

Systematic Review: Smoking Cessation Intervention Strategies for Adults and Adults in Special Populations

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Background: While smoking cessation interventions have been shown to work, questions remain about how to increase their efficacy.

Purpose: To examine strategies for effective tobacco treatment in adults and special populations.

Data Sources: MEDLINE, Cumulative Index to Nursing and Applied Health (CINAHL), Cochrane Library, Cochrane Clinical Trials Register, Psychological Abstracts, and Sociological Abstracts (1 January 1980 to 10 June 2005).

Study Selection: Systematic reviews; randomized, controlled trials; and observational studies.

Data Extraction: Two reviewers independently abstracted data on study design, population, sample size, treatment, outcomes, and quality.

Data Synthesis: Findings from systematic reviews were summarized and compared with findings from original research published beyond date ranges included in the reviews. Strength of evidence was used to assess the body of evidence. Our review included studies evaluating the efficacy of cessation strategies, such as self-help, counseling, single pharmaceutical agents, combined pharmacotherapies, and pharmacotherapies combined with psychological counseling. Research findings consistent with previous reviews show that self-help strategies alone are ineffective, but counseling

and pharmacotherapy used either alone or in combination can improve rates of success with quit attempts. Two studies of self-help materials reported discrepancies across effects. Five studies provided mixed results for counseling interventions. Fourteen studies provided sufficient evidence of the efficacy of single pharmacotherapy, combined pharmacotherapy, and psychological interventions either with or without pharmacotherapy.

Few studies focused on ways to reach or treat special populations. Three studies with hospitalized patients had findings consistent with a previous review showing no strong evidence that clinical diagnosis affected the likelihood of quitting. New evidence was insufficient to address the effectiveness of interventions for persons with coexisting psychiatric conditions and substance abuse problems.

Limitations: Previous systematic reviews variably cover the range of issues we addressed. More recent studies do not fill all gaps, especially those for persons with coexisting disease.

Conclusions: Although self-help strategies alone marginally affect quit rates, individual and combined pharmacotherapies and counseling either alone or in combination can significantly increase cessation. Using effective smoking treatments is strongly encouraged for all populations, especially those with high and heavy rates of smoking, such as psychiatric and substance abuse populations.

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Tobacco use is the leading cause of preventable illness and death in the United States. Once users are dependent on tobacco, quitting is difficult. Nicotine dependence resulting from tobacco use hampers efforts to sustain abstinence from tobacco for a prolonged period or a lifetime (1). Many users make multiple attempts to quit, often without the assistance that could double or even triple their chances of success (1). Proven individual cessation strategies include counseling and behavioral therapy and, except when contraindicated, first-line and second-line medications (1). These strategies may prove especially helpful for individuals motivated to quit smoking in response to pregnancy or hospitalization for a smoking-related condition.

Populations with psychiatric conditions and substance abuse problems have higher rates of smoking and show a lack of responsiveness to smoking cessation treatments (2, 3). More sensitive or specialized strategies and services for smoking cessation may be needed to help patients with

overlapping conditions, such as multiple addictions or psychiatric, cognitive, or medical conditions (2, 3).

As background for a National Institutes of Health conference, our full systematic review (4) synthesized new evidence on individual-based strategies designed to increase the likelihood that adult tobacco users (with and without selected coexisting conditions) will quit. We also compared findings from new studies with those summarized in previous systematic reviews and meta-analyses.

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METHODS

We searched MEDLINE, the Cumulative Index to Nursing and Applied Health (CINAHL), the Cochrane Library, Cochrane Clinical Trials Register, Psychological Abstracts, and Sociological Abstracts from 1 January 1980 through 10 June 2005 using Medical Subject Headings (Appendix Table 1, available at www.annals.org) as search terms or key words when appropriate. We also manually searched reference lists. A technical expert panel helped us to ensure that we included important literature in our search.

We limited our review to human studies conducted in developed countries and published in English (Appendix Table 2, available at www.annals.org, gives specific inclusion and exclusion criteria). We considered studies with samples that consisted of participants who were age 13 years and older, that included both sexes, and that were racially and ethnically diverse. We limited studies to those with 6 months or greater follow-up periods and minimum sample sizes of 30 patients for randomized, controlled trials and 100 patients for other experimental or observational studies. We excluded articles that did not report outcomes related to quit rates; articles that did not provide the minimum information required; and all editorials, letters, and commentaries.

All studies were dually reviewed. We assessed the quality of studies according to how well they met the criteria from the U.S. Preventive Services Task Force (5) and the National Health Service Centre for Reviews and Dissemination (6). We rated the strength of the evidence using the criteria from the Task Force on Community Preventive Services (7). To determine whether the strength of evidence for each study was strong, sufficient, or insufficient, we evaluated the study design, study execution, and the size and consistency of reported effects.

For 4 of the 5 key questions in the evidence report (Appendix Table 3, available at www.annals.org), we relied on several well-conducted systematic reviews. The Table documents the type, quality, treatment format, and outcome for each review. We included original research studies that 1) were published beyond the date range in the systematic reviews, 2) covered topics not covered by the reviews, and 3) provided sufficient detail about their methods and outcomes.

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DATA SYNTHESIS

Literature Reviewed

Of 1288 abstracts, we examined 488 for full article review and retained 102 (Appendix Figure, available at www.annals.org). Of 43 studies relevant to this article, 5

were of good quality (16–20), 23 were fair (21–43), and 15 were poor (not presented here) (44–58).

We report on 28 new studies not included in previous reviews (Appendix Table 4, available at www.annals.org). Twenty-one studies addressed strategies to improve success rates for cessation (16, 17, 21, 22, 24–34, 36, 37, 39, 41–43), including self-help, counseling, pharmaceutical agents, and combinations of pharmaceutical and counseling therapies. Seven studies examined interventions in patients with coexisting conditions and nicotine dependence, including psychiatric conditions and substance abuse problems (18–20, 23, 35, 38, 40), and 5 studies overlapped both categories (24, 30, 31, 33, 39). We reviewed this new body of evidence both independently and within the context of previous reviews.

Alternative Approaches to Smoking Cessation

Self-Help Approaches

Two studies examined a self-help approach to improving cessation rates (26, 33). One study involved patients recently discharged from intensive care units (ICUs) (33); the other included patients undergoing lung cancer screening (26). Patients discharged from intensive care received verbal encouragement to remain nonsmoking at ICU discharge, a self-help ICU rehabilitation manual, and instructions to the immediate family not to smoke near the patient. Patients undergoing lung cancer screening received either a handout listing 10 smoking cessation–related Internet sites or 2 self-help booklets, 1 of which provided information on available pharmacotherapies for nicotine dependence (26).

Patients receiving the ICU rehabilitation package were much less likely to return to smoking after discharge than were the control patients (relative risk, 0.11 [95% CI, 0.02 to 0.64]); the investigators could not determine whether just the smoking cessation advice or the whole package (including an exercise program) was responsible for the high quit rate (33). Seven-day point-prevalence quit rates did not differ significantly between patients in the intervention and control groups undergoing lung cancer screening, although at 1-year follow-up more patients in the intervention group reported an attempt to stop smoking (26). We found insufficient evidence of efficacy for self-help strategies, given the small number of new studies and discrepancies between studies for the same outcome.

Counseling

Five studies evaluated the effects of counseling—2 studies in hospital settings (30, 39), 1 in both primary care clinics and hospitals (24), and 2 in private practices (21, 36). All interventions included nurse counseling, self-help materials, and follow-up contact either in person or by telephone; all were compared with usual care (brief advice to quit smoking, related self-help materials, or both).

Although self-reported abstinence rates were higher in the more comprehensive treatment in 1 study (30), neither

Table. Summary of Review Article Outcomes*

Study, Year (Reference)	Treatment Format	Review Article Outcomes	Studies, n	Type of Review	Quality of Review
Fiore et al., 2000 (1)	Self-help	Self-help was of marginal efficacy. Little evidence supported the view that providing multiple types of self-help, when offered without any person-to-person intervention, significantly enhanced treatment outcomes.	21 RCTs	Meta-analysis	Good
	Counseling and other behavioral therapies	Some support for 3 types of counseling and behavioral therapies: 1) practical counseling (problem-solving skills), 2) social support as part of treatment, and 3) social support outside of treatment.	62 RCTs	Meta-analysis	Good
	Intensity of clinician intervention	Minimal interventions lasting < 3 min increase overall tobacco abstinence rates.	43 RCTs (length of sessions)	Meta-analysis	Good
		Intensive interventions were more effective than less intensive interventions.	35 RCTs (number of contacts) 45 RCTs (number of sessions)		
	Pharmacotherapies	First-line pharmacotherapies, such as bupropion SR or NRTs (e.g., nicotine gum, nicotine inhaler, nicotine patch, and nicotine nasal spray), consistently increase abstinence rates. Second-line pharmacotherapies, including clonidine and nortriptyline, also demonstrated efficacy.	2 RCTs (bupropion SR) 13 RCTs (nicotine gum) 4 RCTs (nicotine inhaler) 3 RCTs (nicotine nasal spray) 27 RCTs (nicotine patch) 5 RCTs (clonidine) 2 RCTs (nortriptyline)	Meta-analysis	Good
Combined pharmacotherapies	Combination of the nicotine patch with self-administered NRT (gum or nasal spray) was more effective than single form of nicotine replacement. Evidence for effectiveness of other pharmaceutical treatments (e.g., antidepressants other than bupropion SR and nortriptyline, anxiolytics, benzodiazepines, β -blockers, silver acetate, and mecamylamine) was not consistent.	3 RCTs (2 studies used nicotine patch with nicotine gum, and 1 study used nicotine patch with nicotine nasal spray)	Meta-analysis	Good	
Task Force on Community Preventive Services, 2005 (8)	Reduce out-of-pocket costs	Reducing out-of-pocket cost for smoking cessation is effective in increasing use of these therapies and number of tobacco users who quit.	5 studies (study designs not reported)	Systematic review without meta-analysis	Good
U.S. Surgeon General, 2000 (9)	Self-help	Evidence was mixed about the efficacy of self-help manuals as an aid to smoking cessation.	31 studies (study designs not reported)	Systematic review with narrative synthesis	Good
	Counseling	Counseling and advice increases smoking cessation rates (which may be further improved) by increasing the frequency and duration of contact.	15 RCTs, 2 meta-analyses	Systematic review with narrative synthesis	Good
	Pharmacotherapies	Consistent evidence shows that pharmacologic treatments for smoking cessation (nicotine replacement therapies and bupropion in particular) can help people quit smoking.	6 meta-analyses (transdermal nicotine) 5 RCTs, 2 meta-analyses (nicotine nasal spray) 3 RCTs, 2 meta-analyses (nicotine inhaler) 2 RCTs, 1 meta-analysis (bupropion), 2 meta-analysis (clonidine), 2 RCTs, 1 meta-analysis (nortriptyline), 2 RCTs, and 2 trials type not specified (other antidepressants and anxiolytics)	Systematic review with narrative synthesis	Good

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Table—Continued

Study, Year (Reference)	Treatment Format	Review Article Outcomes	Studies, n	Type of Review	Quality of Review
el-Guebaly et al., 2002 (10)	Pharmacotherapies	<p>Posttreatment and 12-month quit rates for psychiatric patients appear to be only marginally lower than those for nonpsychiatric patients</p> <p>A majority of reviewed interventions used a combination of medication and educational and cognitive behavioral approaches and are not sufficiently uniform for meta-analysis</p>	24 studies (study designs not reported)	Systematic review with narrative synthesis	Fair
	Cognitive-behavioral therapies plus standard treatment	Integration of cognitive behavioral therapy with standard smoking cessation strategies appears to result in higher quit rates for persons with a history of major depression	7 studies (study designs not reported)	Systematic review with narrative synthesis	Good
Lancaster and Stead, 2005 (11)	Individual counseling	<p>Individual counseling for smoking cessation was more effective than control intervention</p> <p>Meta-analysis did not detect a greater effect of intensive counseling than brief counseling</p>	21 studies (RCTs and non-RCTs)	Systematic review with narrative synthesis	Good
Lancaster and Stead, 2005 (12)	Self-help	Self-help materials to support quit attempts are of limited benefit unless the materials consider each smoker's individual characteristics	17 RCTs	Systematic review with narrative synthesis	Good
	Self-help materials as adjunct to other treatments	Review found no evidence of benefit from adding self-help materials to face-to-face advice or NRT	16 RCTs	Systematic review with narrative synthesis	Good
Prochaska et al., 2004 (2)	Counseling, cognitive behavioral therapy, pharmacotherapies	Intervention effects for smoking cessation were significant at posttreatment and were similar to those in participants in addiction treatment and recovery	18 RCTs	Meta-analysis	Good
	Concurrent treatment	Smoking interventions provided during treatment were associated with 25% increased likelihood for long-term abstinence from alcohol and illicit drugs	11 RCTs	Meta-analysis	Good
	Pharmacotherapies	Subgroup analyses revealed stronger effects among studies that provided NRT and were more recently published (NRT was provided in conjunction with psychosocial interventions)	11 RCTs	Meta-analysis	Good
Lumley et al., 2004 (13)	Health care professional advice, individual and group counseling, peer support, NRT, feedback, provider education	<p>Pregnant women in intervention groups were more likely than those in control groups to quit smoking</p> <p>Interventions reduced low-birth-weight babies and preterm births</p>	48 studies (RCTs and quasi-randomized)	Systematic review with narrative synthesis	Good
	Rewards plus social support	Rewards plus social support resulted in significantly greater smoking reduction than other interventions	2 studies (study design not reported)		

Table—Continued

Study, Year (Reference)	Treatment Format	Review Article Outcomes	Studies, n	Type of Review	Quality of Review
Rigotti et al., 2003 (14)†	In-patient contact	Review found no evidence to assess ≤15-min in-patient interventions >15 min in-patient interventions were not significantly associated with higher quit rates	No studies 3 studies (RCTs and quasi-randomized)	Systematic review with narrative synthesis	Good
	In-patient contact plus short follow-up	In-patient interventions plus follow-up for ≤1 mo did not show a significant benefit	6 studies (RCTs and quasi-randomized)		
	In-patient contact plus long follow-up	In-patient interventions plus follow-up for ≥1 mo was associated with a significantly higher cessation rate compared with controls	9 studies (RCTs and quasi-randomized)		
Melvin and Gaffney, 2004 (15)	Brief counseling, adjuncts to brief counseling, pharmacotherapy, provider education	Smoking status and secondhand smoke exposure should be assessed for all pregnant and postpartum women and parents Review found brief counseling with "5 A's" approach‡ is still the best treatment for light and moderate smokers Pharmacotherapy should be offered to parents who smoke Additional research is recommended on ways to improve disclosure, safety, efficacy of pharmacotherapy, use of biomarker feedback or incentives, partner involvement, and interventions to reduce secondhand smoke	Number of studies included not specified	Systematic review with narrative synthesis	Good

* NRT = nicotine replacement therapy; RCT = randomized, controlled trial; SR = sustained release.

† Miller NH, Smith PM, DeBusk RF, Sobel DS, Taylor CB. Smoking cessation in hospitalized patients. Results of a randomized trial. *Archives of Internal Medicine*. 1997; 157:409-15. (This study is included in both the short- and long-term follow-up treatment categories.)

‡ Ask, Advise, Assess, Assist, Arrange.

hospital-based intervention increased biochemically verified abstinence rates at 12 months after discharge (30, 39). At 6-month follow-up, diabetic patients seen in primary clinics and hospitals who received nurse-managed assistance in quitting were significantly more likely to quit smoking than controls (24). Biochemically validated quit rates were 17.0% for the intervention group compared with 2.3% for the control group ($P = 0.001$).

Three different counseling interventions showed no significant differences in quit rates at 12-month follow-up (21, 36, 39). Two studies reported increased abstinence with counseling treatment (24, 30); only 1 study verified cessation biochemically (24). Although previous reviews showed that counseling was effective, these new studies show mixed results.

Pharmaceutical Monotherapy

Five studies examined the effect of a single pharmaceutical agent on smoking cessation (27, 28, 32, 37, 41): 3 of bupropion (27, 32, 41) and 1 each of nicotine gum (28) and transdermal nicotine and nicotine nasal spray (37). Two studies were based in hospitals (27, 41), and 3 were population-based (28, 32, 37).

Two studies compared 7 weeks of sustained-release bupropion with placebo. In a 6-month study, health care workers motivated to quit smoking received behavioral

counseling and sustained-release bupropion or placebo (27). Continuous smoking abstinence at week 7 was achieved by 43% of patients in the bupropion group and 18% of patients in the placebo group ($P < 0.001$). Side effects, although frequent, were reversible in both groups and generally consistent with those noted in previous studies. In the other study, all participants received 2 months of transdermal nicotine replacement therapy and 3 months of cognitive behavioral counseling and either sustained-release bupropion or placebo (41). The investigators observed a nonsignificant trend for abstinence at 3 months but not at 6 or 12 months among participants randomly assigned to bupropion; biochemical measures of smoking did not significantly differ between groups. Holt and colleagues (32) attempted to determine whether bupropion combined with smoking cessation counseling was effective for the indigenous Maori population of New Zealand. At 3- and 6-month follow-up, rates of abstinence in the bupropion group were significantly higher than rates in the placebo group. A model-based secondary analysis found a risk ratio of 2.44 in favor of bupropion for both time points. Existing recommendations from previous reviews list bupropion as a first-line pharmacotherapy for smoking cessation (1). These new studies showing mixed results offer insufficient evidence to alter this recommendation.

Garvey and colleagues (28) used the Heaviness of Smoking Index to classify smokers planning a cessation attempt as low or high in nicotine dependence and then randomly assigned them to placebo or to 2-mg or 4-mg nicotine gum treatment. Participants also received brief behavioral counseling. At 1 year after cessation, quit rates were 11.2% for low-dependence smokers receiving placebo, 19.5% for those receiving 2-mg gum, and 18.4% for those receiving 4-mg gum ($P = 0.20$ for linear trend). For high-dependence smokers, quit rates at 1 year were 6.1%, 15.7%, and 20.7% for the placebo, 2-mg gum, and 4-mg gum groups, respectively ($P = 0.002$ for linear trend). The interaction of nicotine gum dose and dependence group was not significant. Although the nicotine doses did not differ significantly in effectiveness, both doses were significantly more effective than placebo gum (2 mg, $P = 0.008$; 4 mg, $P = 0.001$) (28).

Lerman and associates (37) conducted an 8-week clinical trial to evaluate the comparative efficacy of transdermal nicotine and nicotine nasal spray, with all participants receiving behavioral group counseling. Abstinence rates for the transdermal nicotine and nicotine nasal spray groups were not significantly different at 6-month follow-up. Interactions in abstinence rates for subgroups of smokers were statistically significant ($P < 0.05$). Smokers who had low-to-moderate dependence levels, were not obese, and were white achieved higher abstinence rates with transdermal nicotine, whereas smokers who were highly dependent, obese, or members of minority groups achieved higher abstinence rates with nasal spray.

Neither the study by Garvey or Lerman and their colleagues found significant differences when different dosages or vehicles of nicotine delivery were tested, but pharmacotherapies were significantly more effective than placebo in each study. These findings, although insufficient in number, are consistent with evidence from previous reviews recommending nicotine replacement therapy for smoking cessation (1).

Combined Pharmacotherapies

Three studies examined the effect of combined pharmacotherapies on smoking cessation (16, 22, 34). Bohadana and colleagues (22) measured the effect of adding a nicotine patch to a nicotine inhaler. They randomly assigned participants to intervention (nicotine inhaler and nicotine patch) or control (nicotine inhaler and placebo patch) groups. Abstinence rates at 6 weeks, biochemically measured, were significantly higher for the intervention group than for the control group (60.5% vs. 47.5%; $P = 0.09$), but the groups did not differ significantly in continuous abstinence at 6- or 12-month follow-up. Jorenby and colleagues (34) randomly assigned participants to 1 of 3 groups: bupropion only, nicotine patch only, or both bupropion and nicotine patch. Participants in the control group received placebo pills and a placebo patch. The biochemically confirmed abstinence rates at 12 months were

15.6% in the placebo group, 16.4% in the nicotine patch group, 30.3% in the bupropion-only group ($P < 0.001$), and 35.5% in the group given both ($P < 0.001$) (34). Abstinence rates were higher with combination therapy than with bupropion alone, but the difference was not statistically significant.

In a double-blind trial, Killen and colleagues (16) examined the efficacy of a smoking cessation treatment that combined nicotine replacement therapy via a transdermal system with the antidepressant paroxetine. Smokers were randomly assigned to 1 of 3 groups: transdermal system and placebo, transdermal system and 20 mg of paroxetine, and transdermal system and 40 mg of paroxetine. Transdermal treatment was provided for 8 weeks; paroxetine or placebo was provided for 9 weeks. Abstinence rates for all participants at follow-up were not significantly different, but a subgroup analysis of adherent patients resulted in statistically significant differences between paroxetine groups and the control group at week 4 ($P < 0.001$).

Of these 3 studies on combined pharmaceutical therapy, 2 found a significant increase in cessation at 12 months compared with 1 pharmaceutical agent alone (22, 34). The third showed no overall benefit from the paroxetine-patch combination but did demonstrate significant differences between paroxetine groups and placebo in the short term (16). Given the small number of new studies on combined pharmaceutical therapy and the fact that only 2 studies demonstrated significant results, evidence is insufficient to make a recommendation about combined pharmaceutical therapy.

Pharmacotherapy and Psychological Interventions

Six studies examined the effect on cessation rates of interventions that consisted of both pharmacotherapy and psychological counseling (17, 25, 29, 31, 42, 43). Four studies were population-based (17, 25, 29, 31); 2 studies included members of a large health care system (42, 43).

One population-based trial examined the effectiveness of the combination of fluoxetine and cognitive behavioral treatment (31). One and 3 months after the quit date, fluoxetine increased the likelihood of abstinence compared with placebo among smokers with minor depression (odds ratio, 1.39 [CI, 1.02 to 1.89]) but not among those with little or no depression; fluoxetine selectively benefited medication-adherent smokers with mild depression. Smokers who were more dependent on nicotine did not derive special benefit from fluoxetine (31).

Using a chronic disease model of smoking, Hall and coworkers (29) measured the effects of long-term antidepressant and psychological treatment. All participants were randomly assigned to 1 of 4 treatment groups (nortriptyline vs. placebo with brief versus extended treatment) and received 8 weeks of a transdermal nicotine patch, 5 group counseling sessions, and active drug treatment or placebo administration. Participants in brief treatment completed the study at this point. Participants in extended

treatment continued taking nortriptyline or placebo until week 52 and received 9 additional monthly counseling sessions. Participants were assessed at baseline and at weeks 12, 24, 36, and 52. At week 52, point-prevalence abstinence rates were 30% for placebo brief treatment, 42% for placebo extended treatment, 18% for active brief treatment, and 50% for active extended treatment (29). Differences were significant for the active extended group at 24, 36, and 52 weeks ($P < 0.009$).

Two studies examined the efficacy of nicotine replacement therapy with additional telephone counseling for smoking cessation (17, 25). Carpenter and colleagues (25) compared nicotine replacement therapy with motivational advice or no treatment in a telephone-only intervention among smokers not currently interested in quitting. They randomly assigned these smokers to receive one of the following: 1) telephone-based reduction counseling and nicotine replacement therapy plus brief advice, 2) telephone-based motivational advice plus brief advice, or 3) no treatment. Over 6 months, more smokers in the reduction-counseling group (43%) and the motivational group (51%) made a 24-hour quit attempt than smokers in the no-treatment group (16%; $P \leq 0.01$) (25). The 2 treatment groups had the same number of quit attempts. Similarly, 18%, 23%, and 4% of participants in each group were abstinent at 6 months ($P \leq 0.01$).

Macleod and associates (17) investigated the effectiveness of telephone counseling as an adjunct to transdermal nicotine replacement therapy patch in smoking cessation. Smokers were randomly assigned either to replacement therapy alone or replacement therapy plus telephone counseling. Continuous abstinence rates over 28 days among participants receiving telephone counseling were significantly greater than among those not receiving telephone counseling at both 3 and 6 months (31.6% vs. 25.1% [$P = 0.04$] and 30.1% vs. 22.4% [$P = 0.01$], respectively). Similarly, 90-day continuous abstinence rates at 6 months were significantly greater for participants receiving counseling (26.7% vs. 18.6%; $P = 0.004$) (17).

Two studies from the same research team examined smoking end points after treatment with sustained-release bupropion (42, 43). In both studies, the researchers randomly assigned smokers to receive 1 of 4 combinations of bupropion (150 mg or 300 mg) and behavioral counseling (tailored mailings or proactive telephone counseling); they assessed point-prevalent smoking status at 3 and 12 months. One study focused on predictors of outcome (42); the other study focused on group differences (43). Findings related to smoking abstinence were the same in both studies. Bupropion dose was not associated with rates of smoking at 12 months. However, the odds ratio for 12-month smoking was higher for those who received the tailored mail program than for those in the telephone-counseling program (odds ratio, 1.24 [CI, 1.06 to 1.47]).

Five of these studies demonstrated significant improvements in abstinence among groups receiving combi-

nation pharmacotherapy and psychological interventions (17, 25, 29, 42, 43). These studies provide sufficient evidence that combined pharmacotherapy and psychological interventions are effective, and 1 study (17) suggested that combined pharmacotherapy and psychological interventions are more effective than pharmacotherapy alone.

Cessation Strategies for Adults in Special Populations

Windows of opportunity open when smokers' awareness of harms associated with tobacco use and their motivation to quit smoking are high. We examined strategies designed to take advantage of these opportunities for individuals who were hospitalized for smoking-related conditions and for pregnant women. We also searched for studies among individuals with comorbid conditions and risk behaviors.

Hospitalized Patients by Diagnosis

Three studies focused on improving cessation rates among hospitalized patients with smoking-related disorders (18, 24, 39). One study involved smoking cessation and relapse prevention among women admitted to the hospital with cardiovascular or peripheral vascular disease (39); another included diabetic smokers (24); and the third involved patients admitted for myocardial infarction, unstable angina, or care after coronary bypass surgery performed at other hospitals (18). All interventions included nurse counseling, self-help materials, and follow-up contact and were compared with usual care (brief advice to quit smoking or related self-help materials). The 3 hospital-based interventions failed to increase biochemically measured smoking abstinence rates at 12 months after discharge. One reported significantly different (biochemically validated) abstinence rates at 6 months (24), and another showed significant differences in self-reported abstinence (not biochemically confirmed) at 12 months (18). These studies provide evidence that intensive counseling when a person is hospitalized for a smoking-related clinical diagnosis does not affect the likelihood of quitting.

Hospitalized Patients by Intensity of Intervention

Four studies examined the effect of varying the intensity of smoking cessation intervention among hospitalized patients (19, 30, 33, 40). One study of patients recently discharged from ICUs reported that those receiving the intervention had a relative risk reduction for smoking of 89% (CI, 98% to 36%), but the increase in abstinence could not be attributed directly to the intervention (33). Another study examining the effects of 3 smoking cessation counseling interventions for hospital patients indicated that 12-month abstinence rates were not significantly different when biochemical measures of smoking were used (30).

Reid and colleagues (19) evaluated the efficacy of a stepped-care approach to smoking cessation treatment among smokers with coronary artery disease. Stepped care

refers to the practice of initiating treatment with a low-intensity intervention and then exposing patients in whom treatment fails to successively more intense interventions. Smokers hospitalized with coronary artery disease were randomly assigned to either an intensive stepped-care treatment (counseling and nicotine patch therapy) or no additional treatment. In another study of this type, Ratner and coworkers (40) designed a counseling and nicotine replacement therapy intervention to help smokers abstain from smoking before surgery, maintain abstinence after surgery, and achieve long-term cessation.

Neither study showed significant differences in 12-month abstinence, but significant differences occurred in the short term. In the stepped-care intervention study, treatment increased smoking cessation rates from 42% to 53% during a 3-month follow-up period ($P = 0.05$) (19). In the study of counseling plus nicotine replacement therapy, participants in the treatment group (73.0%) were more likely to abstain from smoking before surgery than were controls (53.0%) ($P = 0.003$), and they were also more likely to be abstinent 6 months after surgery (31.2% vs. 20.2%) after adjustment for covariates (40). Because only 2 of the 4 studies that varied the intensity of the intervention for hospitalized patients demonstrated positive short-term effects (19, 40), evidence is insufficient to recommend the most effective level of intensity for smoking cessation intervention targeting hospitalized smokers.

Pregnant Women

A study randomly assigned pregnant women and their partners to usual care, a woman-only intervention, or a partner-assisted intervention (38). Follow-up occurred at 28 weeks of pregnancy and 2, 6, and 12 months after delivery. Women in the usual care group received provider advice to quit and a self-help guide. The women-only group received usual care components plus a late-pregnancy relapse prevention kit and 6 counseling telephone calls. Women in the partner-assisted group received the women-only intervention, and their partners received telephone counseling and a guide emphasizing skills to help the women quit smoking. Intention-to-treat analyses showed no significant between-group differences in women's reports of abstinence at any follow-up point (38). In late pregnancy, more partners were abstinent in the partner-assisted condition (15%) than in the usual care condition (5%) ($P = 0.02$). This study provides insufficient evidence to overturn 3 previous reviews concluding that pregnant women who received an active counseling intervention experienced significant reduction in continued smoking in late pregnancy (1, 13, 15).

Psychiatric and Substance Abuse Conditions

People with psychiatric conditions are twice as likely to smoke as the general population and to smoke more heavily than other smokers (10). Alcohol and drug use trigger or exacerbate tobacco use (2); smoking rates for

alcohol and drug users are also greater than those for the general population (1). Given the importance of reaching these populations, we reviewed smoking cessation interventions for populations with coexisting psychiatric conditions and substance abuse problems.

Four studies evaluated smoking cessation efforts in populations with psychiatric conditions and substance abuse problems (20, 23, 31, 35). Two randomized, controlled trials addressed smoking cessation interventions for populations with coexisting psychiatric conditions (23, 31). Hitsman and colleagues (31) hypothesized that smokers with greater depressive symptoms would be more likely to achieve tobacco abstinence when receiving fluoxetine combined with cognitive behavioral therapy than when receiving a placebo and cognitive behavioral therapy. The intention-to-treat analysis failed to yield any stable predictive models for smoking status at 1 week and 1, 3, and 6 months after the quit date. A secondary analysis using treatment-adherent patients only ($n = 169$) found an interaction between fluoxetine treatment and the depression score at 1- and 3-month follow-up. Participants treated with fluoxetine had a positive association between degree of depression and likelihood of abstinence (odds ratio, 1.35 [CI, 1.00 to 1.81]); for controls, the opposite was true, and increasing depression scores were associated with decreasing likelihood of abstinence.

Brown and colleagues (23) compared the efficacy of a standard cognitive behavioral therapy for smoking cessation with one combining standard and cognitive behavioral therapy specifically for depression. The study recruited regular smokers with a history of major depressive disorder determined by structured interviews using the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), ed. 3, revised. All study participants received 8 group counseling sessions over 6 weeks and standard cognitive behavioral therapy. Tailored cognitive behavioral therapy, "The Coping with Depression Course," was provided to the treatment group and served as the intervention (23). Biochemical measures of smoking at 1, 6, and 12 months from the quit date showed the same 7-day point-prevalence abstinence rate in the 2 treatment groups. In a secondary analysis, significant interactions occurred between treatment and recurrent depression and between treatment and heavy smoking (23). Smokers with recurrent major depressive disorder and heavy smokers who received the tailored depression treatment were significantly more likely to be abstinent than those receiving standard cognitive behavioral therapy (odds ratios, 2.3 [CI, 1.05 to 5.03] and 2.62 [CI, 1.18 to 5.83]).

Counseling combined with pharmacotherapy significantly increased abstinence rates for adherent patients and tailored smoking cessation counseling significantly increased abstinence rates among some depressed smokers. In an area in which evidence has been lacking, these studies provide some evidence, albeit still insufficient to make recommendations.

Two studies examined smoking cessation treatments for adult alcohol and substance abusers enrolled in substance use disorder programs (20, 35). Using a prospective cohort study design, Joseph (35) evaluated the feasibility of a smoke-free policy and a nicotine treatment program implemented in a drug and alcohol treatment hospital. Patients admitted to the treatment facility were consecutively enrolled in the study. Before implementation of the smoke-free policy, patients were not provided with specific information about smoking or cessation. After its implementation, patients were required on admission to acknowledge the smoke-free policy, sign a contract agreeing to abstain from nicotine during their treatment, and agree to attend a smoking cessation program designed for substance abusers. The program included didactic lectures on the pharmacology of nicotine, films, and a discussion group. Prepolicy patients completed posthospitalization telephone interviews at 16.2 months, and postpolicy patients completed interviews at 10.7 months. Along with smoking behaviors, the telephone interview assessed the long-term outcome of the patient's chemical dependence. The proportion of patients who abstained from smoking for more than 1 week was significantly higher in the postpolicy group than in the prepolicy group (41% vs. 9%; $P < 0.001$). At the 1-year follow-up interview, 8% of the postpolicy patients and 3% of the prepolicy patients had quit smoking ($P < 0.05$), but approximately 55% of the sample was lost to follow-up. The groups had the same rates of non-nicotine substance use at the 1-year follow-up.

Joseph and colleagues (20) compared the effects of concurrent treatment for nicotine dependence and intensive treatment for alcohol dependence versus a group that received only alcohol dependence treatment for 6 months and then received concurrent treatments for 6 months. Eligible participants included adults who met the criteria for alcohol dependence or abuse according to the DSM, fourth edition, and who smoked more than 5 cigarettes each day for a year. Participants with no interest in quitting were excluded from the study. The nicotine dependence intervention included a 1-hour individual counseling session and up to 3 follow-up sessions. Participants who were in the action stage of change received a free prescription for nicotine replacement therapy unless they declined or had a medical contraindication. A combination of patches and nicotine gum was offered to participants who smoked more than 20 cigarettes per day. Biochemically validated self-reports were collected for both smoking and alcohol outcomes. Seven-day point-prevalence rates of abstinence were assessed at 3, 6, 12, and 18 months; 30-day and 6-month alcohol abstinence was measured at 6, 12, and 18 months.

Using intention-to-treat analysis, the investigators reported 7-day point-prevalence rates of smoking abstinence at 3 months as 15.5% in the concurrent treatment group and 4.4% in the delayed (untreated) group ($P < 0.001$). At 6 months, smoking abstinence rates were 10.5% in the

concurrent treatment group and 5.2% in the delayed (untreated) group ($P = 0.02$). At 9 and 12 months (when both the delayed group and the concurrent group received smoking cessation treatment), the treatment groups did not differ significantly. The rate of prolonged smoking abstinence at 18 months for both groups was similar: 8.8% and 8.9%. Six-month alcohol abstinence at 6, 12, and 18 months was lower in the concurrent treatment group (41%, 33%, and 41%, respectively) than in the delayed treatment group (56%, 42%, and 48%; $P = 0.004$, $P = 0.11$, and $P = 0.01$, respectively) (20).

Interventions using some form of counseling with pharmacotherapy produced significant increases in smoking abstinence rates. However, alcohol abstinence was negatively affected in the concurrent treatment study (20). Although the 2 studies are consistent with previous recommendations stating that people with chemical and nicotine dependence should receive counseling and pharmacotherapy to assist with smoking cessation (1, 2), the body of evidence in our review is insufficient to point to further recommendations for this population.

DISCUSSION

Smoking Cessation Interventions for Adults

We reviewed studies evaluating the efficacy of cessation strategies that previous reviews had not covered. We assessed the body of evidence based on the Task Force on Community Preventive Services model of strength of evidence (7) and evaluated the body of evidence in the context of previous review findings. When our review of new studies resulted in insufficient evidence, recommendations from previous reviews would stand. Sufficient or strong evidence from new studies showing findings inconsistent with previous reviews could overturn existing recommendations. Here, we recap whether the evidence we assembled would change recommendations in previous authoritative publications and guidelines.

First, our findings are consistent with recent reviews (1, 12) showing that self-help has little effect when offered without any person-to-person intervention.

Second, previous reviews indicated that brief individual cessation counseling is efficacious (1, 11), but whether more intense counseling yields a greater effect than less intensive interventions remained unclear (11, 36). Moreover, our review of counseling yielded mixed results. Two studies reported increased abstinence with counseling treatment; 3 showed no effect. Thus, the new evidence is insufficient to overturn previous recommendations to do brief individual counseling.

Third, our review of pharmaceutical approaches is consistent with earlier findings. Nicotine gum is an important aid in smoking cessation, more than doubling the odds of successful quitting. In addition, transdermal nicotine (patches) and nicotine nasal spray are also associated with significant effects on abstinence. Previous meta-analyses suggested that first-line pharmacotherapies, such as

bupropion, or nicotine replacement therapies consistently increased abstinence rates (1). In our review, results were mixed for bupropion because 2 studies showed a significant benefit of bupropion compared with placebo but a third study showed that bupropion was associated with a non-significant trend toward abstinence in the short term but not for longer periods. These mixed findings for bupropion are insufficient to warrant a change in the conclusion of previous reviews that bupropion is a first-line pharmacotherapy for smoking cessation (1, 9).

Fourth, previous reviews recommend combining pharmacotherapies for smoking cessation but did not report consistent evidence about the effectiveness of other pharmaceutical treatments (for example, antidepressants) (1). Three newer studies assessed the efficacy of different combined therapies. Consistent with a previous review (1), 1 study indicated that a nicotine patch plus a self-administered form of nicotine replacement therapy was more effective than a single form of replacement therapy (22). Another reported significant long-term benefit of bupropion alone and in combination with the nicotine patch (34). A third showed no overall benefit of a patch–paroxetine combination but did demonstrate significant differences between paroxetine groups and placebo in the short term (16). Overall, our review of combined pharmacotherapies suggests a benefit for combined pharmacotherapies for smoking cessation.

Fifth, earlier reviews indicated that pharmacotherapies alone or in combination with counseling or cognitive behavioral treatment increase abstinence rates (1, 10). Of 6 additional studies (17, 25, 29, 31, 42, 43), 5 provide sufficient evidence that combined pharmacotherapy and psychological intervention are effective and add to findings from previous reviews that pharmacotherapy either alone or in combination with counseling is effective. A seventh study dealt with a population not represented in earlier reviews but indicated that bupropion combined with smoking cessation counseling was effective in indigenous Maori in New Zealand (32).

Smoking Cessation Interventions for Adults in Special Populations

First, our review of 3 studies involving interventions for hospitalized patients (18, 24, 39) generally agreed with an earlier review of 17 studies showing no strong evidence that intensive counseling significantly affected the likelihood of quitting among hospitalized patients. (14).

Second, 3 previous reviews reported that pregnant women in intervention groups were more likely than those in control groups to quit (1, 13, 15). The 1 newer investigation (counseling to prevent postpartum relapse, a partner-assisted approach) demonstrated no significant improvement in abstinence among women who recently gave birth (38). This study is not sufficient to overturn past recommendations advocating brief advice from a health care professional, individual and group counseling, and

peer support to increase abstinence rates among pregnant women.

Third, our review of the effect of smoking cessation interventions for persons with psychiatric conditions supports previous reviews (1, 10). Two studies confirm existing recommendations that patients with psychiatric conditions should receive smoking cessation treatments recommended for the general population (for example, pharmacotherapy for mildly depressed patients and counseling or cognitive behavioral therapy) (23, 31).

Fourth, previous reviews recommended that people with chemical and nicotine dependence should receive counseling and pharmacotherapy to assist with smoking cessation (1, 2). Two newer studies reported that pharmacotherapy and psychological counseling significantly influenced abstinence rates (20, 35), although alcohol abstinence was negatively affected in a treatment group receiving concurrent therapy compared with a group receiving delayed therapy (20).

Fifth, past reviews showed that pharmacotherapy and psychological counseling interventions were effective in people with chemical and nicotine dependence (2). The results of several newer studies on the impact of smoking cessation treatment on nonnicotine substance use were inconsistent (2, 20, 35); 2 studies reported significant short-term effects for smoking cessation, but only 1 study reported long-term (that is, 12-month) abstinence rates.

In summary, evidence from new research covered in our review was mostly consistent with previous systematic reviews. New studies did not resolve existing inconsistencies about the effectiveness of increasing the intensity of counseling or combined antidepressant pharmacotherapies in patients in whom less intense treatment failed. In short, the information from newer work does not lead to new or different conclusions compared with previous reviews.

Research Gaps in Smoking Cessation Literature

Very few studies examined the effectiveness of multiple intervention formats, combination pharmacotherapy, or adjuncts other than pharmacotherapy to individual counseling. Similarly, few studies examined differences in either withdrawal symptoms or side effects associated with continuation or success of pharmacotherapy; larger, prospective trials are probably needed to increase the evidence base for long-term persistence of effect. Finally, few studies focused on ways to treat special populations such as young adults, minorities, and populations with coexisting conditions, especially psychiatric disorders and substance abuse problems.

Comprehensive research on concurrent treatment for smoking cessation and chemical dependence is warranted in light of conflicting results about adverse effects in persons using alcohol or other drugs. More research explaining interaction effects among depression and smoking cessation interventions is needed for people with mild and clinical depression.

Several studies allude to negative perceptions and attitudes of treatment center staff as barriers to treating nicotine addiction simultaneously with psychiatric conditions, especially substance abuse problems. Research exploring the legitimacy of these statements should be pursued.

Limitations of the Literature

Limitations specific to studies in our review include inadequate description of sampling techniques, high refusal and attrition rates, self-selection of intervention, high rates of nonadherence, lack of adverse events reporting, and findings that are not widely applicable. In short, problems with studies varied considerably, but we underscore problems with study design (including selection of participants), lack of reporting of basic data (baseline; group comparisons), and attrition that future investigators and funding agencies must address.

Implications for Health Care Providers

Tobacco treatment issues differ between smokers in general and smokers with important coexisting conditions. For the broader group, we see 3 main conclusions. First, clinicians can effectively treat tobacco use and dependence in the general population using counseling and first-line pharmacotherapies, especially in combination; self-help approaches alone are unlikely to suffice. Thus, all patients should be screened for tobacco use and offered effective treatment. Inconsistent findings from previous reviews and at least 1 study in this review call into question whether more intensive counseling increases quit rates compared with brief counseling.

Clinicians caring for smokers who have various other disorders, particularly psychiatric diagnoses or conditions involving substance abuse and addiction, face more challenging problems. This review, like previous reports, offers less clear guidance for these patient populations and does not add materially to the body of evidence for such patients. We emphasize that the new work we reviewed supports earlier findings that smoking cessation treatments recommended for the general population, such as counseling and pharmacotherapy, are appropriate interventions for these special populations.

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Appendix Table 1. Medical Subject Headings and Text Words

Medical Subject Headings	
Tobacco use cessation	Comorbidity
Smoking	Depression
Smoking cessation	Depressive disorder
Smoking/prevention and control	Bipolar disorder
Primary prevention	Attention deficit disorder with hyperactivity
Community health aides	Stress disorders, post-traumatic
Community health centers	Diabetes mellitus
Community health nursing	Hypertension
Community health planning	Heart diseases
Community health services	Asthma
Community medicine	Obesity
Community mental health centers	Risk factors
Community mental health services	Risk-taking
Community networks	Choice behavior
Health services needs and demand	Advertising
Health plan implementation	Marketing
Consumer participation	Social marketing
Consumer satisfaction	Patient education
Randomized controlled trials	Diffusion of innovation
Double-blind method	
Single-blind method	
Random allocation	
Text word search terms	
Tobacco	Community
Smoking	Intervention
Cessation	Plan
Quit	Program
	Trial

Appendix Table 2. Smoking Cessation Strategies: Inclusion and Exclusion Criteria for New Studies*

Category	Criteria
Study sample	Humans, all races, ethnicities, and cultural groups KQ 1: Adolescents (age 13–18 y), young adults (age 18–24 y), and diverse populations KQ 2: Adolescents, young adults, adults (age ≥18 y), and diverse populations KQ 3: Adults and diverse populations KQ 4: Adolescents, young adults, and adults KQ 5: Adolescents, young adults, and adults with comorbid conditions and risk behaviors
Study outcomes	KQ 1: Reduced initiation of tobacco use KQ 2: Increased quit rates; greater numbers of smoking cessation participants (i.e., increased participation) KQ 3: Increased quit rates; change in provider behaviors concerning smoking cessation KQ 4: Increased use; increased substitution of smokeless tobacco for smoking; harm reduction KQ 5: Reduced initiation of tobacco use; increased quit rates
Study geography	Developed countries: United States, Canada, United Kingdom, Western Europe, Australia, and New Zealand
Time period	KQ 1: Studies that addressed prevention of adolescent and youth tobacco use: 1 January 2000 to 10 June 2005 Studies that addressed product restrictions in the tobacco industry aimed at countering youth tobacco use: 1 January 1980 to 10 June 2005 KQ 2 and KQ 3: 1 January 1999 to 10 June 2005 KQ 4 and KQ 5: 1 January 1980 to 10 June 2005
Publication languages	English only
Admissible evidence (study design and other criteria)	Original research studies that provide sufficient detail on methods and results to enable use and adjustment of the data and results; relevant outcomes must be able to be abstracted from data presented in the papers Eligible study designs include RCTs Nonrandomized controlled trials Observational studies: prospective and retrospective cohort studies, case–control studies, and cross-sectional studies Single case reports or small case series are excluded Sample sizes must be appropriate for the study question addressed in the paper RCTs: ≥30 participants Observational studies and non-RCTs: ≥100 participants

* KQ = key question; RCT = randomized, controlled trial.

Appendix Table 3. Key Questions for the Full Evidence Report Prepared for the Agency for Healthcare Research and Quality*

- KQ 1. What are the effective population- and community-based interventions to prevent tobacco use in diverse populations of adolescents and young adults?
- KQ 2. What are effective strategies for increasing consumer demand among diverse populations for and use of proven individually oriented cessation treatments?
- KQ 3. What are effective strategies for increasing implementation of proven population-level tobacco use cessation strategies, particularly by health care systems and communities?
- KQ 4. What effect does smokeless tobacco product marketing and use have on population harm from tobacco use?
- KQ 5. What is the effectiveness of prevention and of cessation interventions in populations with co-occurring morbidities and risk behaviors?

* KQ = key question.

Appendix Table 4. Smoking Cessation Intervention Strategies To Improve Success Rates for Quit Attempts*

Study, Year, Setting (Reference)	Design, Exposure, and Follow-up	Intervention	Participants, n	Results	Quality Rating
Studies in adults					
Aveyard et al., 2003 (21) United Kingdom Practice/provider settings	RCT 9 mo 12 mo after baseline	G1: Pro-Change self-help system with workbook and 3 questionnaires to generate tailored feedback G2: G1 plus 3 telephone calls G3: G1 plus 3 nurse visits C1: 2 standard self-help quit guides and 2 tip cards	2471 adults	No statistically significant difference in quit rates between intervention and control groups (G1, 11%; G2, 12%; G3, 10%; C1, 10%) in biochemically confirmed abstinence for 6-mo sustained abstinence and 12-mo point prevalence	Fair
Bohadana et al., 2000 (22) France, Western Europe Practice/provider settings	RCT 26 wk 6 wk and 3, 6, and 12 mo	G1: Nicotine inhaler and nicotine patch C1: Nicotine inhaler and placebo patch	400 adults	Abstinence was greater at 3 mo for intervention group than control group ($P = 0.02$) No significant difference between groups at 6- and 12-month follow-up	Fair
Canga et al., 2000 (24)† Spain, Western Europe; Practice/provider settings Hospital	RCT with systematic randomization 6 mo 6 mo	G1: Interview with nurse; self-help materials; 3 mo of transdermal NRT if eligible; 5 follow-up contacts C1: Usual care for diabetic smokers established in the Navarre diabetes care program	280 young adults, adults	Intervention group was significantly more likely than control group to quit at 6-mo follow-up (validated): ($P \leq 0.001$)	Fair
Carpenter et al., 2004 (25) United States Population-based	RCT 24 wk 3, 6, 12, and 24 wk	G1: Telephone-based reduction counseling and NRT and brief advice to quit G2: Motivational advice (5Rs)† and brief advice C1: No treatment	616 adults	At 6 mo, those receiving either intervention had greater percentages of "24-h quit attempts" (G1, 43%; G2, 51%) than those receiving no treatment (C1, 16%) ($P < 0.01$)	Fair
Clark et al., 2004 (26) United States Hospital Practice/provider settings	RCT Given materials at time of chest CT 1 and 12 mo	G1: Internet cessation resources handout with Web site addresses C1: Standard self-help material—NCI handout, ACS booklet	171 adults, age >50 y	No statistically significant differences in smoking status found at 1-mo or 1-y follow-up	Fair
Dalsgareth et al., 2004 (27) Denmark Hospital	RCT 7 wk 26 wk after baseline	G1: 2 motivating telephone calls, 5 clinic visits, and bupropion SR C1: 2 motivating telephone calls, 5 clinic visits, and placebo	336 adult hospital employees	Continuous abstinence at 26 wk: G1, 18%; C1, 7% ($P = 0.008$)	Fair
Garvey et al., 2000 (28) United States Population-based	RCT 2 mo 1, 7, 14, and 30 d and 2, 3, 6, 9, and 12 mo after cessation	All participants received self-help booklet and brief behavioral counseling (5–10 min per visit, for 1 y) G1: Low dependence, 2-mg gum G2: Low dependence, 4-mg gum G3: High dependence, 2-mg gum G4: High dependence, 4-mg gum	608 adults	Quit rates at 1-y follow-up: Low-dependence smokers: placebo (11.2%); 2 mg (19.5%); 4 mg (18.4%) ($P = 0.20$ for linear trend) High-dependence smokers: placebo (6.1%); 2 mg (15.7%); 4 mg (20.7%); ($P = 0.002$ for linear trend)	Fair
Hall et al., 2004 (29) United States Population-based	RCT Brief: 12 wk Extended: 52 wk 12, 24, 36, 52 wk	G1: Brief nortriptyline: nortriptyline for 12 wk; 5 counseling sessions and NRT patch at week 5 C1: Brief placebo: placebo for 12 wk; 5 counseling sessions and NRT at week 5 G2: Extended nortriptyline: G1 plus extended pharmacotherapy and counseling (1 session per month) for 52 wk C2: Extended placebo: G2 but with placebo used instead of nortriptyline	160 adults	Nortriptyline was more effective than placebo at 12 wk (OR, 0.69 [95% CI, 0.49–0.92]; $P = 0.02$) and 52 wk (OR, 0.47 [CI, 0.30–0.75]; $P = 0.001$); however, 52 wk of nortriptyline did not differ significantly from placebo at that same time frame	Fair
Hennrikus et al., 2005 (30)† United States Hospital	RCT 6 mo 7–18 d and 12 mo after discharge	G1: 2 smoking cessation manuals, community resources directory, medical record label to care providers, postdischarge letter G2: G1 plus extended bedside counseling session and 3–6 telephone calls for 6 mo after discharge C1: 2 cessation manuals and community resources directory	2095 adults	Cotinine-corrected intention-to-treat analysis found percentage of abstinence at 12-mo follow-up ($P > 0.05$) Self-reported abstinence rates were significantly higher for G2 ($P < 0.05$)	Fair
Hitsman et al., 1999 (31)† United States Population-based	RCT 10 wk 1 wk and 1, 3, and 6 mo after quit date	G1: Individual CBT; fluoxetine, 30 mg, for 10 wk; fluoxetine adherence level set at <150 ng/mL G2: Same as G1, except 60-g fluoxetine dose and fluoxetine adherence level set at 300 ng/mL C1: Individual CBT plus placebo	253 adults	No significant results found at 1-, 3-, and 6-mo follow-up Individual differences that predict cessation when fluoxetine is combined with CBT include higher levels of weight concern, degree of depression, and levels of nicotine dependence	Fair
Holt et al., 2005 (32)† New Zealand; Community-based Population-based	RCT 2 mo 3 and 7 wk and 3, 6, 9, and 12 mo after target quit date	G1: Bupropion and counseling C1: Placebo and counseling	134 adolescents, young adults, adults	Intervention group significantly more likely than control group to be continuously abstinent at 3 mo (risk ratio, 2.54 [CI, 1.30–5.00])	Fair
Jones et al., 2001 (33)† United Kingdom Hospital	RCT 6 mo 8 wk, 6 mo after ICU discharge	G1: Verbal encouragement to patients to remain nonsmokers and for immediate family not to smoke in the same room as the patient, plus self-help manual C1: G1 without the manual	61 adults	Of the smokers pre-ICU admission, fewer intervention patients resumed smoking compared with controls at 6-mo follow-up Antismoking advice in rehabilitation package was associated with risk ratio of 0.11 (CI, 0.02–0.64) and reduction in smoking of 89% (CI, 98%–36%)	Fair
Jorenby et al., 1999 (34) United States Community-based	RCT 9 wk 10 wk and 3, 6, and 12 mo after start of study	G1: bupropion and nicotine patch G2: bupropion and placebo patch G3: placebo tablets and nicotine patch C1: placebo tablets and placebo patch	893 adults	Those receiving bupropion and patch were most likely ($P \leq 0.001$) to be abstinent at 6 and 12 mo	Fair

Appendix Table 4—Continued

Study, Year, Setting (Reference)	Design, Exposure, and Follow-up	Intervention	Participants, n	Results	Quality Rating
Killen et al., 2000 (16) United States Population-based	RCT 17 wk 4, 10, and 26 wk	G1: NRT transdermal system patch for 8 wk plus 20-mg paroxetine for 9 wk G2: NRT transdermal system patch for 8 wk plus 40-mg paroxetine for 9 wk C1: NRT transdermal system patch for 8 wk plus placebo for 9 wk	224 adults	No significant differences in abstinence found between groups at any follow-up time period	Good
Lancaster et al., 1999 (36) United Kingdom Practice/provider settings	RCT with systematic randomization 6 wk 3 and 12 mo after quit date	G1: Brief advice to quit from general practitioner, plus extended counseling with a nurse; leaflet on cessation; fact sheet on NRT; invitation to contact the research nurse for more intensive, tailored counseling; NRT if necessary C1: Brief advice to quit from the patients' general practitioners	497 adults	No significant differences found between groups at 3- and 12-mo follow-up	Fair
Lerman et al., 2004 (37) United States Population-based	RCT 8 wk 8 wk and 6 mo	G1: 8 wk of nicotine nasal spray and 7 sessions of behavioral group counseling G2: 8 wk of transdermal nicotine therapy (i.e., patch) and 7 sessions of behavioral group counseling	299 adults	No statistically significant difference found between treatment groups at 6 mo (G1, 12.2%; G2, 15%; $P > 0.20$) Smokers who were highly dependent, obese, or members of minority groups achieved higher rates of abstinence with nasal spray	Fair
MacLeod et al., 2003 (17) Australia Population-based	RCT 10 wk 1, 2, 3, and 6 mo	G1: Nicotine patch and 5 telephone counseling calls C1: Nicotine patch only	854 adults	Telephone counseling improves cessation rates when used with the patch 28-d continuous abstinence rates at 6 mo: G1, 30.6%; C1, 22.4% ($P = 0.01$) 90-d continuous abstinence rates: G1, 26.7%; C1, 18.6% ($P = 0.004$)	Good
Peterson, 2004 (39) [†] United States Hospital	RCT 3 mo 12 mo	G1: Brief physician counseling and usual care plus nurse managed, cognitive-behavioral relapse prevention intervention given before discharge, <5 structured telephone contacts after discharge, and counseling for relapse management as needed C1: Brief physician counseling, self-help pamphlet, and list of community resources	277 adult women	No significant differences between groups at 12-mo follow-up	Fair
Simon et al., 2004 (41) United States Hospital	RCT 7 wk 7 wk and 3, 6, and 12 mo	G1: 7-wk course of bupropion, 2-mo transdermal NRT, 1 visit with counselor (30- to 60-min session), and 5 telephone follow-up calls C1: Same as G1 except participants received placebo instead of bupropion	244 adults (86% male)	No statistically significant differences in smoking cessation rates at end of medication or at 3, 6, and 12 mo Addition of 7-wk treatment with bupropion did not significantly increase quit rates over NRT and counseling	Fair
Swan et al., 2003 and 2003 (42, 43) United States Practice/provider settings	RCT 12 mo 3 and 12 mo	All participants received bupropion SR for 7 wk G1: 150 mg of bupropion SR, brief counseling telephone call the day after quit date, personalized intervention materials, and access to 24-h automated support line G2: G1 except 300 mg of bupropion SR G3: 150 mg of bupropion SR, self-help materials, support materials for family and friends, in-depth telephone counseling session, 4 brief telephone counseling calls, and access to toll-free "quitline" for 1 y G4: G3 with 300 mg of bupropion SR	1524 adults	7-d point prevalence of nonsmoking at 3 mo for 300 mg vs. 150 mg: OR, 1.18 (CI, 1.05–1.32; $P = 0.005$) At 12 mo, moderate vs. minimal counseling: OR, 1.21 (CI, 1.08–1.35; $P = 0.001$) OR for 12-mo smoking was 23% higher for those who received tailored mailings vs. those who received proactive telephone counseling: OR, 1.24 (CI, 1.03–1.47) 300-mg dose was associated with more adverse events	Fair
Studies in special populations					
Brown et al., 2001 (23) United States Population-based	RCT 6 wk 1, 6, and 12 mo	G1: Group CBT for smoking cessation plus additional CBT on coping for depression C1: Group CBT for smoking cessation alone	179 formerly depressed adults	In main analysis, smoking abstinence did not differ when CBT tailored for depression was added; in secondary analysis, CBT tailored for depression had significant interactions with heavy smoking and recurrent depression: OR, 2.30 (CI, 1.05–5.03)	Fair
Joseph et al., 2004 (20) United States Residential program for treatment of substance use disorder	RCT 10 wk 3, 6, 9, 12, and 18 mo	G1: Individual behavioral therapy; recommended nicotine patches (21 mg for 6 wk, 14 mg for 2 wk, and 7 mg for 2 wk) for smokers; combination of patches and nicotine gum for persons who smoked >20 cigarettes per day C: Temporary control group with treatment delayed for 6 mo	499 adults with substance use disorders	At 3 and 6 mo, smoking abstinence rates were significantly greater in treatment groups than in temporary control group ($P < 0.000$ and $P = 0.02$, respectively)	Good
Joseph, 1993 (35) United States Hospital	Prospective cohort study 3 wk 1 y after hospitalization	G1: No specific information on smoking or cessation; smoking allowed in designated rooms and not during group sessions G2: Upon admission, patient signed contract to abstain from nicotine during stay; cessation program provided; clonidine patches available	706 adults enrolled in substance abuse treatment program	Patients who wanted to quit smoking at 3-wk follow-up: prepolicy, 24%; postpolicy, 61% ($P < 0.001$) Patients who quit smoking at 1-y follow-up: prepolicy, 3%; postpolicy, 8% ($P < 0.05$)	Fair

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Appendix Table 4—Continued

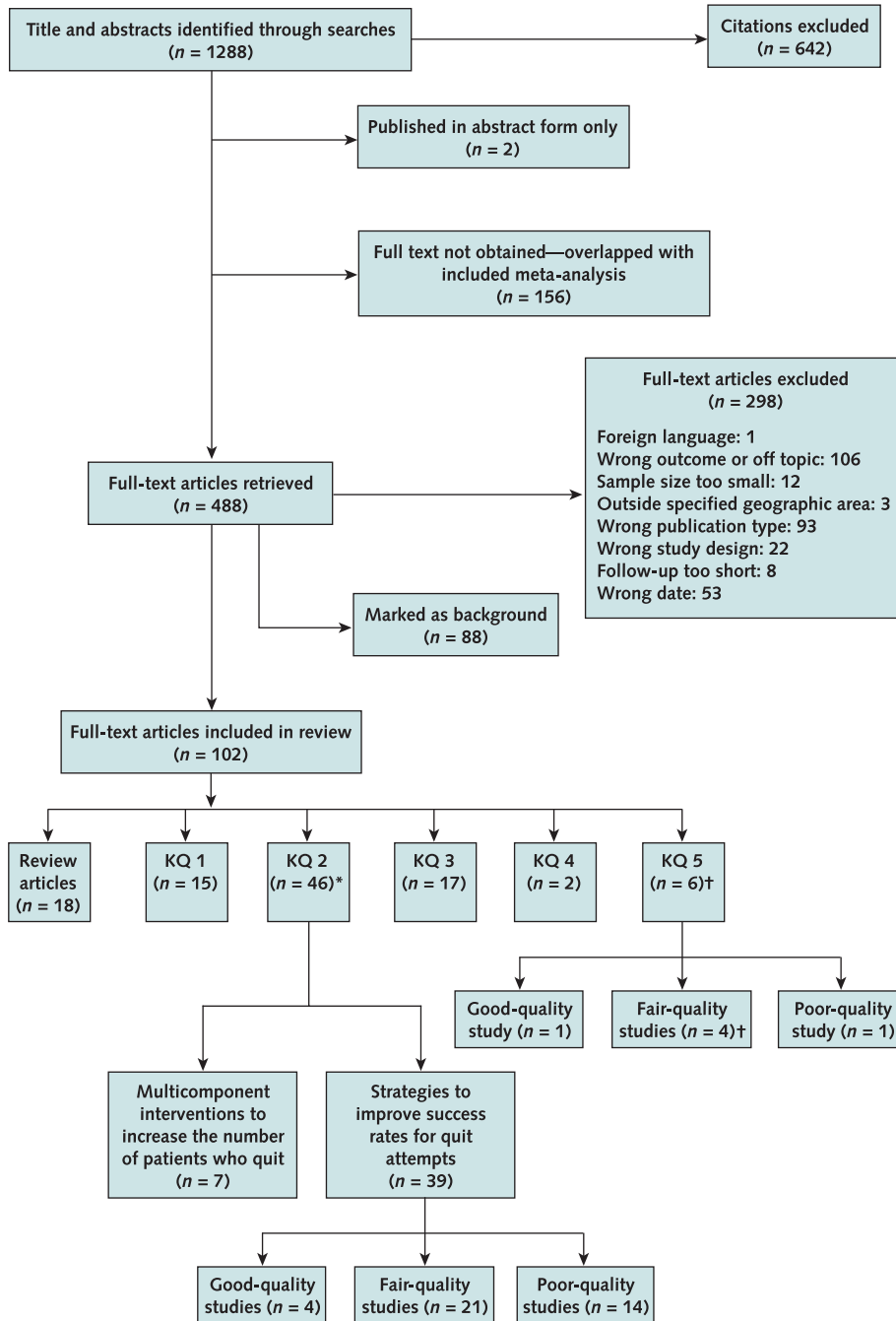
Study, Year, Setting (Reference)	Design, Exposure, and Follow-up	Intervention	Participants, n	Results	Quality Rating
McBride et al., 2004 (38) United States Military medical center	RCT First trimester to delivery and 12 mo postpartum 28 wk pregnant Postpartum 2, 6, and 12 mo	G1: Usual care plus late pregnancy relapse kit and 6 counseling calls G2: G1, plus the partners received telephone counseling and support guide (partners who smoked received cessation aids and counseling) C1: Usual care by provider	583 pregnant women and their partners	No statistically significant difference between groups at any follow-up point In late pregnancy, more partners abstinent in G2 (15%) than C1 (5%); $P = 0.02$	Fair
Quist-Paulsen and Gallefoss, 2003 (18) Norway Hospital: cardiac ward	RCT 5 mo 12 mo	G1: Self-help booklet on how to quit smoking plus cardiac nurse consultation during in-patient days and telephone consultation for up to 5 mo after discharge C1: Group sessions with nurses, with minor emphasis on smoking cessation and no further advice or instruction on how to quit	240 adults	At 1 y, quit rate was greater (57%) in intensive nurse intervention group than in minimal intervention group (37%) (absolute risk reduction, 20 percentage points [CI, 6.4–33.0 percentage points]; $P = 0.004$)	Good
Ratner et al., 2004 (40) Western Canada Teaching hospital	Randomly assigned pretest–posttest control group experiment Not reported 6 and 12 mo	G1: 2 face to face counseling sessions and 9 telephone counseling sessions C1: Standard hospital treatment	237 surgical patients	G1 more likely to be abstinent than C1 (74% vs. 53%; $P = 0.003$) at 6 mo, but difference was not significant at 12 mo after surgery	Fair
Reid et al., 2003 (19) Canada Hospital: tertiary care cardiac facility	RCT 8 wk 3 mo and 1 y	G1: Self-help booklet given in the hospital, then follow-up by nurse counselor at 4 wk after discharge; if patient was smoking, nurse provided three 20-min face-to-face sessions over 8 wk and offered nicotine patch therapy	254 hospitalized patients with coronary artery disease	Smoking cessation rates increased from 42% at hospitalization to 53% at 3-mo follow-up ($P = 0.05$), but difference was not significant at 1-y follow-up	Good

* ACS = American Cancer Society; C = control group; CBT = cognitive behavioral therapy; CT = computed tomography; G = intervention group; ICU = intensive care unit; NCI = National Cancer Institute; NRT = nicotine replacement therapy; OR = odds ratio; RCT = randomized, controlled trial; SR = sustained release.

† General and special populations.

‡ Relevance, Risks, Rewards, Roadblocks, Repetition.

Appendix Figure. Tobacco use: prevention, cessation, and control article disposition.



KQ = key question. *Two studies counted as one because they used the same sample. †One study addressed both KQ2 and KQ5. One study used adolescents and was excluded from the review.