment); pharmacologic treatment; other therapies (including complementary/alternative); pregnancy; adolescents; older adults; prevention (includes physician interactions with children and adolescents, counseling about having a smoke free home, and avoiding environmental tobacco smoke); and other smoking cessation guidelines, reviews of trials, or trials not included above.

### **NUMBER OF SOURCE DOCUMENTS**

Not stated

## **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**

Levels of evidence that reflect the best available literature in support of an intervention or test:

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational trials
- D. Opinion of expert panel

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

Review of Published Meta-Analyses  
Systematic Review

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

Conclusions were based on prospective randomized clinical trials (RCTs) if available, to the exclusion of other data. If RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

### **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

### **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Not stated

### **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

### **METHOD OF GUIDELINE VALIDATION**

Internal Peer Review

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

University of Michigan Health System (UMHS) guidelines are reviewed in clinical conferences of physicians in departments to which the content is most relevant and by leadership in those departments. This guideline was reviewed by members of the following clinical units: Family Medicine, General Medicine, and General Pediatrics. Guidelines are approved by the Executive Committee on Clinical Affairs (ECCA).

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

*Note from the National Guideline Clearinghouse (NGC):* The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on dosing, duration, and instructions for nicotine replacement therapies, bupropion, and varenicline and cost of drugs, counseling and motivational interventions, and considerations for special populations (i.e., pregnant and breastfeeding patients, racial and ethnic minorities, patients with psychiatric co-factors, non-cigarette tobacco users, gender concerns, older smokers, and hospitalized smokers).

The levels of evidence [A-D] are defined at the end of the Major Recommendations.

- **ASK** all patients about smoking status and assess smoker's readiness to quit. Smoking status should be documented in the medical record.
- **ADVISE** all smokers to seriously consider making a quit attempt using a clear and personalized message. Advice as brief as 3 minutes is effective [A].
- **ASSESS** all smokers' willingness to make a quit attempt. If not yet ready to quit, offer motivational intervention using 5 "R's" – relevance, risks, rewards, roadblocks, repetition.
- **REFER** patients interested in quitting within 30 days to a tobacco treatment specialist or other appropriate tobacco cessation program. Alternatively, health care providers can directly provide the following treatment:

#### Treatment Options

- **ASSIST** those ready to make a quit attempt:
  - Set a quit date. Quit date abstinence is a strong predictor of long-term success [C].
  - Give advice on quitting and provide supplementary materials.
  - Prescribe pharmacologic therapy as appropriate. Nicotine replacement therapies, bupropion hydrochloride, and varenicline have been proven effective [A].
- **ARRANGE** follow-up either with phone call or office visit.
  - Prevent relapse by congratulating successes and reinforcing reasons for quitting.
  - Assess any difficulties with pharmacologic therapy.

#### Definitions:

#### Levels of Evidence

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational trials
- D. Opinion of expert panel

## CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document titled, "Clinician's Actions to Help Patients Quit Smoking."

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

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

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Effective interventions and strategies for health care providers to assist patients in smoking cessation

### POTENTIAL HARMS

#### Side Effects of Medications

- **Nicotine Lozenge** - Headache, diarrhea, flatulence, heartburn, hiccups, nausea, coughing, sore throat, and upper respiratory infection (occurring in > 5% of patients)
- **Transdermal nicotine patch** - Skin reactions such as pruritus, edema, rash; sleep disturbance
- **Nicotine gum (polacrilex)** - Jaw fatigue, hiccups, belching, and nausea
- **Nicotine nasal spray** - Nasal irritation/rhinorrhea (98% of patients), sneeze, cough.
- **Nicotine inhaler** - Cough, mouth and throat irritation
- **Bupropion hydrochloride SR (Zyban®)** and **bupropion hydrochloride** - Insomnia and dry mouth. It should be used with caution in patients with predisposition to seizure (i.e., head trauma, alcohol withdrawal, concomitant use with other medications that lower seizure threshold – antipsychotics, antidepressants, theophylline)
- **Varenicline (Chantix®)** - Nausea, insomnia, and unusual dreams; should not be used in conjunction with nicotine replacement therapy (NRT) products

- **Clonidine** - Dry mouth and sedation
- **Nortriptyline** - Dry mouth

Few studies have addressed the safety of nicotine replacement therapy or bupropion in pregnancy directly; however, studies show that less nicotine and fewer metabolites cross the placenta with the use of nicotine replacement therapy than with smoking itself. The U.S. Food and Drug Administration (FDA) pregnancy risk categories are: bupropion – category B, nicotine transdermal, spray and inhaler – category D, nicotine gum – category C, varenicline – category C.

Most smokers who quit will gain weight, but the majority will gain less than 10 pounds.

## CONTRAINDICATIONS

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Bupropion hydrochloride and Bupropion hydrochloride SR (Zyban®) are contraindicated in patients with seizure disorder, major head trauma, eating disorders, and in patients on Wellbutrin® or monoamine oxidase (MAO) inhibitors.

## QUALIFYING STATEMENTS

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These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

#### **Organizing a Health Care Site to Support Smoking Cessation Efforts**

Successful intervention programs require coordinated efforts at a health care site. Several clinic personnel may be involved in operational steps of "Asking, Advising, Assessing, and Referring". Clinicians should help their clinics develop a coordinated plan of tasks and who will perform them. Some specific areas for planning include:

**Record smoking status.** Institute an office system to identify all smokers:

- Identify where smoking status will be recorded. Options include making smoking status part of vital signs, placing smoking status stickers on charts, or including smoking status on a section of the Problem Summary List.
- Determine who will routinely ask and record the information.

- Instruct staff regarding their roles in documentation.
- Reinforce the value of the documentation.

**Smoking cessation follow-up.** Develop a system and assigned role(s) at the health care site to:

- Ensure the availability of patient education materials on smoking cessation.
- Establish procedures for clinicians to provide a designated follow-up person with information on patients who are setting quit dates. Coordinate follow-up phone calls in conjunction with quit dates.
- Provide follow-up cessation counseling as needed at subsequent clinic visits.
- Refer patients to more intensive counseling programs for smoking cessation, as needed.

## IMPLEMENTATION TOOLS

Clinical Algorithm  
Patient Resources

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

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

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Smoking cessation. Ann Arbor (MI): University of Michigan Health System; 2006 Aug. 12 p. [1 reference]

### ADAPTATION

The guideline was adapted from the Public Health Service guideline: Treating tobacco use and dependence. A clinical practice guideline. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2000 Jun. Clinical Practice Guideline.

### DATE RELEASED

1998 Sep (revised 2006 Aug)

**GUIDELINE DEVELOPER(S)**

University of Michigan Health System - Academic Institution

**SOURCE(S) OF FUNDING**

University of Michigan Health System

**GUIDELINE COMMITTEE**

Smoking Cessation Guideline Team

**COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

*Team Leader:* John G Frohna, MD, MPH, Internal Medicine and Pediatrics

*Team Members:* R Van Harrison, PhD, Medical Education; David C Serlin, MD, Family Medicine; Linda A Thomas, MS LLP, UMHS Tobacco Consultation Service

*Guidelines Oversight Team:* Connie Standiford, MD; William E Chavey, MD; R Van Harrison, PhD

**FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

None of the members of the Smoking Cessation Guideline Team have relationships with commercial companies whose products are discussed in this guideline. (The members of the team are listed on the front page of the original guideline.)

**GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Smoking cessation. Guidelines for clinical care. Ann Arbor (MI): University of Michigan Health System; 2001 Feb. 9 p.

**GUIDELINE AVAILABILITY**

Electronic copies: Available for download in Portable Document Format (PDF) from the [University of Michigan Health System Web site](#).

## **AVAILABILITY OF COMPANION DOCUMENTS**

Continuing Medical Education (CME) information is available from the [University of Michigan Health System Web site](#).

## **PATIENT RESOURCES**

The following are available:

- How to quit smoking. University of Michigan Health System; 2005 Oct. Various p. Available from the [University of Michigan Health System Web site](#).
- How to use your nicotine replacement product. University of Michigan Health System; 2005 Oct. Various p. Available from the [University of Michigan Health System 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 summary was completed by ECRI on January 11, 2002. The information was verified by the guideline developer as of February 8, 2002. This summary was updated by ECRI on November 10, 2006. The updated information was verified by the guideline developer on December 12, 2006. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This summary was updated by ECRI Institute on February 5, 2008, following the U.S. Food and Drug Administration advisory on Chantix (varenicline).

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Date Modified: 9/22/2008

