

2008 PHS Clinical Practice Guideline: Treating Tobacco Use and Dependence Update

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Overview

- History of the Guideline
- Developmental process for the 2008 Update
- Ten Key Recommendations
- Special issues
- Dissemination plans
- Discussion

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- **History of the Guideline**
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History

1. 1996 – Initial Guideline; literature from 1975 -1995; approximately 3,000 articles
2. 2000 – Revised Guideline; literature from 1995 -1999; approximately 3,000 articles
3. 2008 - Updated Guideline; literature from 1999 – 2007; approximately 2,700 articles (approximately 8,700 total articles)

The Update

- Began 7-1-06
- Scope remains the clinical treatment of tobacco use and dependence
- Update rather than a full revision
 - Complete analysis (meta-analysis) of 3 - 5 new topics
 - *Challenge: What doesn't get updated?*
- Very similar development process to 1996 and 2000

Sponsors

- Agency for Healthcare Research and Quality
- National Cancer Institute
- National Heart, Lung & Blood Institute,
- National Institute on Drug Abuse
- Centers for Disease Control and Prevention
- The Robert Wood Johnson Foundation
- American Legacy Foundation
- University of Wisconsin-Center for Tobacco Research and Intervention

Panel Members

- Michael C. Fiore, MD, MPH, Chair
- Carlos Roberto Jaén, MD, PhD, FAAFP, Vice-Chair
- Timothy Baker, PhD, Senior Scientist
- William C. Bailey, MD, FACP, FCCP
- Neal Benowitz, MD
- Susan J. Curry, PhD
- Sally Faith Dorfman, MD, MSHSA
- Erika S. Froelicher, RN, MA, MPH, PhD
- Michael G. Goldstein, MD
- Cheryl Heaton, DrPH
- Patricia Nez Henderson, MD, MPH
- Richard B. Heyman, MD
- Howard Koh, MD, MPH, FACP
- Thomas E. Kottke, MD, MSPH
- Harry A. Lando, PhD
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- Robin Mermelstein, PhD
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- C. Tracy Orleans, PhD
- Lawrence Robinson, MD, MPH
- Maxine Stitzer, PhD
- Anthony Tommasello, Pharm BS, PhD
- Louise Villejo, MPH, CHES
- Mary Ellen Wewers, PhD, RN, MPH

PHS Liaisons

- Ernestine (Tina) Murray, RN, MAS, AHRQ (Project Officer)
- Christine Williams, AHRQ
- Glen Bennett, NHLBI
- Stephen Heishman, NIDA
- Corrine Husten, CDC
- Glen Morgan, NCI

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Guideline Development Phases

1. Identify update topics
2. Meta-analysis of topics
3. Panel/liaisons workgroups
4. Establish recommendations and other content
5. Draft text
6. Peer review/public comment
7. Panel approval
8. Federal clearance

Developmental Process

- Topics for the update were solicited from the panel and public (about 100 topics)
- Literature searches conducted on about half of the topics
- Abstracts obtained
- Abstracts reviewed for inclusion/exclusion criteria by literature reviewers
- 11 update topics chosen by the panel
- Full copy of each accepted article read and independently coded by at least 3 literature reviewers (178 articles coded)

Developmental Process

- Evidence tables created by literature reviewers
- Initial meta-analyses conducted
- Panel reviewed relevant literature and meta-analytic results
- Panel formed tentative conclusions, identified need for further analyses
- Additional literature reviews and meta-analyses conducted

Developmental Process

- Panel reviewed updated evidence and made recommendations based on evidence
- Manuscript drafted and reviewed by panel
- Additional manuscript drafts reviewed by panel
- Manuscript draft reviewed by 101 peer reviewers and the public (over 1700 total comments)
- Manuscript revised and reviewed by panel
- Manuscript submitted to PHS on 12-21-07
- Federal clearance and final editing

Final Selected Topics

- 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 medications
- Effectiveness of cessation interventions for individuals with low socio-economic status/limited formal education

Final Selected Topics

- Effectiveness of cessation interventions for adolescent smokers
- Effectiveness of cessation interventions for pregnant smokers
- Effectiveness of cessation interventions for individuals with psychiatric illness and/or non-tobacco chemical dependencies
- Effectiveness of providing cessation interventions as a health benefit
- Effectiveness of systems interventions, including provider training and the combination of training and systems interventions

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#1 Key Recommendation

- 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 Key Recommendation

- 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 Key Recommendation

- 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 Key Recommendation

- 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 Key Recommendation

- 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 Key Recommendation

- 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).
- Clinicians should also consider the use of certain combinations of medications identified as effective in this Guideline.

#6 Key Recommendation

- Seven first-line medications reliably increase long-term smoking abstinence rates:
 - Bupropion SR
 - Nicotine gum
 - Nicotine inhaler
 - Nicotine lozenge
 - Nicotine nasal spray
 - Nicotine patch
 - Varenicline

Varenicline

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 odds ratio (95% C. I.) | Estimated abstinence rate (95% C. I.) |
|------------------------|-----------------------|---|--|
| Placebo | 80 | 1.0 | 13.8 |
| Varenicline (2 mg/day) | 5 | 3.1 (2.5, 3.8) | 33.2 (28.9, 37.8) |
| Varenicline (1 mg/day) | 3 | 2.1 (1.5, 3.0) | 25.4 (19.6, 32.2) |

Medication Mega-meta-analysis

- Combined all medications, long-term medication use and medication combinations
- 83 RCTs
- Both placebo and patch used as reference group
- Yielded relative efficacy

Medication Combinations

| Medication | Number of arms | Estimated odds ratio (95% C. I.) | Estimated abstinence rate (95% C. I.) |
|--|----------------|----------------------------------|---------------------------------------|
| Placebo | 80 | 1.0 | 13.8 |
| Patch (> 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 | 3 | 2.0 (1.2, 3.4) | 24.3 (16.1, 35.0) |

Long-term Medications

| Medication | Number of arms | Estimated odds ratio (95% C. I.) | Estimated abstinence rate (95% C. I.) |
|---------------------------------------|----------------|----------------------------------|---------------------------------------|
| Placebo | 80 | 1.0 | 13.8 |
| Long-Term Nicotine Gum (> 14 weeks) | 6 | 2.2 (1.5, 3.2) | 26.1 (19.7, 33.6) |
| 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) |
| Nicotine Gum (6-14 weeks) | 15 | 1.5 (1.2, 1.7) | 19.0 (16.5, 21.9) |

Relative Efficacy

| Medication | Number of arms | Estimated odds ratio (95% C. I.) |
|---|----------------|----------------------------------|
| Nicotine Patch (reference group) | 32 | 1.0 |
| Varenicline (2 mg/day) | 5 | 1.6 (1.3, 2.0) |
| 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) |

#7 Key Recommendation

- 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.

Combinations: Medication and Counseling

Effectiveness of and estimated abstinence rates for the combination of counseling and medication versus medication alone (n = 18 studies)

| Treatment | Number of arms | Estimated odds ratio (95% C.I.) | Estimated abstinence rate (95% C.I.) |
|---------------------------|-----------------------|--|---|
| Medication alone | 8 | 1.0 | 21.7 |
| Medication and counseling | 39 | 1.4 (1.2, 1.6) | 27.6 (25.0, 30.3) |

Combinations: Medication and Counseling

Effectiveness of and estimated abstinence rates for the combination of counseling and medication versus counseling alone (n = 9 studies)

| Treatment | Number of arms | Estimated odds ratio (95% C.I.) | Estimated abstinence rate (95% C.I.) |
|---------------------------|-----------------------|--|---|
| Counseling alone | 11 | 1.0 | 14.6 |
| Medication and counseling | 13 | 1.7 (1.3, 2.1) | 22.1 (18.1, 26.8) |

#8 Key Recommendation

- 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.

Pro-active Quitlines

Effectiveness of and estimated abstinence rates for quitline counseling compared to minimal interventions, self-help or no counseling (n = 9 studies)

| Intervention | Number of arms | Estimated odds ratio (95% C.I.) | Estimated abstinence rate (95% C.I.) |
|---------------------------------------|-----------------------|--|---|
| Minimal or no counseling or self-help | 11 | 1.0 | 8.5 |
| Quitline counseling | 11 | 1.6 (1.4, 1.8) | 12.7 (11.3, 14.2) |

Pro-active Quitlines

Effectiveness of and estimated abstinence rates for quitline counseling and medication compared to medication alone (n = 6 studies)

| Intervention | Number of arms | Estimated odds ratio (95% C.I.) | Estimated abstinence rate (95% C.I.) |
|------------------------------------|-----------------------|--|---|
| Medication alone | 6 | 1.0 | 23.2 |
| Medication and quitline counseling | 6 | 1.3 (1.1, 1.6) | 28.1 (24.5, 32.0) |

#9 Key Recommendation

- 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 Key Recommendation

- 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.

Intervention as a Covered Health Benefit

Estimated rates of intervention for individuals who received tobacco use interventions as a covered health insurance benefit (n = 3 studies)

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

Intervention as a Covered Health Benefit

Estimated rates of quit attempts for individuals who received tobacco use interventions as a covered health insurance benefit (n = 3 studies)

| Treatment | Number of arms | Estimated odds ratio (95% C.I.) | Estimated quit attempt rate (95% C.I.) |
|-------------------------------------|-----------------------|--|---|
| Individuals with no covered benefit | 3 | 1.0 | 30.5 |
| Individuals with the benefit | 3 | 1.3 (1.01, 1.5) | 36.2 (32.3, 40.2) |

Intervention as a Covered Health Benefit

Estimated abstinence rates for individuals who received tobacco use interventions as a covered benefit (n = 3 studies)

| Treatment | Number of arms | Estimated odds ratio (95% C.I.) | Estimated abstinence rate (95% C.I.) |
|-------------------------------------|-----------------------|--|---|
| Individuals with no covered benefit | 3 | 1.0 | 6.7 |
| Individuals with the benefit | 3 | 1.6 (1.2, 2.2) | 10.5 (8.1, 13.5) |

Systems Interventions: Clinician Training

Effectiveness and estimated abstinence rates for clinician training (n = 2 studies)

| Intervention | Number of arms | Odds Ratio (95% C.I.) | Estimated abstinence rate (95% C.I.) |
|---------------------|-----------------------|------------------------------|---|
| No intervention | 2 | 1.0 | 6.4 |
| Clinician training | 2 | 2.0 (1.2, 3.4) | 12.0 (7.6, 18.6) |

Systems Interventions: Clinician Training and Chart Reminders

Effectiveness of clinician training combined with charting on asking about smoking status (“Ask”) (n = 3 studies)

| Intervention | Number of arms | Odds Ratio (95% C.I.) | Estimated rate (95% C.I.) |
|-----------------------|-----------------------|------------------------------|----------------------------------|
| No intervention | 3 | 1.0 | 58.8 |
| Training and charting | 3 | 2.1 (1.9, 2.4) | 75.2 (72.7, 77.6) |

Systems Interventions: Clinician Training and Chart Reminders

Effectiveness of training combined with charting on setting a quit date (“Assist”) (n = 2 studies)

| Intervention | Number of arms | Odds Ratio (95% C.I.) | Estimated rate (95% C.I.) |
|-----------------------|-----------------------|------------------------------|----------------------------------|
| No intervention | 2 | 1.0 | 11.4 |
| Training and charting | 2 | 5.5 (4.1, 7.4) | 41.4 (34.4, 48.8) |

Systems Interventions: Clinician Training and Chart Reminders

Effectiveness of training combined with charting on arranging for follow-up (“Arrange”) (n = 2 studies)

| Intervention | Number of arms | Odds Ratio (95% C.I.) | Estimated rate (95% C.I.) |
|-----------------------|-----------------------|------------------------------|----------------------------------|
| No intervention | 2 | 1.0 | 6.7 |
| Training and charting | 2 | 2.7 (1.9, 3.9) | 16.3 (11.8, 22.1) |

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Special Populations

- HIV-positive smokers
- Hospitalized smokers
- Lesbian/gay/bisexual/transgender smokers
- Smokers with low SES/limited formal education
- Smokers with medical comorbidities
- Older smokers
- Smokers with psychiatric disorders including substance use disorders
- Racial and ethnic minority smokers
- Women smokers

Low Socio-Economic Status/Limited Formal Education

Effectiveness of and estimated abstinence rates for counseling interventions with low socio-economic status/limited formal education (n = 5 studies)

| Intervention | Number of arms | Estimated odds ratio (95% C. I.) | Estimated abstinence rate (95% C. I.) |
|-----------------------------|-----------------------|---|--|
| Usual care or no counseling | 6 | 1.0 | 13.2 |
| Counseling | 5 | 1.42 (1.0, 1.9) | 17.7 (13.7, 22.6) |

Psychiatric Disorders Including Substance Use Disorders

Effectiveness of and estimated abstinence rates for treatment with bupropion and nortryptiline for smokers with a history of depression (n = 4 studies)

| Intervention | Number of arms | Estimated odds ratio (95% C. I.) | Estimated abstinence rate (95% C. I.) |
|-------------------------------|-----------------------|---|--|
| Placebo | 5 | 1.0 | 13.2 |
| Bupropion SR or nortryptiline | 8 | 3.4 (1.7, 6.8) | 29.9 (17.5, 46.1) |

Specific Populations

- Children and Adolescent Smokers
- Light Smokers
- Noncigarette Tobacco Users
- Pregnant Smokers

Adolescent Smokers

Effectiveness of and estimated abstinence rates for counseling interventions with adolescent smokers (n = 7 studies)

| Adolescent smokers | Number of arms | Estimated odds ratio (95% C.I.) | Estimated abstinence rate (95% C.I.) |
|---------------------------|-----------------------|--|---|
| Usual care | 7 | 1.0 | 6.7 |
| Counseling | 7 | 1.8 (1.1, 3.0) | 11.6 (7.5, 17.5) |

Pregnant Smokers

Effectiveness of and estimated pre-parturition abstinence rates for psychosocial interventions with pregnant smokers (n = 8 studies)

| Pregnant smokers | Number of arms | Estimated odds ratio (95% C.I.) | Estimated abstinence rate (95% C.I.) |
|--|-----------------------|--|---|
| Usual care | 8 | 1.0 | 7.6 |
| Psychosocial intervention (abstinence pre-parturition) | 9 | 1.8 (1.4, 2.3) | 13.3 (9.0, 19.4) |

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Dissemination Activities

- Presented May 7th, - AMA Headquarters, Chicago
- Commentary in *JAMA*
- Summary of Guideline available on-line in the *American Journal of Preventive Medicine*
- Pocket guide for clinicians
- Consumer guide for low-literacy smokers
- Other tools and publications in development

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To view the entire 2008 Guideline Update go to:

<http://www.ahrq.gov/path/tobacco.htm#Clinic>