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Tobacco Use: Prevention, Cessation, and Control

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The information in this report is intended to help health care decisionmakers; patients and clinicians, health system leaders, and policymakers, make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. This project was funded by the National Institutes of Health Office of Medical Applications of Research (NIH OMAR). The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to **epc@ahrq.gov.**

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Structured Abstract

Objectives: The RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (RTI-UNC EPC) systematically reviewed the evidence on (a) the effectiveness of community- and population-based interventions to prevent tobacco use and to increase consumer demand for and implementation of effective cessation interventions; (b) the impacts of smokeless tobacco marketing on smoking, use of those products, and population harm; and (c) the directions for future research.

Data Sources: We searched MEDLINE®, Cumulative Index to Nursing and Applied Health (CINAHL), Cochrane libraries, Cochrane Clinical Trials Register, Psychological Abstracts, and Sociological Abstracts from January 1980 through June 10, 2005. We included English-language randomized controlled trials, other trials, and observational studies, with sample size and follow-up restrictions. We used 15 Cochrane Collaboration systematic reviews, 5 prior systematic reviews, and 2 meta-analyses as the foundation for this report.

Review Methods: Trained reviewers abstracted detailed data from included articles into evidence tables and completed quality assessments; other senior reviewers confirmed accuracy and resolved disagreements.

Results: We identified 1,288 unique abstracts; 642 did not meet inclusion criteria, 156 overlapped with prior reviews, and 2 were not published articles. Of 488 full-text articles retrieved and reviewed, we excluded 298 for several reasons, marked 88 as background, and retained 102. Evidence (consistent with previous reviews) showed that (a) school-based prevention interventions have short-term (but not long-term) effects on adolescents; (b) multicomponent approaches, including telephone counseling, increase the number of users who attempt to quit; (c) self-help strategies alone are ineffective, but counseling and pharmacotherapy used either alone or in combination can improve success rates of quit attempts; and (d) provide training and academic detailing improve provider delivery of cessation treatments, but evidence is insufficient to show that these approaches yield higher quit rates.

Recent evidence on the following topics was insufficient to change prior review findings: (a) effectiveness of population-based prevention interventions; (b) effectiveness of provider-based interventions to reduce tobacco initiation; (c) effectiveness of community- and provider-based interventions to increase use of proven cessation strategies; (d) effectiveness of marketing campaigns to switch tobacco users from smoking to smokeless tobacco products; and (e) effectiveness of interventions in populations with comorbidities and risk behaviors (e.g., depression, substance and alcohol abuse). No evidence was available on the way in which smokeless tobacco product marketing affects population harm.

Conclusions: The evidence base has notable gaps and numerous study deficiencies. We found little information to address some of the issues that previous authoritative reviews had not covered, some information to substantiate earlier conclusions and recommendations from those reviews, and no evidence that would overturn any previous recommendations.

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Appendixes and Evidence Tables for this report are provided electronically at
http://www.ahrq.gov/downloads/pub/evidence/pdf/tobaccouse/tobuse.pdf

Executive Summary

Introduction

The RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (RTI–UNC EPC) conducted a systematic review of the literature on issues of tobacco use, prevention, cessation, and control on behalf of the National Institutes of Health (NIH), Office of Medical Applications of Research (OMAR), through the Agency for Healthcare Research and Quality (AHRQ). OMAR commissioned this review to summarize the available literature, frame the discussions regarding benefits and harms, and highlight the limitations of the entire evidence base for a State-of-the-Science (SOS) conference in June 2006.

We synthesized existing literature on five main research issues needed to make progress toward public health gains worldwide. Specific substantive key questions (KQs) were:

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

Methods

Literature Searches

We searched MEDLINE®, the Cumulative Index to Nursing and Applied Health (CINAHL), The Cochrane Library, Psychological Abstracts, and Sociological Abstracts using Medical Subject Headings as search terms or key words when appropriate; we also manually searched reference lists. With our Technical Expert Panel (TEP), we generated a list of inclusion and exclusion for each question. We limited our review to human studies conducted in developed countries and published in English. We considered studies with participants ages 13 and older, of both sexes, and of diverse racial and ethnic populations. We limited studies to those with study duration of more than 6 months and minimum sample sizes of 30 for randomized controlled trials (RCTs) and 100 for other experimental or observational studies. We excluded articles that did not report outcomes related to our KQs or provide sufficient information to be abstracted. We also excluded all editorials, letters, and commentaries.

Finally, for work on KQs 1, 2, 3, and 5, we relied on prior systematic reviews (publication dates in parentheses):

- The Guide to Community Preventive Services (2005),
- *Treating Tobacco Use and Dependence* (2000),
- *Reducing Tobacco Use: A Report of the Surgeon General* (2000),
- Several Cochrane Collaboration Reviews (1998-2005),
- Treating nicotine use and dependence of pregnant and parenting smokers: an update (2004),
- Smoking cessation approaches for persons with mental illness or addictive disorders (2002),
- A meta-analysis of smoking cessation interventions with individuals in substance abuse treatment or recovery (2004), and
- Growing up tobacco free: preventing nicotine addiction in children and youths (1994).

We included original research studies (1) published beyond the date range included in the systematic reviews, (2) concerning topics related to the questions not covered by the reviews, and (3) providing sufficient detail regarding their methods and outcomes.

We made decisions about including studies only after dual review. We assessed the quality of trials or other types of study using criteria from the U.S. Preventive Services Task Force and the National Health Service Centre for Reviews and Dissemination. We rated strength of evidence using categories (strong, sufficient, insufficient) based on criteria from the Task Force on Community Preventive Services.

Results

KQ 1. Effective Population- and Community-Based Interventions to Prevent Tobacco Use in Adolescents and Young Adults

Population-based interventions. Prior systematic reviews investigating tobacco prevention among adolescents and young adults reported strong evidence of effectiveness for increasing the unit price of tobacco products and mass media campaigns run concurrently with other interventions. Evidence of effectiveness was sufficient for restricting tobacco product distribution, regulating the mechanisms of sale, enforcing access-to-minors laws, and merchant education and training when conducted in conjunction with community mobilization.

Two population-based studies had some success in reducing tobacco initiation among adolescents and young adults. Alone, they provided little conclusive evidence about such programs. One study on regulating and enforcing youth access laws augments sufficient evidence from prior reviews. We found no other research to add to existing evidence for population-based interventions.

Community-based interventions. Prior reviews reported limited and mixed evidence of effectiveness of community-based efforts aimed at tobacco prevention. Sufficient evidence was found for short-term effects (less than 2 years) of school-based prevention programs.

Interventions implemented in a single school year or conducted over multiple school years produced mixed results in 10 school-based studies. Consistent with prior reviews, we found sufficient evidence to demonstrate that prevention measures conducted in schools have positive short-term effects but insufficient evidence for long-term effects. We found no community-based studies.

Provider-based interventions. We did not identify any systematic reviews evaluating provider-based tobacco prevention. Our only provider-based study had no intervention effects, giving us insufficient evidence to determine the effectiveness of such efforts.

KQ 2. Effective Strategies for Increasing Consumer Demand for and Use of Proven Individually Oriented Cessation Treatments

Multicomponent strategies to increase the number of users who attempt to quit. Prior reviews found strong evidence of effectiveness for telephone cessation support to increase tobacco use cessation for adults, especially when combined with other counseling formats. We identified three studies of telephone counseling with related print materials. Consistent with prior reviews, two trials reported significant increases in cessation in the short term. One trial reported no difference.

Two studies showed telephone counseling targeting youth and young adults achieves quit rates comparable to those for adults. Though promising, the small number of studies is insufficient to confirm the effect of telephone counseling for these groups.

Strategies to improve the success of quit attempts. Prior systematic reviews reported consistent evidence that counseling by a trained therapist in one or more face-to-face sessions is effective for assisting smokers in their quit attempts. Evidence was insufficient to evaluate whether groups are more effective than intensive individual counseling or to support the use of particular psychological components beyond typically included support and skills training. Limited evidence suggests that adding group therapy to other forms of treatment produces extra benefit.

Prior systematic reviews reported insufficient evidence of the effectiveness of self-help in assisting smokers in their quit attempts. Meta-analyses reported strong, consistent evidence that pharmacologic treatments for smoking cessation can help people quit smoking and some evidence that the combination of the nicotine patch with a self-administered form of nicotine replacement therapy is more effective than a single form of nicotine replacement.

We identified studies evaluating the efficacy of self-help strategies, counseling, single pharmaceuticals, combination pharmacotherapy, and pharmacotherapy combined with psychological counseling. Studies in our review of strategies to improve success of quit attempts were consistent with previous reviews in finding that self-help strategies alone are not efficacious and that the use of counseling, pharmacotherapies either alone or in combination, or pharmacotherapies combined with psychological counseling increases the likelihood of successful quitting.

Strategies to improve the success of quit attempts for special populations. In a meta-analysis comparing augmented smoking cessation treatment with usual care for hospitalized patients, smoking cessation treatments were effective for hospitalized patients. Another review showed no strong evidence that clinical diagnosis affects the likelihood of quitting among hospitalized patients. The same review found that intensive intervention (inpatient contact plus followup for at least 1 month) with hospitalized patients was associated with a significantly higher quit rate compared to control. Prior reviews of interventions with pregnant smokers included studies with substantial variation in the intensity of the intervention and the extent of reminders and reinforcement through pregnancy and found that participants in intervention conditions experience significant reduction in continued smoking in late pregnancy. An earlier

review showed that smoking cessation treatments are effective across different racial and ethnic minorities and should be offered to members of those groups.

We found results both consistent and inconsistent with prior reviews for interventions with special populations. When evaluating interventions with hospitalized patients by diagnosis, studies in our review were in agreement with findings of a prior review showing no strong evidence that clinical diagnosis affects the likelihood of quitting. Results of our review were inconsistent with two prior reviews indicating that hospitalized patients were more likely to quit smoking as the intensity of intervention increased. Although some studies in our review found significant gains in abstinence in the short term, all studies showed an absence of effect at 12-month assessment. The findings of our review remain consistent with those of prior reviews that counseling does increase the likelihood of abstinence among pregnant smokers. Investigators found quit rates for indigenous Maori in New Zealand similar to those observed in other trials of bupropion. These findings are consistent with an earlier review showing that smoking cessation treatments are effective for racial and ethnic minorities.

KQ 3. Effective Strategies for Increasing the Implementation of Proven Population-Level Tobacco Use Cessation Strategies, Particularly by Health Care Systems and Communities

Community-based strategies. Past systematic reviews reported little convincing evidence that community interventions reduce adult smoking. Three new studies focusing on different strategies and populations produced inconsistent results. Positive results emerged only in a trial using community-based pharmacists to discuss smoking cessation when smokers sought a variety of other services. These results are consistent with prior reviews.

Provider and health care system-based strategies. Prior reviews reported strong evidence of effectiveness for provider reminder systems with provider education, with or without client education, and for multicomponent interventions that include client telephone support. However, they reported insufficient evidence of effectiveness to recommend provider education alone and provider feedback and assessment. Sufficient evidence in our review indicated that implementing provider-based interventions such as training improves provider delivery of cessation treatment, but evidence was insufficient to conclude that implementing these approaches leads to higher abstinence.

In examining interventions in health care systems, we found sufficient evidence that academic detailing improves provider delivery of effective smoking cessation treatments. Family physicians and providers in office-based private practices, public clinics, hospitals, and orthodontist offices improved their knowledge and use of effective strategies from personal educational visits in their own practice setting, including education, audit, and feedback.

The evidence was insufficient to suggest that resultant improvement in treatment practices leads to significant, long-term increases in cessation among those being treated. Too few studies reported quit rates for the population served; those that did showed no long-term, consistent effects on cessation. One study tested the relationship between provider attitudes and smoking behavior on uptake and use of effective interventions, but found no effect.

Evidence was promising but insufficient to suggest that interventions proven effective in earlier trials could be sustained as part of routine care. Only one study examined this important aspect of improving the odds of maintaining an effective program. Investigators found that successfully implementing a proven strategy after completion of the original trial is possible, that

the sustained program produced quit rates comparable with those observed in the trial, and that success was more likely among cancer, cardiovascular, and pulmonary patients.

KQ 4. Effect of Smokeless Tobacco Product Marketing and Use on Population Harm from Tobacco Use

Prior systematic reviews did not address these issues directly. Two new studies focused on smokeless tobacco use. One reported smokers were more likely to quit smoking than become users of smokeless tobacco, and users of smokeless tobacco were significantly more likely than nonusers of tobacco to become smokers. Another study found advertising exposure increased adolescent susceptibility to smokeless tobacco, resulting in a sevenfold increase in current use. We found no evidence on how smokeless tobacco marketing affects population harm. Based on these studies, we found insufficient evidence to draw firm conclusions about the impact of marketing these products on increased use or substitution of smokeless tobacco for smoking.

KQ 5. Effectiveness of Prevention and of Cessation Interventions in Populations with Co-occurring Morbidities and Risk Behaviors

Tobacco cessation for persons with comorbidities. Past reviews agree that, absent relevant studies on smoking cessation in psychiatric populations, clinicians should use smoking cessation treatments recommended for the general population. Three studies evaluated smoking cessation for people with psychiatric conditions. In one, pharmacotherapy was effective (consistent with prior reviews). In a second study, counseling and cognitive behavioral therapy were not effective for adults with a history of major depressive disorder (MDD), except in a secondary analysis categorizing adults into single-episode MDD and recurring MDD. In the third study, motivational interviewing or brief advice was not effective for adolescents hospitalized for psychiatric and substance use problems. Prior reviews did not report effective adolescent interventions. Evidence is insufficient and inconsistent to draw conclusions about the effectiveness of interventions in these populations or to overturn the current recommendation.

Tobacco cessation for persons with substance abuse addictions. Prior meta-analyses reported that people with chemical and nicotine dependency should receive counseling and pharmacotherapy to assist with smoking cessation. These types of interventions had positive short-term effects for stopping smoking but not for long-term abstinence. Two studies of smoking cessation interventions among alcohol and substance abusers reported significant effects for smoking cessation when compared to a control group. Both studies treated nicotine dependency concurrently with other addiction treatment. One study reported no effects on abstinence for other addictive substances; the other reported lower alcohol abstinence with concurrent treatments. The findings support past recommendations that counseling and pharmacotherapy have positive short-term effects for such interventions, but the body of evidence is insufficient, given the number of studies, to merit recommendations.

Discussion

General Conclusions

In most instances, evidence from new research covered in our review was consistent with previous systematic reviews. Even in combination with previous reviews, our findings are insufficient to draw new or different conclusions from those offered by earlier reviews. Overall, the evidence base to address the numerous issues raised for the SOS conference has critical gaps and deficiencies, particularly for questions unaddressed by prior reviews.

Future Research

Lacunae in the literature can be addressed by both future research and improvement in methods. We recommend efforts to examine the following key-question-specific issues, focusing on whether, how, and how well certain programs work to influence tobacco initiation, use, or cessation.

KQ 1: Tobacco prevention

- Effect of tobacco industry and product restrictions (specifically, laws that regulate the content, labeling, promotion, and advertising of tobacco products) on adolescents and young adults;
- Community mobilization with increased enforcement of tobacco youth access laws and regulations;
- Concurrent implementation of effective population-based tobacco interventions (e.g., pricing, restricting access, regulations, and media campaigns) in different combinations;
- Community-based tobacco prevention strategies implemented simultaneously;
- Combinations of school-based interventions with community mobilization, media campaigns, and enforcement of tobacco youth access laws and regulations; and
- Tobacco prevention efforts in provider-based settings for adolescents and young adults.

KQ 2: Attempts to quit tobacco use

- Role of mass media in driving individuals to quit lines and other cessation services;
- Audience research on effectiveness of messages to motivate target audiences of adolescents, young adults, and persons with low income and educational status;
- Comparisons of specific components of telephone counseling and their relative impact on enrollment and continuation, individual motivation to quit, and smoking status;
- Appropriateness of cessation services such as number and timing of calls, role of feedback to the caller's primary provider, and participants' satisfaction;
- Relative population impact of proven cessation interventions, such as proactive telephone counseling support compared with in-person intervention;
- Differential rates of success and enrollment and whether they offset or enhance each other;

- Effectiveness of multiple intervention formats, of combination pharmacotherapy, and of adjuncts other than pharmacotherapy in comparison with individual counseling;
- Ways to reduce withdrawal symptoms and cravings among those attempting to quit using tobacco products;
- Ways to minimize side effects associated with use of individual pharmacotherapies and combined pharmaceutical regimes; and
- Techniques to increase persistence of effect on smoking abstinence over time.

KQ 3: Cessation efforts in different settings

- Ways to reach out to smokers in the general population and to special populations with messages that motivate individuals to become aware of, promote, and use existing cessation services;
- Interventions to change provider practice patterns and related smoking outcomes for patients;
- Academic detailing strategies and their impact across and within practice types;
- Relationship of provider attitudes and smoking behavior to provider use of effective interventions; and
- Institutional barriers hampering adoption of effective strategies in health systems and among providers.

KQ 4: Smokeless tobacco marketing and use

- Impact of tobacco industry marketing on use of smokeless tobacco and whether populations are differentially affected;
- Possible links between point-of-purchase tobacco promotion and advertising and increased use of smokeless tobacco among adolescents and young adults; and
- Treatments to complement efforts aimed at smokeless tobacco cessation.

KQ 5: Populations with psychiatric comorbidities and risk behaviors

- Tailored treatments and therapies for populations with psychiatric comorbidities and risk behaviors;
- Effects of combined pharmacotherapies for population with psychiatric comorbidities and risk behaviors;
- Effects of pharmacotherapy for people with a history of depression and people currently diagnosed with clinical depression;
- Timing (e.g., simultaneous, before, or after) of tobacco use treatment and treatment for psychiatric and substance abuse problems; and
- Barriers to tobacco treatment in patients with other health problems such as contraindications of pharmacotherapy and validity of clinicians' concerns about hindering sobriety.

Improved Methods

Investigators need to use markedly better and more rigorous methods for all new research into tobacco prevention, control, and cessation. Critical improvements include more rigorous and longer studies, standardized definitions of interventions, appropriate measurement tools (including biomarkers for verification), better statistical and analytic approaches (e.g., use of intent-to-treat methods), improved tactics for reducing attrition, and better documentation of methods and results.

Evidence Report

Chapter 1. Introduction

Scope of the Problem

Tobacco use is the leading cause of preventable illness and death in the United States: it causes numerous cancers, heart disease, stroke, complications of pregnancy, and chronic obstructive pulmonary disease.[1,2] Each year, 440,000 deaths and $157 billion in health-related economic costs result from tobacco use.[3] Approximately 44.5 million people, or 20.9 percent of the adult population, reported smoking in 2004.[4] Almost one-third of all tobacco users will die prematurely because of their dependence on tobacco.[5]

Tobacco Use and Its Impact

The morbidity and mortality caused by tobacco use, documented by the reports of the Surgeons General since 1964, are clear and pervasive.[1,2,6] Tobacco use begins primarily in adolescence and frequently leads to nicotine addiction.[7] High rates of tobacco initiation among adolescents,[8] variable smoking cessation rates in general and at-risk populations,[9] and inconsistent implementation of smoking cessation interventions underscore the need for evidence-based research outlining recommended tobacco prevention and cessation strategies. With aggressive marketing of tobacco products, particularly smokeless tobacco, continuing to expand and build market share through product development,[10] smoking cessation interventions must maximize their exposure to tobacco users during critical periods of transition or "teachable moments" to reduce the significant morbidity and mortality rates associated with tobacco use.

Many factors affect an individual's tobacco use and associated tobacco-related mortality and morbidity. Disparities in both are reported by race and ethnicity, gender, level of education, socioeconomic status, and geographic region.[2,11] Individuals most likely to smoke and to suffer and die from smoking-related disease are less educated, more likely to live in poverty, and more likely to be American Indians and Alaska Natives.[8]

Most adult smokers (98 percent) began smoking as adolescents or young adults; 82 percent started before age 18, and 16 percent started between the ages of 18 and 24.[12] Each day more than 3,000 additional children and adolescents become regular tobacco users; one-third of them will die from tobacco-related causes.[13,14]

Predictors for smoking initiation vary by race and ethnicity; for example, black males are more responsive to peer pressure than other groups. Overall, children most likely to begin smoking are those engaged in other unhealthy or risky activities such as drinking, truancy, and delinquency.[12] Preventing youth tobacco initiation and the transition from experimentation to addiction are both difficult. Adolescents are more susceptible than people in other age groups to influences from their families, friends, peers, society, and the tobacco industry that encourage tobacco use.[15]

Half of American youth have tried cigarettes by the time they are seniors in high school, and nearly one-quarter (23 percent) of seniors are current smokers. The prevalence of current smoking among high school seniors peaked in 1997 before beginning a decline that continued through 2004. However, this important decline in smoking has decelerated sharply. Among 8th graders the decline has halted and, because of strong cohort effects for smoking, the decline is

predicted to stop in the upper grades as well. The slowdown in price increases for tobacco products together with reductions in funding at both the national and state levels for antismoking campaigns have contributed to these developments.[16]

The smoking rate among young adults ages 18 to 24 is 23.8 percent, slightly higher than that among high school seniors. The national health objective for 2010 is to reduce the prevalence of cigarette smoking among adults to 12 percent or lower.[8] Because data suggest that smoking initiation is a problem among both adolescents and young adults, a strong focus on preventing tobacco use initiation among these age groups is needed.

Smokeless tobacco can also lead to nicotine addiction and dependence.[17] Two types of smokeless tobacco are sold in the United States: chewing tobacco (i.e., loose-leaf tobacco, plug, or twist) and snuff (i.e., finely ground tobacco that can be dry, moist, or in sachets).[18,19] These products, which contain 28 carcinogens, are known to increase the risk of developing oral cancers.[19] An estimated 7 percent of high school students are current users of smokeless tobacco.[20]

Once users are dependent on tobacco, whether cigarettes or smokeless products, quitting is very difficult, although an estimated 70 percent of smokers would like to quit.[8,21] The drug dependence resulting from tobacco use hampers efforts to sustain abstinence from tobacco for either a prolonged period or a lifetime.[5] As a result, many users make multiple attempts to quit.

In 2004, an estimated 14.6 million (40.5 percent) US adult smokers reported trying to quit by stopping smoking for at least 1 day during the preceding 12 months.[8] In 2000, an estimated 70 percent of smokers said they wanted to quit, but few succeeded without help.[22] Tobacco use treatment doubles quitting success rates.[5]

The rate of smoking is higher among people with psychiatric conditions and substance abuse problems.[9,23] Populations with co-occurring morbidities have shown a lack of responsiveness to smoking cessation treatments; fewer than 15 percent of psychiatric patients quit.[23] For people suffering from alcoholism, quitting tobacco before achieving sustained abstinence is particularly difficult.[24] People with comorbidities often have overlapping conditions such as multiple addictions and/or psychiatric, cognitive, or medical conditions that may require more sensitive or specialized strategies and services for smoking cessation.[9]

Barriers to the use of these services exist for both tobacco users and health care providers. Some smokers are reluctant to disclose their smoking status to their clinicians, do not believe that their clinicians can help them to quit smoking, or assume that they will get “attitude” from their clinicians instead of help with quitting tobacco use.[25] More than one-third of current smokers report that they were never asked about their smoking status or urged to quit by their clinician.[26,27] Fewer than 15 percent of smokers who saw a physician in the past year reported being offered assistance in quitting.[28] Among current smokers and former smokers who were trying to quit and had seen a health care provider in the past year, only 61.8 percent received advice to quit from those providers.[29]

Individuals who continue to use tobacco products put themselves and their families at considerable risk of harm associated with tobacco use. By continuing to use tobacco, they are increasing their risk of smoking-attributable mortality and morbidity. They also expose members of their families and households to secondhand smoke and its health and safety consequences.

Need and Purpose of This Systematic Review

The National Institutes of Health (NIH) Office of Medical Applications of Research (OMAR) reviews and evaluates clinically relevant NIH research program information and promotes the effective transfer of this information to the health care community. OMAR accomplishes this objective through its Consensus Development Program. This includes major Consensus Development conferences and State-of-the-Science (SOS) conferences when only less definitive evidence is available.

As background for an upcoming SOS meeting, OMAR commissioned this systematic review on "Tobacco Use: Prevention, Cessation, and Control" through the Agency for Healthcare Research and Quality (AHRQ). The aim is to summarize the available literature, frame the discussions regarding benefits and harms, and highlight the limitations of the entire evidence base. Through this report, OMAR seeks to increase the scientific rigor of the June 2006 SOS conference.

The findings of our review clarify what is known about effective interventions and strategies for tobacco prevention and treatment as a means of providing authoritative background information for participants at the SOS conference. More broadly, we expect that our findings will be useful to major stakeholders in this arena, including policymakers, advocacy groups and community organizations, directors of smoking prevention and cessation programs, health care providers, smokers, and adolescents and young adults. We also identify future research priorities useful to government agencies and private sector funding organizations.

Uses of This Report

Quite apart from its use at the OMAR SOS conference in June 2006, we anticipate that this report will be of value to members of the various professional organizations whose missions include the prevention and cessation of tobacco use in all populations. These organizations include the American Legacy Foundation, the American Cancer Society, the American Heart Association, the Campaign For Tobacco-Free Kids, the March of Dimes, the National Heart, Lung and Blood Institute, the National Cancer Institute, and the Indian Health Service in the Department of Health and Human Services. More generally, the report will assist these and other organizations in their mission to inform and educate practitioners, policymakers, insurers, media representatives, high-risk populations, youth, and the general public.

From this review, NIH and relevant institutes can guide funding policies by identifying serious gaps in the research on tobacco prevention and cessation strategies in diverse populations, strategies for implementing proven tobacco cessation treatments, and the effects of smokeless tobacco product marketing on population use. This review can also inform practitioners on the current evidence about outcomes associated with tobacco initiation and cessation, as well as tobacco implementation practices and smokeless tobacco marketing and use. Researchers will benefit from the concise analysis of the current status of the field, which will enable them to design future studies to address deficiencies in the field. Health educators can use this report to improve health communication. Finally, policymakers can use this report to allocate resources toward future research and initiatives that are likely to be successful.

Production of This Evidence Report

Technical Expert Panel

We identified experts in the field of tobacco use, prevention, cessation, and control to provide assistance throughout the project. The Technical Expert Panel (TEP) (see Appendix E)* contributes to AHRQ's broader goals of (1) creating and maintaining science partnerships and public-private partnerships and of (2) meeting the needs of an array of potential customers and users of this product. The TEP served as both a resource and a sounding board during the project. Our TEP comprised seven individuals: one clinical educator, three representatives from professional and advocacy groups concerned with smoking and health, and three experts in social marketing, media campaigns, and prevention.

To ensure accountability and scientifically relevant work, we asked the TEP for advice at all stages of the project. TEP members participated in conference calls and e-mail exchanges to

- Refine the analytic framework and key questions at the beginning of the project,
- Refine the scope of the project, and
- Discuss inclusion and exclusion criteria.

Because of their extensive knowledge of the literature on these topics and their active involvement in professional organizations and in the clinical field, we also asked TEP members to participate in external peer review of the draft report.

A Note on Terminology

Adolescents are defined as individuals ages 13 to 18, and young adults are defined as college age, approximately 18 to 24 years of age. Adults are defined as individuals ages 18 and older and overlap the young adult category. Comorbidity and co-occurring morbidities refer to a dual diagnosis of concurrent disorders such as depression and nicotine addiction.

Organization of this Report

Chapter 2 describes our methods, including the development of key questions and their analytic framework, our search strategies, and inclusion/exclusion criteria. In Chapter 3, we present the results of our literature search and synthesis on five of the six key questions that OMAR posed for this review. We also report on the numbers of publications reviewed, present findings on prior reviews and current literature, and grade the quality of all articles. Chapter 4 discusses these findings further, rates the overall strength of the bodies of literature, and highlights methodological shortcomings of the extant research; the chapter also offers recommendations for future research (of particular interest to NIH and AHRQ) and restates the major conclusions. Appendices (available electronically at http://www.ahrq.gov/clinic/tp/tobusetp.htm) begin with a detailed description of our search strings (Appendix A), followed by our quality rating forms (Appendix B), detailed evidence tables (Appendix C), a list of excluded

* Appendixes cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/tobusetp.htm.

studies (Appendix D), and acknowledgments, including the TEP and peer reviewers (Appendix E).

Chapter 2. Methods

In this chapter, we document the procedures the RTI International–University of North Carolina Evidence-based Practice Center (RTI–UNC EPC) used to develop this comprehensive evidence report on tobacco use prevention, cessation, and population harm. To provide a framework for the review, we first present the key questions and their underlying analytic framework. We then discuss the previous publications and analyses on which we built our systematic review. Following that section, we describe our strategy for identifying articles relevant to our key questions, our inclusion/exclusion criteria, and the process we used to abstract relevant information from eligible articles and generate our evidence tables. We also discuss our criteria for grading the quality of individual articles and rating the strength of the evidence as a whole. Finally, we explain the peer review process.

Key Questions and Analytic Framework

This report spans key questions regarding prevention of tobacco use among youth, tobacco cessation for diverse populations of adults in a variety of settings, and population harm resulting from smokeless tobacco marketing. Table 1 lists the key questions (KQs) as they were related from the Agency for Healthcare Research and Quality (AHRQ).

Table 1. Final Key Questions

KQ 1.	What are the effective population- and community-based interventions to prevent tobacco use among adolescents and young adults, including among diverse populations?
KQ 2.	What are effective strategies for increasing consumer demand for and use of proven individually oriented cessation treatments, including among diverse populations?
KQ 3.	What are effective strategies for increasing the implementation of proven population-level tobacco use cessation strategies, particularly by health care systems and communities?
KQ 4.	What is the effect of smokeless tobacco product marketing and use on population harm from tobacco use?
KQ 5.	What is the effectiveness of prevention and cessation interventions in populations with co-occurring morbidities and risk behaviors?
KQ 6.	What research is needed to make the most progress and greatest public health gains nationally and internationally (based on work for questions 1–5)?

Key Questions

KQ 1 seeks to understand how to use community- and population-based interventions to prevent initiation of tobacco use among adolescents and young adults across diverse populations. For those individuals who do become dependent on tobacco products, eventual disease, disability, and death can be avoided if they quit using tobacco products. KQ 2 seeks to identify strategies that increase the likelihood that tobacco users will want and use effective individual treatments. Because creating demand for tobacco use cessation is insufficient as a strategy if tobacco users do not respond by using these services or if effective treatments and strategies are not available in communities and health care systems, KQ 3 asks for a summary of proven strategies to increase the implementation of proven population-level tobacco use cessation strategies in health care systems and communities.

Although consensus exists around some tobacco use cessation strategies, controversy surrounds other suggested strategies for harm reduction, such as the use of smokeless tobacco products. Arguing that the harm associated with smoking cigarettes is much greater for both the individual and for those around the smoker than the harm associated with products that are not

directly smoked, marketers are promoting smokeless tobacco use as a safer and much less costly alternative to smoking. KQ 4 asks about the effect of smokeless tobacco product marketing and use on population harm. This complex question requires us to assess, with regard to tobacco-related morbidity and mortality, (1) the impact of smokeless tobacco marketing on smokeless tobacco initiation, (2) the prevalence of smokeless tobacco use alone and/or the substitution of smokeless tobacco for cigarette smoking, and (3) the association of smokeless tobacco use with overall harm and changes in harm (either positive or negative).

Although most cessation strategies are appropriate for most special populations, recent reviews have highlighted issues of effectiveness with some populations, such as those with co-occurring morbidities and risk factors;[30] this population is the focus of KQ 5. Finally, KQ 6 focuses on directions for future research prompted by answers to the above topics.

Recent systematic reviews have identified effective strategies at the individual, community, and population levels for preventing initiation, helping tobacco users to quit, and implementing strategies within the health care system and communities that help tobacco users to quit. These reviews dealt with issues affecting diverse populations, including populations with co-occurring morbidities and risk behaviors. The issues driving these recent reviews are similar to those issues addressed in KQs 1, 2, 3, and 5 of this review. Therefore, we updated or expanded searches completed for these recent reviews or undertook entirely new searches for issues not addressed in recent reviews. We explain our search and synthesis strategy in more detail below.

Analytic Frameworks

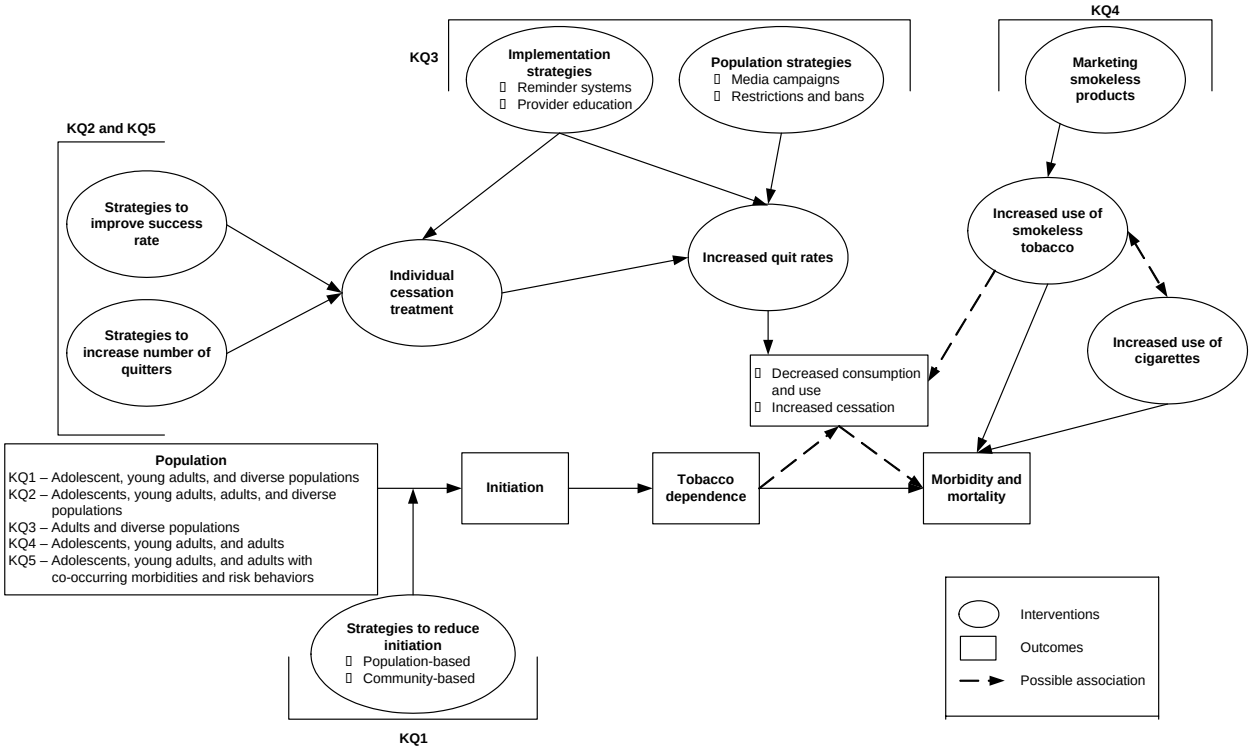
Our overall analytic framework (Figure 1)**,** describes the progression from tobacco initiation to tobacco dependence to tobacco-related morbidity and mortality, along with populations of interest, intervention strategies, and possible associations and outcomes for all KQs except KQ 6 (on research).

Figure 2 depicts in more detail the relationship of our overall model to issues relating to each of the KQs. The framework indicates the population of interest, the level of intervention (individual or population), activities evaluation (e.g., prevention, cessation, marketing), and the expected outcomes of the intervention. To understand what is known about how to interrupt this progression from initiation to dependence to disease, disability, and death, we focused this systematic review on individual, community, and population strategies for tobacco use prevention, cessation, and control.

Previous Reviews

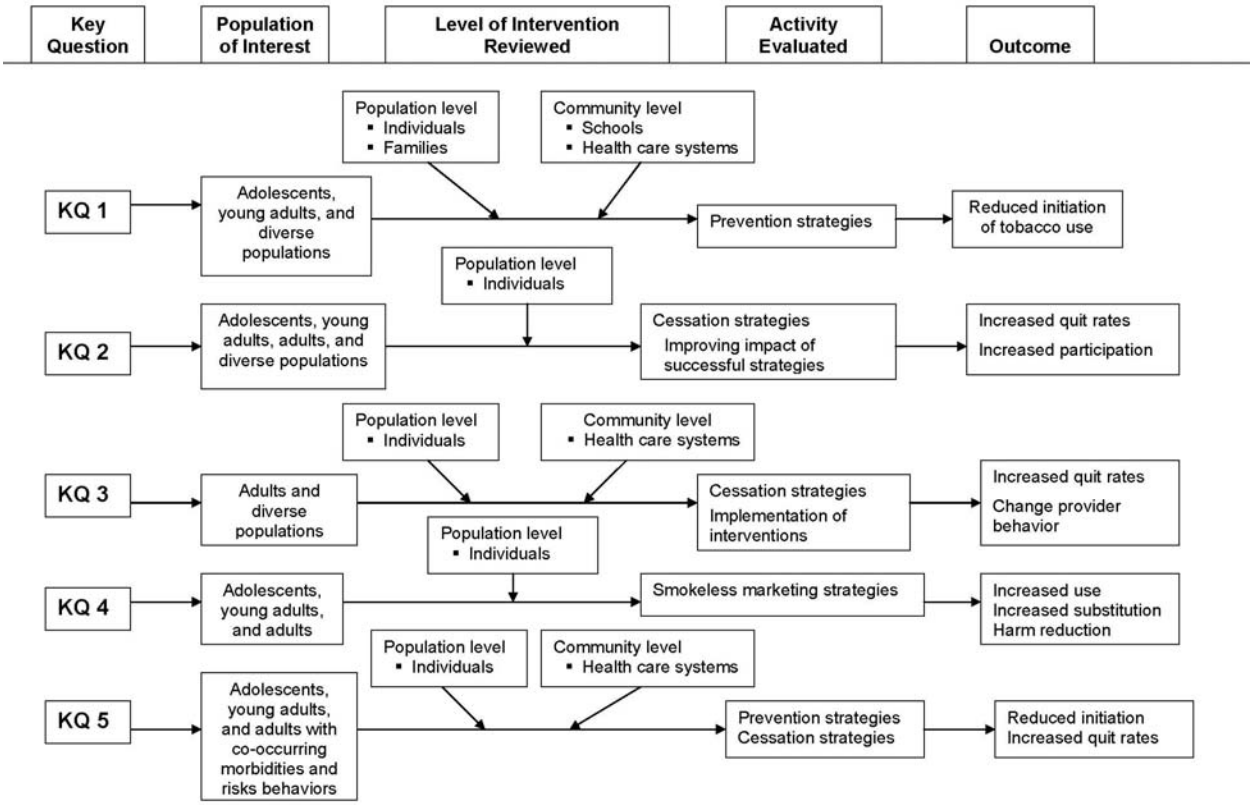
A good deal of research has been published on these issues, and some has been compiled in previous overviews and syntheses. Where possible, we elected to include systematic reviews as updates. We selected previous reviews that specifically covered all or parts of the key questions above as the basis for this report (see Chapter 3, Table 5). As a result, if studies already evaluated in existing reviews that met our inclusion criteria addressed the same outcomes of interest for the KQs, we did not reabstract data from them. By contrast, we did examine and extract data from studies published after these existing reviews for this report. To make this approach clear, we briefly describe existing appraisals of the evidence on each KQ (as depicted in Figures 1 and 2) before presenting our specific methods of literature searches and analysis.

Figure 1. Overall analytic framework for tobacco use, initiation, and cessation



Adapted from Hopkins et al., 2001[31]

Figure 2. Analytic framework for smoking cessation



Adapted from Hopkins et al., 2001[31]

KQ 1. Effective Population- and Community-Based Interventions to Prevent Tobacco Use

For KQ 1, we focused our review on five main strategies:

1. Unit price increases on tobacco products,
2. Mass media education campaigns combined with other interventions to reduce tobacco use initiation,
3. Interventions to reduce youth access to tobacco products (i.e., laws that regulate and enforce bans on sales of tobacco products to, or their purchase or consumption by, children and adolescents),
4. School-based education interventions to prevent tobacco use, and
5. Tobacco industry and product restrictions (i.e., laws that regulate the content, labeling, promotion, and advertising of tobacco products).[31]

Recently, the *Guide to Community Preventive Services* (hereafter, *Community Guide*) reviewed strategies 1, 2, and 3 and studies that combined two or more interventions in a coordinated effort to restrict minors' access to tobacco products.[7] The Institute of Medicine's

report, *Growing Up Tobacco Free*,[32] and the 2000 report of the Surgeon General, *Reducing Tobacco Use*,[2] reviewed all five strategies. The Cochrane Collaboration reviewed strategies 2[33] and 4.[34]

We undertook new searches for strategies not yet reviewed by the *Community Guide* (i.e., numbers 4 and 5), updated the searches for strategies 1 through 3, and searched for strategies other than those identified above. We explored the literature for the differential effect of prevention strategies among diverse populations, including those among adolescents and young adults who are most likely to initiate tobacco use and become regular users.

KQ 2. Effective Strategies for Increasing Consumer Demand for and Use of Individually Oriented Cessation Treatments

Interventions to increase the number of tobacco users who seek assistance in quitting and who successfully quit include efforts to increase the number of users who attempt to quit, to improve the success rate for quit attempts, and to support both of these goals.[7] This question focuses on both sets of interventions.

Proven individual strategies for helping smokers to quit include counseling and behavioral therapy and, except when contraindicated, the use of firstline and secondline medications.[5] More often than not, individuals are trying to quit without the type of assistance that can double or even triple the chances of success.[5] Other strategies intended to motivate tobacco users to attempt to quit or to reduce relapse among recent quitters include telephone support and mass media interventions.

Telephone support provides an option for individuals reluctant to discuss tobacco use with their health care providers. In some cases, telephone support also allows on-demand assistance, provides a no-cost service, or includes provision of pharmacotherapies. These features remove or at least mitigate some of the barriers that tobacco users may perceive or experience in their attempts to receive assistance from their health care providers.

Mass media interventions are designed and implemented to provide cessation information and motivation for tobacco users who are trying to quit.[7] The three main subtypes of mass media interventions are campaigns, cessation series, and cessation contests. Mass media campaigns provide brief, recurring messages; cessation series consist of broadcasted instructional segments; and cessation contests are community-wide events of short duration that recruit and motivate users of tobacco products to participate in a program to quit by a certain date.[7] Mass media intervention strategies can also drive tobacco users to call telephone quit lines, thereby increasing the number of smokers who seek help.[7]

Reviews of community interventions to increase tobacco use cessation have focused on four main approaches: (1) multicomponent efforts to increase patient tobacco use cessation, which include telephone information or counseling support; (2) mass media campaigns combined with other interventions; (3) mass media cessation series; and (4) mass media cessation contests. The *Community Guide* focused on all four issues,[7] the 2000 Surgeon General's Report focused on only the second and third,[2] the Clinical Practice Guideline focused on the first,[5]and the Centers for Disease Control and Prevention (CDC) Best Practices publication focused on the second.[35]

Using the searches in the sources identified above as a base, we updated the searches for all strategies. We expanded searches for interventions lacking sufficient evidence at the time of the most recent review, for new interventions or strategies introduced in the literature since the most recent review, and, to the extent possible, for the differential impact of all strategies on diverse

populations. Our cessation searches specifically looked for studies related to the following factors: race or ethnicity, socioeconomic status, education level, gender, age (i.e., adolescents and adults), hospitalization, and pregnancy.

KQ 3. Effective Strategies for Increasing Implementation of Population-Level Tobacco Use Cessation Strategies

The Cochrane Collaboration published a systematic review focused on community interventions.[36] Reviews of health care system interventions to implement effective treatments appear in the *Community Guide*,[7] the 2000 Surgeon General's report,[2] the Clinical Practice Guideline,[5] and Melvin and Gaffney.[37]

The Cochrane Collaboration review assesses the effectiveness of community interventions in reducing the prevalence of smoking among adults (18 years of age and older).[36] It addressed two main questions: (1) Do community-based interventions reduce smoking (measured by prevalence, cigarette consumption, quit rates, or initiation rates) compared with no intervention in comparison communities? (2) Which characteristics of these studies are related to their efficacy? Selected studies evaluated the effectiveness of community interventions in which smoking behavior change was a part of the intervention program using either a controlled trial that randomized communities or geographical regions or a nonrandomized controlled trial that allocated communities or geographical regions.

Even when tobacco users feel comfortable approaching their providers, they may not receive effective treatments. Some providers indicate that they do not know how to intervene effectively with smokers,[38] that they experience disappointment and discouragement given the cyclical nature of relapse and remission they observe among smokers,[5] and that they are not trained to deal with co-occurring morbidities and risk behaviors. Finally, for both providers and tobacco users, the costs associated with providing or receiving effective treatment are barriers. For example, many providers are not reimbursed for cessation counseling, and tobacco users may have no health insurance or only limited health insurance coverage for cessation treatments.

Recent reviews of interventions that help providers and health care systems implement strategies to increase cessation of tobacco use by clients highlight numerous, sometimes multifaceted programs. Among programs studied are provider reminder systems with or without client education,[2,5,36,37] health care provider education alone or with feedback and assessment,[5,7,36,37] reduction of client out-of-pocket costs for effective cessation therapies,[2,5,7] and multicomponent interventions that include client telephone support.[5,7,36,37] Melvin and Gaffney reviewed the literature for interventions that increase the likelihood that health care providers will provide effective strategies to pregnant and postpartum women either proactively or in response to client demand.[37]

We updated and expanded, as necessary, the recently completed reviews on both community and health care interventions. The existing reviews on these topics were comprehensive and needed little expansion. We expanded searches for interventions lacking sufficient evidence at the time of the most recent review and for new interventions or strategies introduced in the literature since the most recent review.

KQ 4. Effect of Smokeless Tobacco Product Marketing and Use

KQ 4 asks us to examine whether substituting smokeless tobacco for smoking results in less smoking-related harm on a population basis and whether smokeless tobacco marketing leads to

greater use and/or substitution of smokeless tobacco for smoking. Evidence in reports of the Surgeons General and other sources link smokeless tobacco causally with oral leukoplakia and oral cancers.[2,39] Smokeless tobacco may also increase the risk of cancers in other sites.[17] We examined the harms associated with smokeless tobacco use and determined whether others have used data on these harms to model the potential health effects of substituting smokeless tobacco for smoking. Some studies' approaches to promoting smokeless tobacco use are related to current use of these products.[40-45]

We are unaware of any studies that have followed the entire analytic framework we suggest—assessing (1) the impact of marketing smokeless tobacco on its use or its substitution for smoking cigarettes, (2) the impact of smokeless tobacco use on overall harm, and (3) the possibility of reduced harm associated with smokeless tobacco use in terms of overall tobacco-related morbidity and mortality. We reviewed the relevant literature to determine whether any studies describe any or all of these relationships. We believe that assessing the public health significance of harm reduction associated with smokeless tobacco use will be difficult given that only 3.4 percent of Americans ages 12 and older used these products in the past month.[2] Also, this statistic includes women's smokeless tobacco use and deflates the importance of this health issue because most of these users are young men. The current rate of smokeless tobacco use is 6 percent among men and only 0.3 percent among women.[20]

We also note that recently some tobacco companies have begun to market their smokeless tobacco products directly as less harmful alternatives to tobacco, likening them to nicotine replacement products and emphasizing that smokeless tobacco does not carry the same risks to others as smoking does with secondhand or environmental tobacco smoke.[46] We searched for studies examining this harm reduction relationship. The review for KQ 4 focuses on adolescents, young adults, and adults, especially in relation to harm reduction for tobacco-related morbidity and mortality. We focused on studies of marketing approaches for adolescents and young adults given their routine and repeated targeting by the tobacco industry and their greater likelihood of using smokeless tobacco products. However, we believe that it is too early to determine if these harm reduction approaches to smokeless tobacco marketing are effective in increasing its use.

KQ 5. Effectiveness of Interventions in Populations with Co-Occurring Morbidities and Risk Behaviors

The term "psychiatric comorbidity," as used in the *Treating Tobacco Use and Dependence* clinical practice guideline, refers to the co-occurrence of smoking with another psychiatric disorder.[5] We use this narrow definition because individuals with psychiatric illnesses are approximately twice as likely as the general population to smoke tobacco. These individuals also tend to smoke more heavily than other smokers.[47-50]

Co-occurring risk behaviors include those behaviors that trigger tobacco use, such as alcohol or other substance use or abuse. As many as 20 percent of patients seeking smoking cessation services may have a history of alcohol abuse or dependence.[48-50] Among abusers of alcohol and drugs, smoking occurs at rates well above population averages (e.g., greater than 70 percent).[51-53]

Treatment of individuals with these co-occurring morbidities or other risk behaviors remains a controversial topic, because some believe that smoking cessation and nicotine withdrawal exacerbate a patient's comorbid condition and, thereby, present unique case management challenges.

The clinical practice guideline examined the efficacy of tobacco treatment among patients with psychiatric comorbidity.[5] Another recent review of smoking cessation approaches for individuals with mental illness or addictive disorders examined empirical studies conducted between 1991 and 2000.[30] The majority of interventions combined medication and psychoeducation. We updated and expanded these reviews to examine the effectiveness of cessation interventions in populations with co-occurring morbidities and risk behaviors.

No previous review addressed the effectiveness of prevention interventions in this population. We examined studies identified through searches focused on populations with co-occurring morbidities and risk behaviors to determine if any analyses reported smoking prevention and cessation outcomes. We found few studies on smoking cessation and no studies on prevention (because the population is already smoking).

KQ 6. Needed Research

Current systematic reviews include recommendations for further research and areas of insufficient evidence. Through this newer review, we identified findings that are both consistent and inconsistent with previously identified needs for research, and we pinpointed important gaps in research.

Literature Review Methods

Inclusion and Exclusion Criteria

After discussions with our Technical Expert Panel (TEP), we generated a list of article inclusion and exclusion criteria (Table 2) for these KQs. We limited our review to human studies conducted in developed countries and published in English. We considered studies with participants ages 13 and older of both genders from diverse racial and ethnic populations.

We excluded editorials, letters, commentaries, articles that did not report outcomes related to our key questions, and studies that did not provide sufficient information to be abstracted. To avoid reporting short-term fluctuations among the populations and to ensure sufficient sample sizes to observe changes over time, we limited our review to randomized controlled trials (RCTs) with 30 or more individuals or observational studies and nonrandomized controlled trials with 100 or more individuals, followed for a minimum of 6 months, with or without comparison groups. Our TEP concurred with this plan.

Literature Search and Retrieval Process

Databases and search terms. To identify the relevant literature for our review, we conducted systematic searches based on search terms and hand-searched reference lists. We searched standard electronic databases: MEDLINE®, the Cumulative Index to Nursing and Applied Health (CINAHL), Cochrane Collaboration libraries, Cochrane Clinical Trials Register, Psychological Abstracts, and Sociological Abstracts.

Table 2. Tobacco use: inclusion/exclusion criteria

Category	Criteria
Study population	Humans, all races, ethnicities, and cultural groups **KQ 1**: Adolescents (13-18 years of age), young adults (18-24 years of age), and diverse populations **KQ 2**: Adolescents, young adults, adults (18 years of age and older), and diverse populations **KQ 3**: Adults and diverse populations **KQ 4**: Adolescents, young adults, and adults **KQ 5**: Adolescents, young adults, and adults with comorbidities 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: January 1, 2000, to June 10, 2005 Studies that addressed product restrictions in the tobacco industry aimed at countering youth tobacco use: January 1, 1980, to June 10, 2005 **KQ 2 and KQ 3**: January 1, 1999, to June 10, 2005 **KQ 4 and KQ 5**: January 1, 1980, to June 10, 2005
Publication languages	English only
Admissible evidence (study design and other criteria)	Original research studies that provide sufficient detail regarding 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 • Randomized controlled trials (RCTs); • Nonrandomized controlled trials; and • 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 or more participants Observational studies and nonrandomized controlled trials: 100 or more participants

KQ, key question

Based on the inclusion/exclusion criteria specified above, we generated a list of Medical Subject Heading (MeSH) search terms, supplemented by key word searches to search MEDLINE® (Table 3). Comparable terms were used to search other databases. Finally, we asked our TEP and external peer reviewers to suggest articles that we might have missed.

Article selection process. Once we had identified articles through the electronic database search, review articles, and bibliographies, we examined abstracts and the full text of the articles to determine whether the studies met our inclusion criteria. Two reviewers initially evaluated abstracts for inclusion or exclusion; only one reviewer was needed to include an article, but two reviewers were required to exclude an article. Dr. Ranney, the Study Director, reconciled all conflicts. As articles appeared that met inclusion criteria at the abstract review stage, we obtained the article's full text. For the full text review, two reviewers read each article and determined whether it met our eligibility criteria. Again, Dr. Ranney adjudicated any disagreements. Dr. Ranney and Dr. Cathy Melvin, our Scientific Director, reviewed articles excluded by the first two reviewers and assigned reasons for exclusion or, when appropriate, included them in the pool for abstraction.

Table 3. Medical subject headings and text words

Medical Subject Headings	
Tobacco use cessation	Marketing
Smoking cessation	Social marketing
Smoking/prevention and control	Choice behavior
Smoking (and as text term)	Advertising
Primary prevention	
Community networks	Tobacco, smokeless
Community health services	Spit tobacco (text term)
Community health planning	Chewing tobacco (text term)
Community health aides	Dip tobacco (text term)
Community health nursing	Oral tobacco (text term)
Community health centers	
Community mental health services	Comorbidity
Community medicine	Risk-taking
Community mental health centers	Risk factors
	Depressive disorder
Randomized controlled trials	Depression
Single-blind method	Bipolar disorder
Double-blind method	Attention deficit disorder with hyperactivity
Random allocation	Stress disorders, post-traumatic
	Diabetes mellitus
Consumer satisfaction	Hypertension
Consumer participation	Heart diseases
Health services needs and demand	Asthma
	Obesity
Health plan implementation	
Diffusion of Innovation	
Patient education	

Literature Synthesis

Development of Evidence Tables and Data Abstraction Process

Senior staff for this systematic review jointly developed evidence tables using two designs: one design for primary data collection studies and one for systematic reviews. The designs are intended to provide sufficient information so that readers can understand the study and determine its quality; we emphasized presenting information essential to answering the main questions. The formats of the two sets of evidence tables were based on successful designs used for prior systematic reviews.

The primary data collection evidence tables contain information on

- Study characteristics (author, year, study setting, funding source, time period covered);
- Research objective, population, and study design (inclusion, exclusion criteria);
- Sample design (technique and size);

- Definitions of smoking;
- Intervention methods, description, and assessment;
- Baseline data;
- Statistical analysis, data verification, and dependent variables;
- Results (outcome measures); and
- Quality rating and comments.

The evidence tables for systematic reviews report on

- Study demographics (author, year, geographic area, funding source, time period covered);
- Study characteristics (inclusion criteria, population, characteristics of studies, method of review, study design, what studies are included in the meta-analysis);
- Aim of review;
- Main results; and
- Quality rating (adverse events).

For this work, the RTI-UNC EPC team decided to abstract data from included articles directly into a proprietary systematic review database program, TRIALSTAT. We trained data abstractors intensively, thoroughly familiarizing them with the abstraction form design (Appendix B[†]), required information and formats, and examples of abstracted articles. As the work progressed, we shared various reporting requirements with abstractors to ensure that information appeared in a consistent and easily understandable manner.

For the primary data literature, the first reviewer (a research assistant from the University of North Carolina at Chapel Hill) entered data from the article into the database. The second, senior reviewer (either Dr. Ranney or Dr. Melvin) read the article and edited the initial table entry for accuracy, completeness, and consistency. For the systematic review literature, Dr. Ranney entered data from the review into the database, and Dr. Melvin read the article and edited the initial table entry for accuracy, completeness, and consistency. In both cases, the two abstractors reconciled all disagreements by consensus discussion.

The final evidence tables are presented in their entirety in Appendix C. Below are the table titles for each question. Within each evidence table, entries are listed alphabetically by the last name of the first author. Abbreviations and acronyms used in the tables appear in a glossary at the beginning of the appendix.

- KQ 1
  - Evidence Table 1. Effective population-based interventions
  - Evidence Table 2. Effective school-based interventions
  - Evidence Table 3. Effective provider-based interventions
- KQ 2
  - Evidence Table 4. Multicomponent interventions to increase the number of users who quit smoking
  - Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations

[†] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/tobusetp.htm.

- KQ 3
  - Evidence Table 6. Population-based strategies to increase the implementation of proven population-level tobacco use cessation strategies
  - Evidence Table 7. Provider and health care systems strategies to increase implementation of population-level tobacco use cessation
- KQ 4
  - Evidence Table 8. Effect of smokeless tobacco product marketing and use on population harm from tobacco use
- KQ 5
  - Evidence Table 9. Tobacco cessation interventions for persons with co-occurring morbidities and risk behaviors
- Systematic Review and Meta-analysis
  - Evidence Table 10. Systematic and meta-analysis reviews

Quality and Strength of Evidence Evaluation

Quality of studies. We assessed the internal validity (i.e., quality) of trials based on predefined criteria developed by the US Preventive Services Task Force (ratings are good, fair, or poor)[54] and the National Health Service Centre for Reviews and Dissemination.[55] We assessed and reported external validity (i.e., generalizability) but did not use these judgments in our quality ratings.

We developed three quality rating forms, two for the primary data literature (one for randomized controlled trials and one for observational studies and non-randomized controlled trials) and the other for the systematic review literature. We tested several drafts of these forms, revising them as needed to ensure that they efficiently captured the desired information. The final grading forms can be found in Appendix B. Elements of internal validity assessment for primary data literature included, among others, randomization and allocation concealment, similarity of compared groups at baseline, use of intention-to-treat analysis, and overall and differential attrition. The assessment of the systematic review literature focused on issues of validity, such as whether the search strategy was systematic and comprehensive, and issues of reliability, including whether the authors used a standard method of critical appraisal.

Two independent reviewers assigned quality ratings; they resolved any disagreements by discussion and consensus or by consulting a third, independent party. Primary data articles that had one or two minor study design issues were considered "good"; an example of such an article is one in which an intention-to-treat analysis was not conducted, but the author addressed the issue of loss to followup by surveying those who did not complete the study. We had a wide and diverse range of "fair" articles, which were articles that had several minor study design issues, such as lack of reporting on baseline group differences or a weak sampling technique. Articles that had multiple major study design issues, such as postrandomization of exclusions, high refusal rates, high attrition rates, no comparison of groups at baseline, and lack of information about control or comparison groups, received a quality grade of "poor."

All but one of the systematic literature reviews and meta-analyses were of good quality; the exception was "fair." The systematic reviews assessed were primarily from the Cochrane Collaboration, which is known for conducting comprehensive literature searches and employing stringent appraisal criteria. The two meta-analyses were of high quality; one is recognized in the field of tobacco control as the "gold standard," and the other was rated "good."

Strength of the available evidence. We rated the strength of the evidence for the interventions based on the criteria developed for the Task Force on Community Preventive Services,[56] which we deemed most applicable to the study designs in this review (Table 4). Our evaluation employed three domains to determine the strength of the evidence for each intervention: quality of the research, including design suitability and study execution; quantity of studies, including the number of studies and the adequacy of the sample size; and consistency of findings among the studies. The available evidence for an intervention was determined to be strong, "sufficient," or "insufficient."

Bodies of evidence rated as strong included an adequate number of studies that were of good or fair quality, had study designs that were appropriate for the intervention being evaluated or issue being addressed, and were consistent in the direction of their findings. Sufficient bodies of evidence also contained studies of good or fair quality, but the suitability of the studies' designs was not as consistently appropriate and, therefore, more relevant studies were required to rate the evidence in the category. As per the Task Force model, the reasons for determining that a body of evidence was "insufficient" included unsuitable study designs, too few studies to determine the effectiveness of an intervention, too small an effect size, and inconsistent findings among studies of an intervention.[56] We graded the strength of evidence applicable to each of the key questions separately.

Table 4. Modified body of evidence assessment table from *Guide to Community Preventive Services*

Evidence of Effectiveness	Execution of Study Design	Design Suitability	Number of Studies
Strong	Good	Greatest	At least 2 studies
	Good	Greatest or moderate	At least 5 studies
	Good or fair	Greatest	At least 5 studies
Sufficient	Good	Greatest	At least 1 study
	Good or fair	Greatest or moderate	At least 3 studies
	Good or fair	Greatest, moderate, or least	At least 5 studies
Insufficient	Insufficient execution	Insufficient design	Too few studies

Task Force on Community Preventive Services, 2005[56]

Peer Review Process

Among the more important activities involved in producing a credible evidence report is conducting an unbiased and broadly based review of the draft report. External reviewers for this report included clinicians and representatives of professional societies and advocacy groups, including TEP members (see Appendix D).[‡] We charged peer reviewers with commenting on the content, structure, and format of the evidence report and asked them to complete a peer review checklist. We revised the report, as appropriate, based on their comments.

[‡] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/tobusetp.htm.

Chapter 3. Results

This chapter presents results of our literature search and our findings for five key questions (KQs) regarding tobacco prevention, cessation, and control. These form the background for a State-of-the-Science (SOS) conference scheduled for June 12–14, 2006, under the auspices of the Office of Medical Applications Research (OMAR) of the National Institutes of Health (NIH). We report here on the following issues:

- KQ 1, initiation of tobacco use among young people;
- KQ 2, demand for and use of cessation treatments;
- KQ 3, increasing use and implementation of health care and community cessation programs;
- KQ 4, impact of smokeless tobacco product marketing on use, and
- KQ 5, cessation treatments for individuals with comorbidities and risk behaviors.

KQ 6 is covered in Chapter 4 and deals with the limitations of these bodies of literature and our recommendations for future research.

We discussed specific approaches for the first three KQs with our Technical Expert Panel (TEP) because, as noted in Chapter 2, we had a considerable pool of existing publications on which to draw. In each section below, we report first on previous reviews that covered the KQ, then on specific details about the yields of the literature searches and characteristics of the studies, and finally on literature pertaining to each question. Where appropriate, we provide summary tables presenting selected information on each included study that had a quality rating of good or fair.

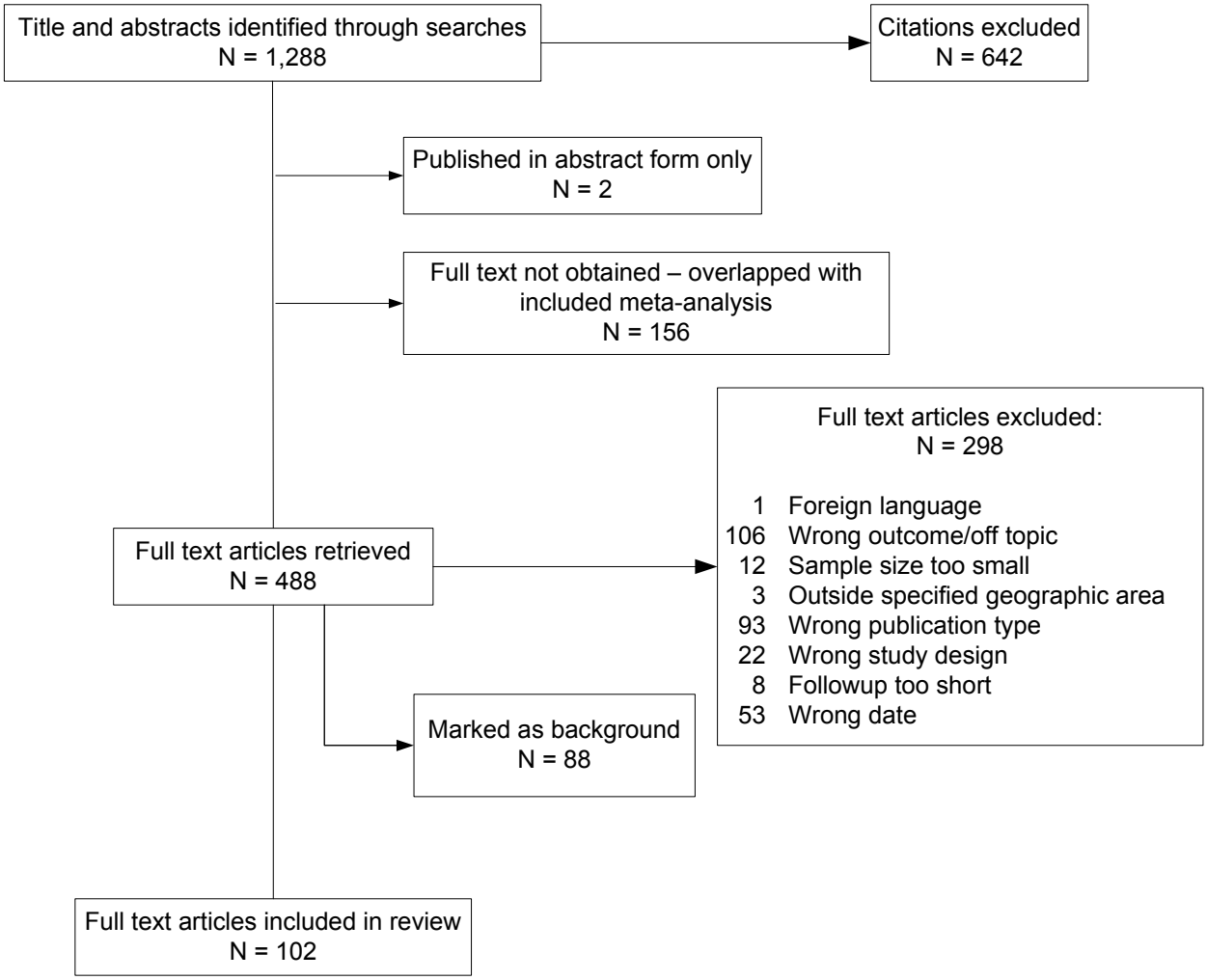
Appendix C* contains all the full evidence tables for each question. Evidence tables are organized by major analytic topic; studies are then listed alphabetically by author. A glossary at the beginning of the appendix defines all acronyms and abbreviations appearing in the tables. If several articles report on a single study, they are grouped in a single entry (row); if a study or article has information concerning more than one KQ, it appears in every relevant evidence table.

Results of Literature Searches

Our literature searches yielded 1288 possible articles (see Figure 3). (Appendix A presents the search terms and yield for each database searched in June 2005.) Beginning with the 1,288 titles and abstracts, we excluded 642 entries at the abstract level because it was apparent that they did not meet our inclusion criteria.

* Appendixes cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/tobusetp.htm.

Figure 3. Tobacco use: prevention, cessation, and control article disposition



To focus our review on the most rigorous research and avoid duplicating previous reviews, we did a cross-walk (i.e., checked for duplicate articles) between the 644 citations and the citations from related systematic reviews and meta-analyses (Table 5). Articles that overlapped with systematic reviews and meta-analyses are listed in Appendix D. This process further narrowed the pool to 488 articles, which we then pulled and fully reviewed. Of the reviewed articles, 102 studies were included in this report. Table 5 lists the systematic reviews, meta-analyses, and dates of included literature used as a basis for topics equivalent to KQs 1, 2, 3, and 5.

Specifically, the following publications have extensively covered tobacco prevention and cessation intervention strategies in diverse populations:

- *The Guide to Community Preventive Services* (2005),
- *Treating Tobacco Use and Dependence* (2000),
- *Reducing Tobacco Use,* A Report of the Surgeon General, (2000),
- The Cochrane Collaboration reviews (1998–2005),
- *Treating nicotine use and dependence of pregnant and parenting smokers,* (2003),

- A meta-analysis of smoking cessation interventions with individuals in substance abuse treatment or recovery (2004),
- Smoking cessation approaches for persons with mental illness or addictive disorders (2002), and
- Growing up tobacco free: preventing nicotine addiction in children and youths (1994).

The cross-walk identified 156 common citations. Because these reviews served as the starting point for the evidence-based report, we did not abstract the 156 shared citations.

Table 5. Systematic reviews and meta-analysis used for this report

Review Type	Authors	Topic	Included Research
Cochrane	Ebbert JO, Rowland LC, Montori V, Vickers KS, Erwin PC, Dale LC, Stead, LF[57]	Interventions for smokeless tobacco use cessation	1992 to Mar. 2004
Cochrane	Lancaster T, Stead LF[58]	Physician Advice for Smoking Cessation	1974 to 2003
Cochrane	Lancaster T, Stead L[59]	Self-help interventions for smoking cessation	1981 to Apr. 2005
Cochrane	Lancaster T, Stead LF[60]	Individual behavioural counseling for smoking cessation	1984 to Feb. 2005
Cochrane	Lumley J, Oliver SS, Chamberlain C, and Oakley L[61]	Interventions for promoting smoking cessation during pregnancy	1976 to Mar. 2004
Cochrane	Moher M, Hey K, Lancaster T[62]	Workplace interventions for smoking cessation	1981 to Feb. 2005
Cochrane	Rigotti NA, Munafo MR,Murphy MFG, Stead LF[63]	Interventions for smoking cessation in hospitalised patients	1974 to 2002
Cochrane	Secker-Walker RH, Gnich W, Platt S, Lancaster T[36]	Community interventions for reducing smoking among adults	1970 to Jan. 2002
Cochrane	Sowden A, Arblaster L[33]	Mass media interventions for preventing smoking in young people	1983 to Aug. 1998
Cochrane	Sowden A, Stead L[64]	Community interventions for preventing smoking in young people	1983 to Sept. 2002
Cochrane	Stead LF, Lancaster T[65]	Group behaviour therapy programmes for smoking cessation	1981 to Feb. 2005
Cochrane	Stead LF, Lancaster T, Perera R[66]	Telephone counseling for smoking cessation	1991 to Oct. 2002
Cochrane	Thomas R[34]	School-based programmes for preventing smoking	1980 to Jan. 2002
Systematic review	el-Guebaly N, Cathcart J, Currie S, Brown D, Gloster S[30]	Smoking cessation approaches for persons with mental illness or addictive disorders	1990 to 2000
Meta-analysis	Fiore MC, Bailey WC, Cohen SF, et al.[5]	Clinical practice guideline update: Treating Tobacco Use and Dependence	1995 to 1999
Meta-analysis	Prochaska JJ, Delucchi K, Hall SM[9]	A meta-analysis of smoking cessation interventions with individuals in substance abuse treatment or recovery	1991 to 2003
Systematic review	Lynch BS, Bonnie RJ[32]	Growing up tobacco free: preventing nicotine addiction in children and youths	1990 to 1993
Systematic review	Melvin, CL, Gaffney, C[37]	Treating nicotine use and dependence of pregnant and parenting smokers: An update	1994 to 2003
Systematic review	US Department of Health and Human Services	Reducing tobacco use: a report of the Surgeon General	Not reported
Systematic review	Zaza S, Briss PA, Harris KW[7]	The Community Preventive Services Guide: Tobacco (Chapter 1)	1976 to May 2000

We included original research studies that (1) were published beyond the date range included in the systematic reviews, (2) concerned topics related to the questions not covered by the reviews, and (3) provided sufficient detail regarding their methods and outcomes. The approaches for each specific question are as follows. For KQ 1, we included studies published between January 1, 2000, and June 10, 2005, that addressed topics 1 through 4 in Chapter 2. We also relied on the synthesis of previous reviews and meta-analyses for research and recommendations published before 2000. We included all primary data collection studies that addressed product restrictions in the tobacco industry (i.e., laws that regulate the content, labeling, promotion, and advertising of tobacco products), which represents subjects that the other systematic reviews did not cover. For KQ 2 and KQ 3, we included studies published between January 1, 1999, and June 10, 2005. We relied on the synthesis of past reviews and meta-analyses for research and recommendations published before 1999. For KQs 4 and 5, we included research found between January 1, 1980, and June 10, 2005, pertaining to the specific question.

KQ 1. Effective Population- and Community-Based Interventions to Prevent Tobacco Use

The primary goals of population- and community-based interventions are to prevent or delay experimentation with tobacco and to prevent the transition from experimentation to regular use. Additionally, these interventions motivate and encourage people to quit. For the purpose of this report, population-based interventions employed traditional population sampling techniques such as random-digit dialing, and nationwide surveys to recruit participants and collect data. These interventions are easily generalizable to large groups of people. Community-based interventions are directed at a distinct segment of society that shares similarities or fellowship, and generalizability is limited by the uniqueness of the community studied.

As shown in our analytic frameworks for KQ 1 (in Chapter 2), we examined the effectiveness of population- and community-based strategies to prevent tobacco use by reducing tobacco initiation among adolescents and young adults. Prevention of tobacco use is measured by differences or changes in (1) self-reported tobacco use among adolescents and young adults, (2) self-reported purchases of tobacco products, (3) tobacco obtained from commercial sources (e.g., vending machines), and (4) retailer sales of tobacco products to minors.[7]

Population-Based Interventions to Limit Access and Reduce Initiation

Nicotine addiction begins at an early age; 89 percent of adult daily smokers have tried cigarettes before age 18.[32] In 2004, current use of tobacco was reported by 28 percent of high school students and 11.7 percent of middle school students.[8] Cigarettes are the most commonly used tobacco product for both middle and high school students.

Population-based intervention efforts to reduce tobacco use initiation among adolescents and young adults include at least four mechanisms: (1) increases in the unit price of tobacco products; (2) laws that regulate and enforce bans on sales, purchases, and consumption of tobacco products by underage youth; (3) laws that regulate the content, labeling, promotion, and advertising of tobacco products; and (4) mass media education campaigns.

Synthesis of prior systematic reviews. Past reviews have evaluated interventions to limit access to tobacco products and reduce tobacco use initiation among adolescent and young adults.

They include (1) increasing the unit price of tobacco products, (2) enforcing tobacco laws and regulations, (3) implementing tobacco industry and product restrictions, and (4) disseminating mass media campaigns.[2,7,32,33]

Increasing the unit price of tobacco products. An increase in the excise tax on tobacco, which requires passage of legislation or a statewide referendum, results in an overall increase in the cost of tobacco products. For adolescents and young adults with limited incomes, higher prices make cigarettes less attractive.[7] Several earlier reports agree on the positive effects of economic approaches to reducing tobacco initiation.[2,7,32] Recommendations from the Institute of Medicine state that a tax increase of $2.00 for each pack would make tobacco less accessible and raise money for tobacco control, health care, and other uses. Unit price has a direct influence on the demand for cigarettes.[2] Eight studies that evaluated intervention strategies that increased the price of tobacco products provided price elasticity of demand estimates by combining information on local tobacco product prices and price changes or differences in survey responses over time on tobacco use and consumption.[7] A 10 percent price increase in tobacco prices results in an approximately 4 percent decrease in consumption of tobacco products by adolescents (13 to 18 years of age). A similar strong effect is found for young adults (18 to 24 years of age).[7]

Enforcing tobacco laws and regulations. Minors obtain tobacco from retailers (merchants), commercial sources (vending machines), and social sources (other adults); all contribute to initiation and regular use of tobacco.[7] Restricting distribution, regulating the mechanisms of sale, enforcing minimum age laws, and providing merchant education and training have some success in reducing minors' access to tobacco.[2] Multicomponent interventions designed to reduce minors' access to tobacco include numerous strategies: stronger restrictions on retailer sales of tobacco products; restrictions directed at youth purchases, possession, and use; active reinforcement of tobacco sales laws; and retailer education interventions with or without reinforcement.[7,32] Thirteen multicomponent studies, with 10 different combinations of interventions, investigated how restricting minors' access to tobacco affects tobacco initiation. Only five of these studies used differences or changes in tobacco use among youth as the outcome variable. Four of the studies coordinated community mobilization efforts with retailer education with enforcement, stronger local ordinance for retailers, enforcement of retailer sales laws, school-based education, or local ordinances directed at youth tobacco purchase, possession, or use.[7] Interventions to reduce youth access to tobacco products that combined two or more interventions in a coordinated effort decreased students' self-reported tobacco use by 5.8 percentage points over a period of 2 to 4 years.[7]

Tobacco industry and product restrictions. In 1998, the Master Settlement Agreement prohibited tobacco advertising that targets people under 18 years of age. Despite this agreement, tobacco companies consistently allocate a higher proportion of their expenditures for advertising of youth brands to youth-oriented magazines.[67] Reviews on tobacco industry and product restriction are still in progress.[31] Strategies for regulating tobacco packaging, labeling, and contents are long-term steps, recommended by the Institute of Medicine Committee on Preventing Nicotine Addiction in Children and Youths,[32] to sustain progress toward reducing health consequences of tobacco use. Warnings on cigarette packages in the United States are weaker and less conspicuous then those in other countries. In addition, purchasers of tobacco do not receive information about toxic constituents in tobacco smoke. To protect adolescents and young adults from inducement that might influence their decision to start smoking, implementing stricter regulations on packaging, advertising, and promotion is imperative and will likely reduce both prevalence and uptake of tobacco use.[2]

Mass media education campaigns. Mass media education campaigns disseminate brief recurring messages with the intent of providing information that will motivate children and adolescents to remain tobacco free.[7] Campaign methods include broadcast messages on television and radio, billboards, print, and movies. Media campaigns increase awareness of the strategies that the tobacco industry uses to promote tobacco and they attempt to facilitate changes in both tobacco use behaviors and public tobacco policies. They also use educational messages relating to demand reduction to provide information and support to adolescents to help them decide to remain tobacco free.[7] Reviews of mass media campaigns and community interventions that include a media component report some evidence that these are effective, particularly when combined with other intervention activities such as school- and community-based education programs and increases in excise taxes on tobacco.[33,64]

A review of 12 studies evaluated the effectiveness of mass media campaigns in reducing tobacco use among adolescents.[7] The studies conducted the media campaign in conjunction with other intervention strategies such as school- and community-based educational programs, contests, and increased excise taxes. Mass media campaigns conducted concurrently with other interventions generally showed reductions of tobacco use among youth in the intervention communities. Five of these studies reported absolute differences in self-reported tobacco use. The media campaigns decreased the number of adolescents using tobacco by approximately 2.4 percentage points.[7] Campaigns that last 2 years increase the effectiveness of the campaign.

Synthesis of current literature. Fifteen original studies examined interventions designed to reduce tobacco initiation among adolescents and young adults (KQ 1).[68-82] In reviewing these studies, we used a three-level component rating scale to assess the quality of each study. We rated them good, fair, or poor based on the rigor of the study design and how well the study was conducted. Quality review ratings for KQ 1 consisted of 1 good rating, 12 fair ratings, and 2 poor ratings (poor ratings had one or more fatal flaws in design or conduct of the study). Therefore, we discuss 13 studies for KQ 1. Information on the two studies we rated as poor are in the evidence tables (Appendix C).[†] We organized the KQ 1 studies by population-based (Evidence Table 1), school-based (Evidence Table 2), and provider-based interventions (Evidence Table 3).

Population-based interventions to reduce tobacco initiation. Two of the 13 studies were population-based.[73,79] As shown in Table 6, the studies were conducted in the United States and received quality ratings of fair. Sample sizes ranged from 1,316 to 3,831 adolescents ages 12 to 17. One study addressed youth access, specifically youth access ordinances and regulations,[79] and the other was an intervention designed to prevent adolescent tobacco and alcohol use by targeting family risk factors.[73]

We did not find studies implementing other prevention strategies related to unit price of tobacco products, tobacco industry and product restrictions, or media campaigns alone or in combination with other tobacco prevention interventions. With the exception of tobacco industry and product restrictions, these interventions have been covered extensively in past systematic reviews. New studies investigating these topics either did not meet our inclusion criteria, in particular did not report on the outcome variable for KQ 1 (i.e., reduced initiation of tobacco use among adolescents and young adults), or are not in publication.

[†] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/tobusetp.htm.

Table 6. Effective population-based interventions

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Ennett et al., 2001[73] United States 48 contiguous states	RCT 4 mailings over 14 months 3 and 12 months	G1: Booklets mailed to parents followed by telephone discussion with health educator and parents C1: Did not receive "Family Matters" program	1,316 adolescent-parent pairs (adolescents ages 12–14 years)	Effects present for non- Hispanic whites only (n=791) Adolescents in the control group were more than 1.5 times as likely to smoke at the 3-month followup than adolescents in the intervention (OR, 1.59; *P* = 0.008, lower bound CI, 1.19 for a one-way test of significance) Program parents were more likely to discuss peer and media influences and set rules about smoking	Fair
Thomson et al., 2004[79] United States Boston, MA	Cross-sectional NA NA	G1: parent involvement in community-level tobacco ordinances	3,831 youth (12–17 years)	Youth living in towns that ban free-standing displays were less likely to perceive tobacco as easy to purchase (AOR, 0.6; 95% CI, 0.5-0.9; *P* = 0.007) Increased perceived access was associated with being older (*P* < 0.0001) and male (*P* ≤ 0.002)	Fair

AOR, adjusted odds ratio; C1, control group; CI, confidence interval; G1, intervention group 1; NA, not applicable; NR, not reported; OR, odds ratio; RCT, randomized controlled trial.

Restricting adolescents' access to tobacco products is a population-based intervention aimed at reducing tobacco initiation. A study using Massachusetts statewide youth tobacco access ordinances and regulations examined the effects of these provisions on youth perceived access to tobacco products, youth purchase attempts, and youth tobacco use.[79] In this cross-sectional study, the investigators surveyed youth from across Massachusetts using a random sample of households. Interviewers collected demographic data from the adult resident, screened for eligibility, and requested permission to interview all youth in the household between the ages of 12 and 17. After excluding inconsistent reports of resident's town, zip code, or telephone exchange and towns having no identified youth respondents, interviewers collected data from 3,831 participants in 314 towns. The Massachusetts Tobacco Control Program produces a biannual report on six provisions of youth access ordinances from each town:

1. Licensing (requires retailers to have a license to sell tobacco products),
2. Fines for merchants who sell tobacco products to minors;
3. Vending machine restrictions (a complete ban or restricted to adult-only establishment)
4. Ban on free-standing displays of tobacco products
5. Ban on sale of single cigarettes and
6. Ban on distribution of free samples.

The six provisions were used as predictor variables in the analysis. Additionally, a measure of antismoking sentiment provided a baseline measure in each town before expansion of the local youth access ordinance. The antismoking measure was highly correlated with the town-level

socioeconomic measure. The outcome variables were dichotomous; smoking status was defined as "ever smoker" (has smoked or puffed a cigarette in one's lifetime) or "current smoker" (has smoked at least one cigarette in the past 30 days).[79]

In the fully adjusted model, only two provisions were statistically significant and only one in the expected direction. Youth living in towns that ban free-standing displays were less likely to perceive tobacco as easy to purchase (adjusted odds ratio [AOR], 0.6; 95% confidence interval [CI], 0.5-0.9; $P = 0.007$). Counterintuitively, youth reported easy access in towns that required tobacco vendors to have a license (odds ratio [OR], 1.3; 95% CI, 1.1-1.5; $P = 0.009$). Overall, 37 percent believed that it was easy to buy cigarettes in their town. No associations were found between youth access ordinances and attempts to purchase or between ordinances and tobacco use. Individual factors associated with increased attempts to purchase were associated with being older ($P \leq 0.01$) and male ($P = 0.004$). Individual factors associated with tobacco use were being older, living with a smoker, and having a close friend who smokes ($P < 0.0001$).[79]

The second population-based study enrolled 1,316 adolescent-parent pairs throughout the contiguous United States through random-digit dialing into a family-directed program called Family Matters.[73] Pairs completed baseline interviews by telephone, were matched with another pair by date and time of completion, and were randomly assigned to either receive the Family Matters program or serve as controls. This program used both global attributes of families, such as supervision and attachment, and substance-specific family characteristics, such as parental drug use, to reduce tobacco initiation. The program assumes that changing global family characteristics (supervision, supportiveness, involvement, and communication) and substance-specific characteristics (parent expectations and attitudes toward child's drug use; parental monitoring, rules, and encouragement about drug use; availability of and outside influences regarding drugs; parental drug use) will change a third domain—adolescent cognitions regarding drug use and, in turn, will ultimately influence adolescent use.[73]

The investigators completed successive mailings of four booklets to parents and their 12- to 14-year-old children between July 1996 and September 1997 (1 year and 2 months). Following each mailing, telephone discussions occurred between parents (or guardians) and health educators. Families who completed the program spent an average of 4.5 hours doing the program; parents spent an additional hour talking with the health educator by telephone. The program measured exposure to the Family Matters program, adolescent tobacco and alcohol use, three sets of mediator variables, and sociodemographic characteristics at 3- and 12-month followups. Self-reported smoking status, without biochemical verification, categorized never-smoked adolescents as nonusers and adolescents who smoked even a puff of a cigarette as users.[73]

Baseline data showed fewer non-Hispanic whites students in the Family Matters intervention than in controls. The effects of the intervention were present only among non-Hispanic white adolescents—a subset of the population (n = 791). Adolescents in the control group were more than 1.5 times as likely to smoke at the 3-month followup assessment than adolescents in the Family Matters intervention (OR, 1.59; $P = 0.008$, lower bound CI = 1.19 for a one-way test of significance). No significant effects were evident at the 12-month followup. The conceptual model underlying the Family Matters program was validated for non-Hispanic whites only.[73]

Community-Based Interventions to Prevent Tobacco Initiation

Community-based interventions are coordinated, widespread programs in a particular geographic area, such as a school district, or in a grouping of people who share common interests

or needs.[64] The Surgeon General's report on *Reducing Tobacco Use*[2] and two Cochrane reports on school-based programs and community interventions review smoking prevention strategies for young people.[34,64]

Synthesis of prior systematic reviews. Previous reviews have found limited support for school- and community-based interventions to reduce tobacco use initiation among adolescents and young adults.[34,64] No prior systematic reviews were identified for provider-based interventions. School-based interventions reviewed include various educational strategies. Examples include classroom programs or curricula that provided information, used social influence approaches, and taught social competence. These programs often moved beyond the school population to involve parents and the community.[34] Community-based interventions for preventing smoking among young people integrate an array of strategies such as community empowerment, dissemination of health education materials, media advocacy, youth antitobacco activities, contests, letters to schools and parents, school programs, and use of peer leaders to raise awareness and discourage tobacco use.[64]

School-based smoking prevention programs. Schools in the United States have existing tobacco use prevention policies and programs, but current interventions are not optimal. Effective educational strategies conducted in conjunction with other interventions such as mass media and community activities, can postpone or prevent smoking onset in 20 percent to 40 percent of adolescents.[2] Such multifaceted programs reach adolescents on multiple levels by enlisting the positive influences of parents, community organizations, the mass media, and school programs.

An extensive review of all randomized controlled trials (RCTs) of behavioral interventions in schools to prevent tobacco use (ages 5 to 12 and 13 to 18) identified 16 studies of acceptable quality.[34] The various strategies included information-giving methods, social influence approaches, generic skills training, and community interventions. Short-term positive effects were found in eight studies; however, no long-term effects were significant. Long-term is defined as 2 years after the end of the program; anything less than 2 years was considered a short-term effect.[34]

Community-based smoking prevention interventions. Some support exists for the premise that community interventions are effective at reducing the uptake of tobacco in young people. Of 13 studies comparing community interventions to no interventions, only 2 showed lower smoking prevalence. A comparison of a multicomponent community intervention with a community receiving a mass media campaign alone also showed a lower rate of smoking prevalence. Three studies compared community interventions to school-based interventions, but only one found differences in reported smoking prevalence.[83]

Synthesis of current literature. Of the 13 studies addressing KQ 1, 10 involved school-based efforts[68-72,74-76,81,82] and 1 tested a provider-based intervention.[80] Sample sizes ranged from 26 to 99 schools and 103 to 8,352 participants. These studies were conducted in the United States (5), the Netherlands (2), Australia (1), Canada (1), Norway (1), and the United Kingdom (1). We rated one study as good and the rest as fair.

Community interventions have been covered comprehensively in past systematic reviews.[2,64] We did not identify any community-based tobacco prevention studies; those that we learned about either did not meet our inclusion criteria or are not yet in publication.

School-based interventions to reduce tobacco initiation. An effective method for reaching adolescents and young adults is to use school systems. Implementing tobacco prevention interventions in schools is convenient and allows for both optimum exposure of the intervention

strategies and regular assessment of effectiveness. The school-based tobacco prevention studies in this report are heterogeneous in terms of prevention strategies, definitions of tobacco use, and length of follow-up assessments. Biochemical verification of self-reported smoking status, unless otherwise stated, was not used in these studies. Virtually all the studies defined smoking status differently.

Table 7 lists the various definitions of abstinence and tobacco use in the 10 school-based tobacco prevention studies reviewed. Interventions that sustain significant outcomes 2 years after the end of the intervention are considered to have long-term effects. School-based tobacco prevention programs were divided by length of exposure. Programs were implemented either within a single school year or over multiple school years. Single-year interventions are discussed first, followed by multiple-year interventions.

Table 7. School-based tobacco prevention program smoking status definitions

Author/Year	Smoking Status	Definition of Smoking Status
Single-School-Year Smoking Prevention Programs		
Ausems et al., 2004[68]	Never smoker	Never smoked a cigarette or even took a puff of a cigarette
	Noncurrent smoker	Smoked in the past but not in the past month
	Current smoker	Smoked during the past month
Aveyard et al., 2001[69]	Nonweekly smoker	Smoked less than one cigarette per week
	Regular weekly smoker	Smoked at least one cigarette per week
Crone et al., 2003[71]	Nonsmoker	Never smokers, experimenters that no longer smoke, and quitters
	Smoker	Smokes at least once a week or less than once a week and experimenters that continue to smoke
Perry et al., 2003[75]	Nonsmoker	Not specified
	Current smoker	Measured by amount of current tobacco use (response categories not specified)
Unger et al., 2004[81]	Nonsmoker	Never smokers
	Smoker	Tried smoking between 6th and 7th grade
Multiple-School-Year Smoking Prevention Programs		
Brown et al., 2002[70]	Never smoker	No history of smoking
	Tried once	Tried once
	Experimental smoker	Smoked less than once a week
	Quit	Smoked and quit
	Regular	Smoked weekly
Ellickson et al., 2003[72]	Ever smoker	Lifetime use
	Past-month smoker	Frequency of use within past month
	Weekly Smoker	Frequency of use within past year
Josendal et al., 2005[74]	Nonsmoker	Nonsmokers and smoked less than weekly
	Smoker	Smoked daily or weekly
Schofield et al., 2003[76]	Nonsmoker	Did not smoke within the past 7 days
	Smoker	Smoked within the past 7 days
Winkelby et al., 2004[82]	Nonsmoker	Never smoked or former tobacco smokers
	Experimental smoker	Smoked less than one pack per week
	Regular smoker	Smoked more than one pack per week

Five school-based interventions were conducted within a single school year.[68,69,71,75,81] As shown in Table 8, these interventions used classroom instruction, computer-based programs, competition, parent involvement, community advocacy, and personalized letters. Students were in grades six through eight in middle, lower secondary, and vocational schools.

Table 8. Effective school-based interventions

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Single School Year Interventions					
Ausems et al., 2004[68] The Netherlands Middle and high (school level); vocational schools	RCT 5 months 6, 12, and 18 months	G1: In school: 3 lessons G2: Out of school: 3 tailored letters G3: Both C1: Control, not described	36 schools Number of students not reported	At 12 months, the in-school intervention prevented more students from continuing to compared with controls (OR = 0.49, 95% CI, 0.29 – 0.84) At 18 months, the tailored letters intervention prevented more smoking initiation compared with the controls (OR = 0.42, 95% CI, 0.18 – 0.96)	Fair
Aveyard et al., 2001[69] United Kingdom Adolescents (ages 13 to 24) living in West Midlands	RCT Up to 6 sessions over an academic year 1 and 2 years	G1: 3 computer-based program lessons with videos and 3 classroom lessons related to Transtheoretic Model C1: Standard lessons	52 schools 8,352 students	At 1- or 2-year followup, no evidence of change in stage or regular smoking	Fair
Crone et al., 2003[71] The Netherlands Lower secondary schools	RCT 8 months 8 and 20 months	G1: 3 classroom lessons on knowledge, attitudes, and social influence C1: Usual drug prevention program	26 schools 2,562 students	At 20 months, nonsmokers who became smokers increased less in intervention groups than control group, the program successfully decreased smoking for regular smokers and maintained nonsmoking for nonsmokers versus control Those with perceived social pressure were more likely to be smokers	Fair
Perry et al., 2003[75] United States Middle and junior high schools in Minneapolis/St. Paul, Minnesota	RCT 8 months 8 and 20 months	G1: D.A.R.E. curriculum taught by police officers (10 sessions) G2: G1 plus D.A.R.E. Plus—peer led, parental involvement in extracurricular activities Control: Delayed program—D.A.R.E. offered in next school year	24 schools 6,237 students	D.A.R.E. Plus significantly less likely than D.A.R.E. to show an increase in current smoking or intentions to use tobacco for boys No significant differences for girls	Fair

C1, Control Group; D.A.R.E., Drug Abuse Resistance Education; G1, intervention group; RCT, randomized controlled trial

Table 8. Effective school-based interventions (continued)

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Unger et al., 2004[81] United States 6th and 7th graders in Southern California	RCT 8 weeks over an academic year 12 months	G1: 8 weekly classroom sessions by health educators relating smoking issues to several cultures C1: Without the cultural references	16 schools 1,970 students	Overall, intervention effect was not significant Hispanic boys in the intervention group were less likely to report ever smoking at 1 year followup than the control group	Fair
Multiple School Year Interventions					
Brown et al., 2002[70] Canada High schools (9th and 10th grades)	RCT Students receiving tobacco prevention in elementary schools recruited for intervention in 9th and 10th grade At the end of each academic year	G1: Extracurricular activities, teacher-facilitated C1: Usual care	30 schools, 2,776 students	Male never smokers at baseline in the intervention group were significantly less likely to become "regular" smokers in 10th grade than controls No significant effect for females	Fair
Ellickson et al., 2003[72] United States Urban, rural, and middle schools in South Dakota	RCT NR (11 lessons in 7th grade and 3 lessons in 8th grade) 18 months	G1: 11 interactive teaching lessons in 7th grade, and 3 lessons in 8th grade, booster lessons in 9th and 10th G2: Same as G1 but no booster sessions C1: Regular prevention curriculums	55 schools 4,276 students	Treatment results for G1, G2 combined through 8th grade; other results NR At 18 months, cigarette initiation rates in G1+G2: were significantly lower than in the controls Project ALERT significantly reduced proportion of new smokers	Fair
Josendal et al., 2005[74] Norway 7th to 9th grade schools	RCT Minimum class and lessons 5 times per year: 8 hours in 7th grade; 5 hours in 8th grade; 6 hours in 9th grade End of each academic year—7th, 8th, 9th grade	G1: Classroom (5 times per year), teacher in-service, parental involvement G2: Same as GI, but no teacher in-service course G3: Same as GI, but no parental involvement C1: Education on smoking and health, but about half of the number of hours as in G1 or G2	99 schools 4,223 students	Full program (G1) had significantly fewer smokers than controls across all 3 years Intervention without the parental involvement or the teacher in-service (G2 or G3) had significantly fewer smokers than the controls Odds of becoming a smoker (daily, weekly, any) during the intervention period were significantly lower in the full program group (G1) than in the controls	Good

Table 8. Effective school-based interventions (continued)

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Schofield et al., 2003[76] Australia 7th to 10th grades in New South Wales school district	RCT 2 school years 24 months	G1: Self-help, group counseling, social support C1: Offered and received none of the experimental activities	22 schools 1,852 students	Proportion of students who smoked in past 7 days did not differ significantly by treatment condition, intervention not effective Significantly greater improvement in smoking knowledge for the intervention group compared with the control Positive attitudes toward smoking significantly decreased among smokers	Fair
Winkelby et al., 2004[82] United States High Schools (11th or 12th grades) in San Francisco and San Jose, California	RCT Weekly lessons and activities over an academic semester At the end of each semester and 6 months after the end of the semester	G1: Three-phase advocacy and empowerment C1: Existing substance abuse curriculum, not specific to tobacco	10 continuation high schools 813 students	Regular smokers had greatest statistically significant net decrease in tobacco use No differences in nonsmokers at baseline between intervention and control groups in uptake of smoking at followup	Fair

One study implemented the intervention in a primarily Hispanic population,[81] another in primarily non-Hispanic, white populations,[75] and the other studies did not specify ethnicity of the population studied.[68,69,71] The sample size for the five studies implementing within-school-year interventions ranged from 16 to 52 schools and 1,970 to 8,352 students.

The length of exposure students received was as short as 8 weeks[81] and as long as 8 months.[75] Followup assessments ranged from 6 months to 24 months. All prevention strategies included classroom lessons that included educational instruction typically combined with one or several other activities such as group discussion, role-play, videos, skills training, or computer-based lessons.[68,69,71,75,81] Drug Abuse Resistance Education (D.A.R.E.), a well-known, school-based tobacco prevention program in the United States, also included parent involvement and a community youth action team in the multicomponent intervention.[75]

Three single-year smoking prevention programs compared their effects with those in control groups that received either standard smoking information, the original drug prevention program already in place, or the same classroom lessons without cultural sensitivity.[69,71,81] An 8-month prevention program used educational strategies and competition to reduce tobacco initiation in 26 lower secondary education (mean age 13) schools in The Netherlands.[71] Three lessons on knowledge, attitudes, and social influences were followed by a class agreement either not to start smoking or to stop smoking for the next 5 months. To increase students' motivation, the National Institute Against Smoking rewarded classes in which less than 10 percent of the students were

smokers at the end of the 5 months; it also conducted a photography contest to find the best photograph that expressed a nonsmoking class.[71]

Smoking status measured by self-report was assessed at baseline, at the end of the intervention, and at 1-year followup. At the end of the intervention, the proportion of nonsmokers who became smokers had increased less in the intervention group (9.6 percent) than in the control group (14 percent) (OR, 0.61; 95% CI, 0.41-0.90). The proportion of smokers had also increased significantly less in the intervention group (2.6 percent) than in the control group (7.9 percent) (OR, 0.62; 95% CI, 0.43-0.90). The groups did not differ significantly at 1-year followup.

Aveyard et al. implemented a computer-based tobacco prevention intervention in 52 schools in West Midlands, United Kingdom.[69] During school year 9, students ranging in age from 13 to 14 years received three class lessons and three interactive computer sessions (including video clips of young people discussing their smoking). The intervention continued throughout the ninth-grade year; the investigators administered a self-report questionnaire at baseline and at years 1 and 2.[69] At followup in years 1 and 2, the intervention and control groups did not differ significantly in effect (year 1: AOR, 1.14; 95% CI, 0.93-1.39; year 2: AOR 1.06; 95% CI, 0.86-1.31).[69]

Project FLAVOR (Fun Learning about Vitality, Origins, and Respect), a school-based program that incorporates a curriculum sensitive to multiple cultures, focused on psychosocial risk factors to prevent tobacco initiation in eight of 16 middle schools in Southern California.[81] The students were predominantly Hispanic (57 percent) and Asian American (27 percent) sixth and seventh graders. The culturally sensitive intervention programs provided eight weekly classroom sessions conducted by health educators that addressed smoking-related psychosocial concepts through activities such as role-playing, trivia games, and art projects.[81]

Students were surveyed at baseline and at 1-year followup. Overall, 8 percent of the intervention group and 11 percent of the control group initiated smoking (OR, 0.75; 95% CI, 0.48-1.18), but this difference was not significant. For one subgroup—Hispanic male never smokers—the intervention prevented smoking initiation between the two grades (OR, 0.49; 95% CI, 0.27-0.88).[81]

Two single-school-year smoking prevention programs compared classroom instruction to an alternative, more innovative tobacco prevention program.[68,75] Vocational students (mean age 13) in 36 schools in The Netherlands participated in an in-school and out-of-school intervention to reduce tobacco initiation.[68] The in-school and out-of-school interventions and a combined in- and out-of-school intervention were compared with a control group (not described). The in-school intervention had three classroom lessons consisting of educational instruction by the teacher reading from the workbook, a classroom discussion, a workbook task, and an additional task that summarized the main points of the lesson. The out-of-school intervention comprised three tailored letters with smoking prevention messages; the letters were illustrated with a picture puzzle and several cartoons. It also included a competition in which students could win CD vouchers. The letters were mailed to students' homes at 3-week intervals.[68]

Students' self-reported their smoking status at pretest and 6, 12, and 18 months following the intervention. Immediate treatment effects were not apparent at 6 months; at 12 months the in-school intervention was more effective at discontinuing smoking than the control condition (OR, 0.49; 95% CI, 0.29-0.84). At 18 months, the tailored out-of-school intervention was effective in preventing smoking initiation compared with the control condition (OR, 0.42; 95% CI, 0.18-

0.96). The combined approach was not as successful as the in-school and the out-of-school efforts.[68]

D.A.R.E., based on the decisionmaking model, has been widely implemented in elementary schools and extensively evaluated. D.A.R.E. Plus, a new multicomponent curriculum used in middle and high schools, has received less attention than the original program.[75] An independent evaluation of D.A.R.E. and D.A.R.E. Plus in 24 Minnesota middle and junior high schools was conducted with seventh- and eighth-grade students (51.6 percent male, 67.3 percent white, 7.5 percent African American, 12.7 percent Asian American, 3.6 percent Hispanic, 4.0 percent American Indian, and 4.9 percent of mixed or other ethnicity). The research team matched students on socioeconomic status, drug use, and size of school and randomly assigned schools to one of three conditions: D.A.R.E. only, D.A.R.E. Plus, or control group. The D.A.R.E. program, taught by trained D.A.R.E. police officers, consisted of 10 sessions providing skills in resisting influences to use drugs, building character, and building citizenship skills. The D.A.R.E. Plus program has three components: (1) "On the VERGE," a classroom-based, peer-led, parental involvement program; (2) Youth Action Teams to implement in-school extracurricular activities; and (3) Youth Action Teams to address neighborhood and school-wide issues. The control group was eligible to receive D.A.R.E. Plus in 2001.[75]

Students received D.A.R.E. and D.A.R.E. Plus for about 8 months from September 1999 through April 2000.[75] The researchers collected baseline measures from seventh graders in fall 1999; the first followup was in spring 2000 (i.e., at the end of the intervention); and the final data collection occurred among eighth-grade students in spring 2001 (i.e., 12 months following the intervention). Self-reported smoking status was reported through surveys.[75]

The investigators used a three-level, linear, random-coefficient model to test for significant differences over time; they reported group slopes. No outcomes comparing D.A.R.E. with the control schools were significant. Boys in the D.A.R.E. Plus condition were significantly less likely than those in the control schools to show increases in tobacco use and intentions to use tobacco ($P = 0.04$). Boys in the D.A.R.E. Plus condition were significantly less likely than those in the D.A.R.E. condition to show increases in tobacco use and intentions to use tobacco ($P = 0.04$). No effects for tobacco use among girls were significant.[75]

Interventions implemented within a school year were able to reduce tobacco initiation among adolescents shortly after the completion of the intervention.[68,71] Two studies reviewed in this report found effects for boys but not girls; one of these studies, the culturally sensitive intervention, reduced tobacco initiation exclusively among Hispanic boys.[75,81]

Several school-based interventions (in the United States, Australia, Canada, and Norway) occurred over multiple school years.[70,72,74,76,82] The interventions included classroom instruction, teacher training, parent involvement, extracurricular school activities, community assessment, advocacy, and projects.[70,72,74,76,82] Students ranged from seventh graders through 12th graders. Study populations varied. One study implemented the intervention in a primarily Latino population;[82] another involved both rural and urban communities with a high percentage of Native Americans (12.5 percent nonwhite);[72] and the other studies did not specify ethnicity of the population.[70,74,76] The sample size for the five multiple-year studies ranged from 22 to 99 schools and 813 to 4,276 students.

Students were exposed to smoking prevention interventions from 2 to 3 years. Investigators collected follow-up measures at the end of the interventions[70,72,74,76,82] and up to 6 months following conclusion of the interventions.[82] Two studies used control groups that were later eligible for the intervention;[72,76] other control groups received some type of prevention

activities.[70,74,82] Only two multiple-year studies relied significantly on classroom instruction;[72,74] the other tobacco prevention studies used multicomponent interventions that included school, family, and community activities.[70,76,82]

Project ALERT, a well-known adolescent drug prevention program, aims to change students' perceptions of drug norms and the social, emotional, and physical consequences of drug use. A revised version of Project ALERT emphasizes curbing alcohol misuse (rather than abstinence), increases attention to current smokers, and brings parents into the prevention process.[72]

In urban and rural communities in South Dakota, Project ALERT was evaluated in 55 middle schools with seventh- and eighth-grade students (13 percent nonwhite; 51 percent male).[72] The curriculum included 11 lessons in seventh grade and three lessons in 8th grade that used interactive teaching methods focusing on motivation and resistance skill-building. Another important element of this program was home learning, which sought to involve parents in substance use prevention. The control schools receive a delayed experimental program at the conclusion of the study.

Students completed surveys at baseline in the fall of seventh grade and 18 months later in the spring of 8th grade. Self-reported smoking status was validated by collecting salivary cotinine levels for a random subsample of 654 students. At 18 months, cigarette initiation rates in Project ALERT (25.5 percent) were significantly lower than in the control group (31.6 percent, $P < 0.01$). From the baseline assessment to the 18-month followup, Project ALERT reduced the proportion of new smokers by 19 percent ($P < 0.01$).[72]

BE smokeFREE comprises an intensive intervention conducted over 3 school years. The program delivered classroom sessions at least five times per year from sixth through 8th grade.[74] A nationally representative sample of 99 secondary schools in Norway implemented this program.[74] Three treatment groups—the model intervention (i.e., classroom instruction, teacher in-service training, and parent involvement), the model intervention without the teacher in-service, and the model intervention without parent involvement—were each compared with a control group. The classroom instruction contained nontraditional school activities such as videos, games, and group work. The intervention used 8 hours in seventh grade, 5 hours in eighth grade, and 6 hours in ninth grade. During eighth grade, however, students and teachers requested adjustments to the intervention. Therefore, in ninth grade, students developed, carried out, and evaluated their own campaign to promote a smokefree lifestyle among the seventh graders. Parent involvement (not described) was included in the intervention. The control group received education on smoking and health but only for about half the number of hours as the intervention groups.[74]

Students self-reported smoking behaviors on surveys administered by teachers at the end of each of the 3 academic years. The proportions of smokers were significantly higher in the control group than in the model intervention for all 3 follow-up years (1995, $F = 5.66$; $P < 0.01$; 1996, $F = 7.19$; $P < 0.001$; 1997, $F = 4.05$; $P < 0.05$). In both the interventions without teacher in-service training and without parent involvement, the proportions of smokers on all follow-up occasions were higher than in the model intervention but lower than in the control group (1995, $F = 2.84$; $P < 0.01$; 1996, $F = 3.98$; $P < 0.001$; 1997, $F = 2.46$; $P < 0.05$). The odds of becoming a smoker during the intervention period were significantly lower in the model intervention than in the control group for daily smoking (Wald's 9.81, $P = 0.02$), for weekly smoking (Wald's 15.65, $P = 0.0001$), and for any smoking (Wald's 16.54, $P = 0.0001$).[74]

Several school-based tobacco prevention programs not only involve students but also include parents and surrounding communities. In one particular intervention, students were recruited

from elementary schools with tobacco prevention programs.[70] Thirty Canadian high schools selected for the study enrolled at least 30 students who had participated in an elementary school smoking prevention study; receiving such students was an eligibility requirement for schools.[70]

In the 15 intervention schools, the investigators recruited teachers, staff, students, and community members to participate in antismoking activities. Teachers helped students, staff, and community members to plan and implement prevention and cessation activities tailored to each intervention school to build commitment and strengthen school social norms toward not smoking. The research staff provided consultation, conducted semiannual workshops for teachers and student leaders, developed resources for dissemination to all intervention schools, produced newsletters, and provided a $1,000 per school annual budget.

Students in the ninth and tenth grades were exposed to the intervention for 1 year; data on smoking status were collected by survey at the end of the year. Investigators collected a "bogus" biochemical verification using carbon monoxide (CO) breath samples to enhance validity of the self-reported data. The control schools had "usual" programs but these were not described.[70]

Extracurricular activities produced by the intervention schools consisted of quit-and-win contests, poster contests, displays, health fairs, and smoking surveys (not associated with the study survey). On average, 3.8 intervention activities occurred in the 9th grade and 3.5 activities in 10th grade. At baseline, intervention schools had a marginally higher proportion of students who had previously been in the elementary intervention condition ($P = 0.10$). After adjusting for the baseline difference, male nonsmokers at baseline were significantly less likely to be "regular" smokers in 10th grade in the intervention schools than males in the control schools (9.8 percent vs. 16.4 percent, $P = 0.02$). Among females, intervention and control groups did not differ.[70]

High schools from San Francisco and San Jose, California, were randomly allocated in a school-based intervention study conducted in 10 continuation high schools.[82] Advocacy activities related to advertising, availability, and use of tobacco were implemented in the intervention school to reduce tobacco initiation among students. Twenty-five 11th and 12th grade students volunteered to participate from each school (43 percent Latino, 21 percent white, 15 percent of mixed ethnicity, 13 percent Asian or Pacific Islander, 4 percent African American, and 4 percent other).[82]

The three-phase intervention lasted 2 years. It included advocacy and empowerment classes that dispelled misconceptions about cigarette smoking and raised students' awareness of environmental influences (e.g., tobacco company advertising). It also helped students to develop advocacy skills (e.g., by practicing persuasive communication) and to conduct a community assessment and advocacy project. The control groups received an existing substance abuse curriculum not specific to tobacco that was developed for continuation high school students.[82]

Students completed surveys at baseline, at the end of the semester, and 6 months after the end of the intervention. The two groups differed slightly at baseline for smoking and sociodemographic characteristics, but the investigators did not report percentages. The results, reported as net percentage changes from baseline smoking to after intervention, showed no significant changes after the intervention or at 6-month followup for nonsmokers (0.2 percent net change, $P = 0.93$).[82]

Using community organization theory, one group studied 7th through 10th grade students in 22 schools in New South Wales, Australia; the researchers encouraged intervention schools to adopt their own Health Promoting Schools (HPS) program.[76] A key individual identified for each school took responsibility for planning, implementing, and monitoring HPS strategies such as developing a minimum set of health promotion actions for the school.

The schools received this community-based tobacco prevention intervention for 2 years. In November 1995, the investigators collected baseline data; in November 1997, they administered a posttest survey to the same cohort. They used a self-reported retrospective diary; students reporting having smoked any amount of cigarettes within the past 7 days were considered smokers.

In the final analysis, the research team matched pre-post data, which considerably reduced the sample size (N = 1,852). The odds of males smoking at posttest were almost half the odds of females (AOR, 0.55; 95% CI, 0.35-0.87). The proportion of students who had smoked in the last week did not differ significantly by treatment condition, indicating that the intervention was not effective.[76]

*Provider-based interventions to reduce tobacco initiation***.** Only one study (Table 9) used providers to reduce tobacco initiation.[80] The study participants were survivors of pediatric cancer from St. Jude Children's Research Hospital in Memphis, Tennessee, who were currently disease-free and at least 1 year from completion of antineoplastic therapy. On enrollment, the investigators randomly assigned 103 patients, stratified by age (ages 10 to 13 years and ages 14 to 18 years), gender, and race, to the tobacco-risk counseling intervention or a standard care group. The intervention occurred in a single session with periodic reinforcement of tobacco goals by telephone. A physician feedback letter reinforced the antitobacco messages, and tobacco literature was mailed to the patient. To reinforce previously established goals and address barriers, the investigators did follow-up telephone counseling at 1 and 3 months. Patients in the control group were asked about their tobacco use and briefly advised about the health risks associated with tobacco use. All tobacco users were advised to stop; nonsmokers were encouraged to continue to resist tobacco.[80]

Table 9. Effective provider-based interventions

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Tyc et al., 2003[80] United States St Jude's Children's Research Hospital, Memphis, Tennessee	RCT Education and counseling over 3 months 6 and 12 months	G1: Self-help, individual counseling, health professional telephone counseling, video C1: Brief advice to stop smoking or continue not smoking	103 cancer survivors (10 to 18 years of age)	Intervention group had higher mean knowledge and perceived vulnerability scores and lower intention-to-use tobacco scores	Fair

C, Control Group; G, Intervention Group; RCT, randomized controlled trial.

Patients in the intervention and control groups were assessed by questionnaire at baseline and at 6 months and 12 months following the intervention.[80] Baseline measures were similar across the two groups; 95.1 percent of the participants were classified as nonsmokers. At 12 months, multivariate comparison of difference scores for patient smoking status (12-month scores minus baseline scores) found no differences (all were $P > 0.10$), indicating the intervention had no effect on smoking initiation.

KQ 2. Effective Strategies for Increasing Consumer Demand For and Use of Proven Individually Oriented Cessation Treatments

We discuss KQ 2 in two main parts: evidence concerning interventions aimed at increasing the number of smokers who attempt to quit, and evidence about strategies for improving the impact of those interventions. As with KQ 1, in both cases we first review the existing information from recent systematic reviews, and then we turn to the new literature uncovered by our searches. Appendix C[‡] presents the two evidence tables (Evidence Tables 4 and 5) with the details of studies from the current literature.

Increasing the Number of Users Who Attempt to Quit

Spontaneous and unassisted rates of tobacco use cessation among tobacco users are low (3 percent to 10 percent).[5] Interventions to increase the number of tobacco users who seek assistance in quitting and who successfully quit include efforts to increase the number of users who attempt to quit, improve the success rate for quit attempts, and achieve both of these goals.[7]

Proven individual strategies for helping smokers to quit include counseling, behavioral therapy, and, except when contraindicated, the use of first-line and second-line medications.[5] More often than not, individuals are trying to quit without assistance that can double or, in some cases, triple their chances of success.[5]

Synthesis of prior systematic reviews. Reviews of population-wide interventions to increase tobacco use cessation have focused on five elements: (1) multicomponent efforts to increase patient tobacco use cessation, which include telephone information or counseling support; (2) mass media campaigns combined with other interventions; (3) mass media cessation series; (4) mass media cessation contests; and (5) increases in the unit price of tobacco products. The Task Force on Community Preventive Services (hereafter, Task Force) focused on all five issues.[7] The 2000 update of the 1996 Agency for Health care Policy and Research (AHCPR) guideline (*Treating Tobacco Use and Dependence*)[5] and a 2003 Cochrane Review concentrated on the first topic (multicomponent efforts).[66]

Multicomponent efforts. Based on a systematic review of 32 studies evaluating the effectiveness of telephone cessation support, the Task Force found strong evidence of effectiveness for telephone cessation support to increase tobacco use cessation when implemented with other interventions such as educational approaches or clinical therapies in clinical and community settings.[7] Telephone support was coordinated with additional interventions, including client education, provider-delivered counseling, nicotine replacement, a smoking cessation clinic, and a televised cessation series. Effective telephone counseling interventions combined either proactive telephone support (i.e., the provider initiated contact) or reactive telephone support (i.e., the caller initiated contact, with provider followup) and client cessation materials. In the 30 studies comparing differences in cessation of tobacco use based on use of or exposure to telephone support, tobacco use cessation increased 2.6 percentage points (range, -3.4 to +23) in follow-up periods of 5 weeks to 34 months (median, 12 months).[7]

[‡] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/tobusetp.htm.

On the basis of a meta-analysis of various formats of psychosocial treatments (e.g., self-help, proactive telephone counseling, group counseling, and individual counseling), Fiore et al. found proactive telephone counseling to be effective at increasing abstinence rates relative to no intervention (OR, 1.2; 95% CI, 1.1-1.4).[5] The estimated abstinence rate based on this meta-analysis was 13.1 percent (95% CI, 11.4-14.8). The guideline update also found, as did the Task Force, that interventions delivered in multiple formats increased abstinence rates compared with no format. Odds ratios for one format were 1.5 (95% CI, 1.2-1.8); for two, 1.9 (95% CI, 1.6-2.2) and for three or four, 2.5 (95% CI, 2.1-3.0). Estimated abstinence rates were 15.1 (95% CI, 12.8-17.4), 18.5 (95% CI, 15.8-21.1), and 23.2 (95% CI, 19.9-26.6), respectively, compared with a no-counseling format.

In another meta-analysis using all less-intensive intervention arms as the control (as opposed to those providing tailored self-help materials), telephone counseling increased quit rates (OR, 1.56; 95% CI, 1.38-1.77).[66] Investigators found no differences in quit rates in four trials that added telephone counseling support to a face-to-face intervention, in four trials that added telephone counseling support for users of nicotine replacement therapy, or in trials comparing different types of telephone counseling.

Mass media campaigns combined with other interventions. Mass media educational campaigns employ brief, recurring messages over time to provide information or motivation to tobacco users and others (e.g., family members, households, peers) with the goal of increasing or improving efforts to stop using tobacco products. Campaigns can focus on cessation, include cessation themes within a broader range of tobacco messages, or be combined with other interventions such as an excise tax increase or other related, community-wide education efforts.

Mass media campaigns, when combined with other activities, were effective in increasing tobacco use cessation by approximately 2 percentage points, in reducing overall tobacco consumption measured on a population basis by almost 13 percent, and in lowering the prevalence of tobacco use by approximately 3 percentage points.[7] Mass media campaigns can also increase the number of people who seek telephone support for quitting smoking. The Task Force found "strong" evidence of the effectiveness of such campaigns when combined with activities to increase tobacco use cessation and reduce tobacco consumption; activities include excise tax increases or other community-wide educational efforts.[7]

Mass media cessation series. Mass media cessation series consist of broadcasted instructional segments designed to recruit, inform, and motivate users of tobacco products to try quitting and to succeed.[7] Cessation series can be coordinated with broadcasts or print promotions that precede the series itself, community education, or organization of cessation groups in the community. Such series can last a period of several weeks to several months.

After reviewing nine studies evaluating cessation series, the Task Force found insufficient evidence to determine the effectiveness of such interventions in increasing the number of people who successfully stop using tobacco products.[7] Studies included cessation series combined with other interventions such as community education, organized cessation groups or programs, or telephone support.

Mass media cessation contests. Cessation contests are community-wide events of short duration that use mass media to recruit and motivate users of tobacco products to participate in a program to quit by a certain date or during a specified time period. Mass media and small media (e.g., posters and flyers) promote available services and recruit tobacco product users.

The Task Force found insufficient evidence to determine the effectiveness of such contests in increasing the number of people who quit using tobacco products.[7] This conclusion was based on only one study that showed some improvement in self-reported cessation at 6-month followup.

Summary. Proactive telephone counseling is effective in increasing tobacco use cessation. Mass media education campaigns combined with other interventions are also effective in increasing tobacco use cessation. However, other types of mass media education, such as media cessation series and cessation contests, were not found to be effective.

Synthesis of current literature. Seven randomized trials describing multicomponent interventions to increase tobacco use cessation met inclusion criteria (Table 10). Four involved counseling support; of these, three investigated proactive telephone counseling and support for cessation,[84-86] and one trial of genetic susceptibility counseling incorporated smoking cessation counseling.[87] Two other studies were long-term follow-up studies of intervention effect; one study included participants in a randomized trial of a computer-tailored smoking intervention[88] and the other included participants in a randomized trial of the Lung Health Study (LHS) smoking intervention.[89] The final study focused on adolescents to examine the effectiveness of a family-directed program addressing tobacco and alcohol use among teens.[90] We did not find any new articles meeting our criteria that addressed the effects of mass media and tobacco price on increasing the number of tobacco users who attempt to quit or who are successful in quitting.

Adults were the target group in four studies,[86-89] and adolescents and young adults were the target group in the other three.[84,85,90] Trials enrolling only adults examined interventions designed to increase tobacco use cessation by providing proactive telephone counseling support[86] and incorporating genetic susceptibility to lung cancer into smoking cessation counseling.[87] Of the studies enrolling only adolescents and young adults, one tested the efficacy of self-help materials with or without proactive telephone counseling to increase cessation among teen smokers;[84] the other examined the effects of telephone counseling on smoking cessation among smokers 18 to 25 years of age and smokers over 25 years of age.[85]

For the trials, recruitment strategies included radio and newspaper advertisements,[86] contact with youth in shopping malls and an amusement park,[84] telephone calls to a random sample of families with children 12 to 14 years of age,[90] chart review and clinician referral,[87] and a survey of callers to a national quit line.[85] In the studies of persistent intervention effect, investigators recruited the original subjects in one study by mailed announcements to a random sample of residents in a defined area[88] and, in the other, by random sample of an unspecified population for a multicenter trial.[89]

Smokers were defined in various ways at intake: daily smokers;[86] daily smokers for 1 year and with an expired CO level of greater than 8 parts per million (ppm);[89] having smoked a cigarette within the last week;[84] more than an occasional smoker;[88] current, daily smokers willing to make a quit attempt within the next 2 weeks;[85] smokers with some level of lung impairment;[87] and use of tobacco on 1 or more days during the past 30 days.[90]

Interventions were very different across trials, although all involved distribution of self-help print materials. Some interventions were tailored to stages of change; others were not. The intervention in one trial had five conditions involving combinations of counseling with variable numbers of follow-up calls (two or six) and different print materials (booklet or pamphlet).[86] In another intervention group, participants received an eight-page personal counseling letter written by a computer according to answers that participants gave on a 62-item enrollment questionnaire and two 16-page self-help booklets corresponding to their current stage of change and the next stage of change.[88] At 2, 4, and 12 months after entering the study, intervention participants

Table 10. Multicomponent interventions to increase the number of users who quit smoking

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Bauman et al., 2000[90] United States Population-based	RCT 2 months 3 and 12 months postcompletion or dropout	G1: Mailing of booklets and telephone counseling C1: NR	85 parent-adolescent pairs	No statistically significant difference in tobacco use between control and treatment for baseline cigarette users	Fair
Etter et al., 2004[88] Switzerland, Western Europe Population-based	RCT 12 months 7 and 24 months post-baseline	G1: Tailored counseling letters and booklets C1: A single letter identifying person as part of the control group	2,934 adults	At 7 months, significantly more people in the intervention than in the control group were abstinent for at least 1 month (G1: 5.8%; C1: 2.2%; $P \leq 0.001$) No difference between groups at 24 months.	Fair
Lipkus et al., 2004[84] United States Community-based	RCT 2 months 4 and 8 months post-baseline	G1: 2 self-help booklets in mail; 6-minute video; 3 telephone counseling C1: 2 self-help booklets in mail; 6-minute video; no telephone counseling	402 adolescents	No differences in abstinence at 4- or 8-month followup or for sustained abstinence Participants completing more counseling calls were more likely to report cessation at 4 and 8 months (8-month OR = 1.54, 95% CI, 1.15-2.07, $P < 0.007$)	Fair
McBride et al., 2002[87] United States Practice/ provider settings	RCT 10 weeks 6 and 12 months	G1: Provider advice to quit smoking; referral to smoking specialist; self-help guide; if eligible, nicotine patches G2: Self-help guide; if eligible, nicotine patches and refills; biomarker feedback and tailored booklet	557 adults; low SES; African American	Significantly more participants of G2 than G1 were not smoking at 6 months (G1: 10%, G2: 19%; $P = 0.03$) and had sustained abstinence (G1: 5%, G2: 11%; $P = 0.08$)	Fair
Murray et al., 2002[89] United States, Canada Practice/ provider settings	RCT 3 months 11 years	G1: Ipratropium bromide inhaler, placebo inhaler C1: Usual care	4,517 adults	More participants in G1 than in C1 had sustained abstinence (G1: 21.9%, C1: 6.0%; $P \leq 0.001$)	Fair

ACS, American Cancer Society; C, control group; G, intervention group(s); NR, not reported; OR, odds ratio; RCT, randomized controlled trial; SES, socioeconomic status.

Table 10. Multicomponent interventions to increase the number of users who quit smoking (continued)

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Rabius et al., 2004[85] United States Population-based	RCT Varies by quit date, up to 5 followup calls, up to 2 weeks postquit date 3 and 6 months	G1: ACS booklets and standard advice plus up to 5 sessions of proactive telephone counseling C1: ACS booklets and standard advice	3,522 young adults, adults	G1 group had higher rates of 48-hour abstinence than C1 group at 3 months (18–25 years: G1: 19.6%, C1: 9.3%; $P < 0.005$; over 25 years: G1: 15.1%, C1: 9.6%; $P < 0.001$) Participants abstinent at 3 months were called at 6-month followups: (18–25 years: G1: 9.8%, C1: 3.2%; $P < 0.01$;over-25 years: G1: 8.8%, C1: 5.3%; $P < 0.005$)	Fair
Smith et al., 2004[86] Canada Population-based	RCT 3, 6, and 12 months	G1: Telephone counseling, 2 follow-up calls, booklet G2: Telephone counseling, 2 follow-up calls, pamphlet G3: Telephone counseling, 6 follow-up calls, booklet G4: Telephone counseling, 6 follow-up calls, pamphlet C1: Print materials only	632 adults	Intervention groups combined (G1, G2, G3) had significantly higher continuous abstinence rates than control group: (G1, 2, 3: 5%, C1: 1%; $P \leq 0.05$)	Fair

could answer tailoring questions again to receive a new letter. In another trial, content of calls was customized and based on each participant's stage of readiness to quit.[84] Calls were designed to encourage use of self-help booklets, move the participant toward quitting, and assist those ready to quit.[84] In another study, the intervention used three booklets with standard advice plus up to five sessions of proactive telephone counseling.[85] One study incorporated genetic susceptibility for lung cancer counseling and related print material (an eight-page test result booklet) into usual smoking cessation counseling.[87] Only one trial included nicotine replacement therapy as part of the study, but the therapy was made available to both the intervention and control groups.[87]

Followup to assess smoking status occurred at various times in the current trials: 3 and 6 months;[85] 3 and 12 months;[90] 3, 6, and 12 months;[86] 4 and 8 months;[84] and 6 and 12 months.[87] In the persistence of effect studies, followup occurred at 7 and 24 months[88] and at 11 years.[89] Followup occurred at the specified time after baseline in three studies,[84,87,88] after the quit date in one,[85] and after completion of the intervention in another.[90]

Outcome measures included various definitions of abstinence: 1-month abstinence (not smoking even a puff of a tobacco cigarette, cigar, or pipe in the last 4 weeks);[88] 1-week abstinence (not smoking even a puff of a tobacco cigarette, cigar, or pipe in the past 7

days);[84,86-88] no smoking in the past 48 hours;[85] and self-reported cessation with no time frame specified.[89] Continuous abstinence, which five studies used as a primary outcome, was defined as abstinence at all reporting periods.[84-87,89]

Smoking status results. Of the four trials of counseling support, three focused on telephone counseling and associated print materials.[84-87] One study reported statistically significant increases in continuous abstinence among those receiving telephone counseling compared with control participants receiving only print materials (5 percent vs. 1 percent, $P < 0.05$).[86] Another study reported statistically significant higher rates of prevalence of reported abstinence during the past 48 hours for participants in the treatment group compared with those in the control group in two age categories (younger than 18 years of age and 18 to 25 years of age). At 3-month followup, differences by age were 19.6 percent vs. 9.3 percent ($P < 0.005$) for younger smokers and 15.1 percent vs. 9.6 percent for older smokers.[85] The trial of counseling support showed that smoking cessation was greater for the group receiving genetic feedback and counseling than for controls at 6 months but not at 12 months.[87] Finally, one trial failed to show any significant group differences in either abstinence at each follow-up assessment or in continuous abstinence.[84]

Other outcomes. Beyond smoking status, four studies also assessed other primary and secondary outcomes associated with multicomponent interventions: quit attempts, days of smoking abstinence, and use of nicotine replacement. One study of persistent effect found that more participants in the intervention group than in the control group reported making a 1-month quit attempt and having more days of smoking abstinence.[88] More participants in the intervention group than in the control group had used nicotine replacement products in two studies.[85,88] Two studies showed no difference in nicotine replacement therapy use across groups.[86,87]

Adolescents and young adults. Two studies in this review showed that telephone counseling that targets youths achieved success comparable to that shown for adult smokers.[84,85] This finding suggests that younger smokers can benefit from telephone counseling. Three-month quit rates were 19.6 percent for persons 18 to 25 years of age who received telephone counseling and 9.3 percent for those who received self-help booklets only ($P < 0.005$). The proportions reporting abstinence during the preceding 48 hours at both the 3- and 6-month follow-up interviews were also significantly different in the treatment group for this age cohort (9.8 percent vs. 3.2 percent, $P < 0.01$)[85]

Persistence of effect. Two studies reported long-term follow-up results of previous RCTs. The trial of a computer-tailored smoking cessation program showed, at the 7-month assessment, a significant increase in 4-week abstinence rates and 7-day quit rates compared with rates for controls. At 24 months after intervention, these differences had disappeared.[88] The second follow-up study found that smokers exposed to an aggressive smoking intervention program who sustained abstinence for a 5-year period were very likely to still be abstinent after 11 years.[87,89]

Improving the Success Rate of Quit Attempts

Synthesis of prior systematic reviews. *Self-help approaches.* In a meta-analysis including self-help as one format for assisting smokers in their quit attempts, Fiore et al. showed that self-help was of marginal efficacy.[5] Further meta-analysis of studies in which self-help constituted the sole difference in treatment arms also indicated that self-help is 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.

Lancaster and Stead reported that providing smokers with materials to support quit attempts is of limited benefit unless the materials take into account each smoker's individual characteristics.[59] Advice and behavioral counseling can help smokers to quit.[59] Giving the same type of support via written materials or other media has not been found to be very helpful, although people given no other support may experience a small benefit.

These same authors examined 33 trials that compared self-help materials to no intervention or tested materials used in addition to advice.[59] In 11 trials in which self-help was compared with no intervention, a pooled effect just reached statistical significance (N = 13,733; OR, 1.24, 95% CI, 1.07-1.45). Four other trials in which the control group received alternative written materials did not show an effect for the smoking self-help materials. The review failed to find evidence of benefit from adding self-help materials to either face-to-face advice or to nicotine replacement therapy.

Seventeen trials used materials tailored for the characteristics of individual smokers; meta-analysis by Lancaster and Stead supported a small benefit for tailored materials (N = 20,414; OR, 1.42; 95% CI, 1.26-1.61).[59] The evidence was strongest for tailored materials compared with no intervention, but it also showed that tailored materials were more helpful than standard materials. A small number of other trials failed to detect benefits from using additional materials or targeted materials or to find differences between different self-help programs.

Counseling. In another review, Lancaster and Stead looked at trials of counseling by a trained therapist in one or more face-to-face sessions (separate from medical care).[60] All trials involved sessions lasting more than 10 minutes, with most including further telephone contact for support. A review of 21 trials with more than 7,000 participants showed that individual counseling for smoking cessation was more effective than the control (OR, 1.56; 95% CI, 1.32-1.84). In a subgroup of three trials in which counseling had been tested as an adjunct to nicotine replacement therapy, the point estimate of effect was smaller and did not reach significance (OR, 1.34; 95% CI, 0.98-1.83). Meta-analysis did not detect a greater effect of intensive counseling than brief counseling, although the confidence intervals are wide and do not exclude the possibility of a clinically useful dose-response effect (OR, 0.98; 95% CI, 0.61-1.56).

In another review by Stead and Lancaster of 16 studies that compared a group program with controls receiving no intervention, cessation increased with the use of a group program (N = 4,395; OR, 2.04; 95% CI, 1.60-2.60).[65] In seven trials, group programs were more effective than no intervention controls (N = 815; OR, 2.17; 95% CI, 1.37-3.45). No evidence emerged that group therapy was more effective than a similar intensity of individual counseling. Also, limited evidence suggested that programs with components for increasing cognitive and behavioral skills and avoiding relapse were more effective than programs of the same length or shorter without these components.

Group therapy was shown to more than double the chances of quitting as compared with self-help and other less intensive interventions.[65] Evidence is insufficient to evaluate whether groups are more effective than intensive individual counseling and to support the use of particular psychological components in a program beyond the support and skills training normally included. Only limited evidence suggests that adding group therapy to other forms of treatment (adjunctive group therapy), such as advice from a health professional or nicotine replacement, produced extra benefit.[65] Not all smokers making a quit attempt want to attend group meetings, but those who do are likely to find the meetings helpful if such activities offer assistance equivalent to intensive individual counseling.[65]

In updating the 1996 AHCPR clinical practice guideline, Fiore et al. found that minimal interventions lasting less than 3 minutes increased overall tobacco abstinence rates.[5] They also reported a strong dose-response relation between length of person-to-person contact during a counseling session and successful treatment outcomes. In general, intensive interventions were more effective than less intensive interventions.

The Fiore et al. review also indicated that intensive interventions for smoking cessation should include an assessment to ensure that tobacco users are willing to make a quit attempt using an intensive treatment program.[5] Other assessments can provide information useful in counseling (e.g., stress level, presence of comorbidity), but little consistent evidence exists to show that a smoker's status on a specialized assessment is useful in treatment matching. Regardless of their standing on specialized assessments, all smokers have the potential to benefit from cessation interventions. Tailored interventions based on specialized assessments (e.g., stages of change) do not consistently produce higher long-term quit rates than nontailored interventions of equal intensity. Because of the evidence of a strong dose-response relation, the intensity of a smoking cessation program should be defined as a session lasting longer than 10 minutes, with four or more sessions, for a total contact time longer than 30 minutes.

In terms of format, Fiore et al. used meta-analysis to compare self-help, proactive telephone counseling, group counseling, and individual counseling with no format.[5] All four formats increased the likelihood of success in quitting; group counseling (OR, 1.3; 95% CI, 1.1-1.6) and individual counseling (OR, 1.7; 95% CI, 1.4-2.0) had the two highest odds ratios.

The use of adjuvant self-help material is optional, but follow-up assessment intervention procedures should be used.[5] Smoking cessation interventions that used more than two formats were more effective than interventions that used a single format.

Particular types of counseling and behavioral therapies are especially effective.[5] Practical counseling (e.g., problem-solving and skills-training approaches) and the provision of intratreatment social support and extratreatment social support (e.g., help in securing social support outside of treatment) are associated with significant increases in abstinence rates, as are aversive smoking techniques (e.g., rapid smoking). Tobacco dependence treatments are effective across diverse populations (e.g., populations varying in gender, age, and ethnicity).

The review in the 2000 Surgeon General's report found that pharmacologic treatment of nicotine addiction, combined with behavioral support, enabled 20 percent to 25 percent of users to remain abstinent at 1 year after treatment.[2] Even less intense measures, such as physicians' advising their patients to quit smoking, produced cessation rates of 5 percent to 10 percent.

Evidence was mixed on the efficacy of self-help manuals as an aid to smoking cessation. Programs using advice and counseling—whether minimal or more intensive—have helped a substantial proportion of people quit smoking. The success of counseling and advice rises with the intensity of the program and may be improved by increasing the frequency and duration of contact.

Pharmaceuticals. Fiore et al. found that pharmacotherapies such as bupropion sustained release (SR) or nicotine replacement therapies (e.g., nicotine gum, nicotine inhaler, nicotine patch, nicotine nasal spray) consistently increased abstinence rates.[5] They conducted two sets of meta-analyses. One meta-analysis examined first-line pharmacotherapies (i.e., those agents found to be safe and effective for smoking cessation and approved by the US Food and Drug Administration [FDA] for such use). The other was for second-line pharmacotherapies (i.e., agents where evidence of their efficacy for treating tobacco dependence exists, but they have a more limited role than first-line pharmacotherapies both because the FDA has not approved them

for a tobacco dependence treatment indication and because they raise more concerns about potential side effects than first-line medications).

First-line pharmacotherapies, which include bupropion and the nicotine replacement therapies, consistently increased abstinence rates.[5] Second-line pharmacotherapies, including clonidine and nortriptyline, also demonstrated efficacy. The combination of the nicotine patch with a self-administered form of nicotine replacement therapy (either gum or nasal spray) was more effective than a single form of nicotine replacement. Evidence was inconsistent on effectiveness of other pharmaceutical treatments (e.g., antidepressants other than bupropion SR and nortriptyline, anxiolytics, benzodiazepines, beta-blockers, silver acetate, and mecamylamine).

The Surgeon General's report indicated strong, consistent evidence that pharmacologic treatments for smoking cessation (nicotine replacement therapies and bupropion, in particular) can help people quit smoking.[2] Clonidine and nortriptyline may have some utility for smoking cessation, but, as noted, the FDA has not approved them for this indication.

Synthesis of current literature. We identified 31 studies not covered by earlier publications that involved self-help, counseling, and pharmaceutical therapies. (Table 11).[91-121] Of these, we rated 10 articles as poor quality and do not discuss them further in this section.[92-96,108,110,111,117,118] Detailed data on all studies can be found in Evidence Table 5.

Self-help approaches. Two studies examined a self-help approach to improving cessation rates. One study involved patients recently discharged from intensive care units (ICUs).[115] This intervention included (1) verbal encouragement to remain nonsmoking at ICU discharge and at 8-week and 6-month clinic follow-up visits, (2) instructions for patient's immediate family not to smoke in the same room as the patient, and (3) a 6-week self-help ICU rehabilitation manual for the patient and his or her relatives. The manual emphasized the importance of remaining nonsmoking and provided practical tips for smoking cessation along with other general tips.

Patients receiving an ICU rehabilitation package were much less likely to return to smoking after discharge from the ICU than control patients, even though control patients received verbal encouragement to quit smoking during the recovery period.[115] The investigators could not determine whether the smoking cessation advice in the ICU rehabilitation package or the whole package in general was responsible for the high quit rate. Including an exercise program in the package may have enhanced the likelihood of quitting smoking.

The other trial included patients undergoing lung cancer screening.[109] Participants in one intervention group received a handout with a list of 10 Internet sites related to stopping smoking and a brief description of each site; those in another group received two self-help booklets for smoking cessation, one of which provided up-to-date information on available pharmacotherapies for nicotine dependence.

In this trial, the groups did not differ significantly in 7-day point prevalence quit rates or in advancement in motivational readiness.[109] At 1-year followup, more of the subjects receiving Internet-based resources reported making a stop attempt (68 percent vs. 48 percent; $P = 0.011$).

Counseling. Five studies evaluated the effects of counseling—two studies in the hospital setting,[112,120] one in a combination of primary care clinics and hospitals,[119] and two in private practices.[105,121] All female adult smokers were eligible for enrollment in one hospital-based studies[120] and all adult smokers in the other.[112] All diabetic adult and young adult smokers were eligible for enrollment in the combined-setting study.[119] All interventions included nurse

Table 11. Strategies to improve success rates for quit attempts for general and special populations

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Aveyard et al., 2003[105] United Kingdom Practice/ Provider Settings	RCT 9 months 12 months post baseline	G1: Pro-Change self-help system with workbook and 3 questionnaires to generate tailored feedback G2: G1 plus three telephone calls G3: G1 plus three 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-months sustained abstinence and 12-months point prevalence	Fair
Bohadana et al., 2000[91] France, Western Europe Practice/provider settings	RCT 26 weeks 6 weeks; 3, 6, and 12 months	G1: Nicotine inhaler and nicotine patch C1: Nicotine inhaler and placebo patch	400 adults	Abstinence was greater at 3 months for intervention group than control group (P = 0.02) No significant difference between groups at 6- and 12-month followups	Fair
Canga et al., 2000[119] * Spain, Western Europe Practice/provider settings Hospital	RCT with systematic randomization 6 months 6 months	G1: Interview with nurse; self-help materials; 3 months 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	Those in the intervention were significantly more likely than those in the control to quit at 6-month followup (validated): ($P \leq 0.001$)	Fair
Carpenter et al., 2004[98] United States Population-based	RCT 24 weeks 3, 6, 12 and 24 weeks	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 months, those receiving either intervention had greater percentages of “24 hour quit attempts” (G1: 43% and G2: 51%) than those who received no treatment (C1: 16%) ($P < 0.01$)	Fair
Clark et al., 2004[109] United States Hospital Practice/provider settings	RCT Given materials at time of chest CT scan 1 and 12 months	G1: Internet cessation resources handout with Web site addresses C1: Standard self-help material—NCI handout, ACS booklet	171 adults, > 50 years of age	No statistically significant differences in smoking status found at 1-month or 1-year followup	Fair

ACS, American Cancer Society; C, Control Group; CBT, cognitive behavioral therapy; CT, computed tomography; ICU, intensive care unit; G, Intervention Group(s); NCI, National Cancer Institute; ng/ml, nanogram per milliliter; NRT, nicotine replacement therapy, RCT, randomized controlled trials.

*: General and special populations

†: Special populations only

Table 11. Strategies to improve success rates for quit attempts for general and special populations (continued)

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Dalsgareth et al., 2004[106] Denmark Hospital	RCT 7 weeks 26 weeks post-baseline	G1: 2 motivating phone calls, 5 clinic visits, and sustained-release bupropion hydrochloride C1: 2 motivating phone calls, 5 clinic visits, and placebo	336 adult hospital employees	Continuous abstinence at 26 weeks: G1 = 18% C1 = 7% *P* = 0.008	Fair
Garvey et al., 2000[107] United States Population-based	RCT 2 months 1, 7, 14, 30 days and 2, 3, 6, 9, and 12 months post-cessation	All subjects received Self help booklet and brief behavioral counseling, (5-10 minutes per visit, for 1 year) 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	At 1 year follow-up quit rates for low dependence were Placebo 11.2% 2 mg gum 19.5% 4 mg gum 18.4% (NS) High dependence smokers quit rates at 1 year 2 mg gum compared to placebo (15.7% vs. 6.1%, *P* = 0.02) 4 mg gum compared to placebo (20.7% vs. 6.1% *P* = 0.002)	Fair
Hall et al., 2004[97] United States Population-based	RCT Brief: 12 weeks Extended: 52 weeks 12, 24, 36, 52 weeks	G1: Brief nortriptyline: nortriptyline for 12 weeks; 5 counseling sessions and NRT patch at week 5 C1: Brief placebo: placebo for 12 weeks; 5 counseling sessions and NRT at week 5 G2: Extended nortriptyline: G1 + extended pharmacotherapy and counseling (1/month) for 52 weeks C2: Extended placebo: G2 but used placebo instead of nortriptyline	160 adults	At 12 weeks nortriptyline was more effective than placebo (OR = 0.69, 95% CI; 0.49-0.92, *P* = 0.02) and placebo at 52 weeks (OR = 0.47; 95% CI; 0.30-0.75, *P* = 0.001); however 52 weeks of nortriptyline did not differ significantly from placebo at that same time frame	Fair

Table 11. Strategies to improve success rates for quit attempts for general and special populations (continued)

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Hennrikus et al., 2005[112] *	RCT	G1: 2 smoking cessation manuals; community resources directory; medical record label to cue to providers; postdischarge letter	2,095 adults	Cotinine corrected intention-to-treat analysis found percentage of abstinence at 12-month followup ($P > 0.05$) NS	Fair
United States	6 months				
Hospital	7 to 18 days, 12 months postdischarge	G2: G1 plus extended bedside counseling session and 3 to 6 telephone calls for 6 months postdischarge			
		C1: 2 cessation manuals and community resources directory			
Hitsman et al., 1999[113]	RCT	G1: Individual cognitive behavioral therapy, fluoxetine 30mg for 10 weeks, fluoxetine compliance level set at < 150ng/ml	253 adults	No significant results found at 1, 3, and 6 month followup.	Fair
United States	10 weeks				
Population-based	1 week, 1, 3, and 6 months postquit date	G2: Same as G1, except fluoxetine dose of 60mg and fluoxetine compliance level set at 300ng/ml		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	
		C1: Individual cognitive behavioral therapy plus placebo			
Holt et al., 2005[114] *	RCT	G1: Bupropion; counseling	134 adolescents; young adults; adults	People in the intervention group were significantly more likely than those in the control to be continuously abstinent at 3 months	Fair
New Zealand	2 months	C1: Placebo and counseling			
Community-based	3 and 7 weeks, 3, 6, 9, and 12 months posttarget quit date				
Population-based					
Jones et al., 2001[115] *	RCT	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	61 adults	Of the smokers pre-ICU admission, more returned to smoking in the control group at 6-mos followup	Fair
United Kingdom	6 months				
Hospital	8 weeks, 6 months postICU discharge	C1: G1 without the manual			

Table 11. Strategies to improve success rates for quit attempts for general and special populations (continued)

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Jorenby et al., 1999[116] United States Community-based	RCT 9 weeks 10 weeks, 3, 6, and 12 months post 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 buproprion and patch were most likely ($P \leq 0.001$) to be abstinent at 6 and 12 months	Fair
Killen et al., 2000[99] United States Population-based	RCT 17 weeks 4, 10 and 26 weeks	G1: NRT transdermal system patch for 8 weeks plus 20 mg paroxetine for 9 weeks G2: NRT transdermal system patch for 8 weeks plus 40 mg paroxetine for 9 weeks C1: NRT transdermal system patch for 8 weeks plus placebo for 9 weeks	224 adults	No significant differences in abstinence groups found between groups at any follow up time period	Good
Lancaster et al., 1999[121] United Kingdom Practice/provider settings	RCT with systematic randomization 6 weeks 3 and 12 months postquit date	G1: Brief advice to quit from general practitioner, plus: extended counseling 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 month followups	Fair
Lerman et al., 2004[100] United States Population-based	RCT 8 weeks 8 weeks and 6 months	G1: 8 weeks of nicotine nasal spray and 7 sessions of behavioral group counseling G2: 8 weeks 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 months (G1: 12.2%, G2: 15%, NS) Smokers who were highly dependent, obese, or members of minority groups achieved higher rates of abstinence with nasal spray	Fair

Table 11. Strategies to improve success rates for quit attempts for general and special populations (continued)

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
MacLeod et al., 2003[104] Australia Population-based	RCT 10 weeks 1, 2, 3 and 6 months	G1: Nicotine Patch and 5 telephone counseling calls C1: Nicotine Patch only	854 adults	Telephone counseling improves cessation rates when used in conjunction with the patch 28-day continuous abstinence rates at 6-months: G1 30.6%, C1 22.4%, *P* = 0.01 90-day continuous abstinence rates G1 26.7%, C1 18.6%, *P* = 0.004	Good
McBride et al., 2004[122] † United States Military Medical Center	RCT First trimester to delivery and 12 months postpartum 28 weeks pregnant Postpartum 2, 6, and 12 months	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: 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 group (15%) than C1 group (5%) *P* = 0.02	Fair
Peterson 2004[120] * United States Hospital	RCT 3 months 12 months	G1:Brief physician counseling and usual care plus nurse managed, cognitive behavioral relapse prevention intervention given pre-discharge, <5 structured telephone contacts discharge, and relapse management counseling as needed C1: Brief physician counseling, a self-help pamphlet, and list of community resources	277 adults women	No significant differences between groups at 12 month follow ups	Fair
Quist-Paulsen et al., 2003[123] † Norway Hospital – cardiac ward	RCT 5 months 12 months	G1: Self-help booklet on how to quit smoking plus cardiac nurse consultation during in-patient days and phone consultation for up to 5 months following 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 one year, the quit rate was far greater (57%) in the intensive nurse intervention versus the minimal intervention group (37%) (absolute risk reduction 20%, 95% CI 6.4-33.0; *P* = 0.004)	Good

Table 11. Strategies to improve success rates for quit attempts for general and special populations (continued)

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Ratner et al 2004[124] † Western Canada Teaching hospital	Randomized pretest-posttest control group experiment NR 6 and 12 months	G1: 2 face to face counseling sessions and 9 telephone counseling sessions C1: Standard hospital treatment	237 surgical patients	Those receiving the counseling (73%) were more likely to be abstinent than the controls (53%) (*P* = 0.003) at 6 months but the difference is not significant at 12 months after surgery	Fair
Reid et al 2003[125] † Canada Hospital, tertiary care cardiac facility	RCT 8 weeks 3 months and 1 year	G1: Self-help booklet given in the hospital, then follow-up by nurse counselor at 4 weeks after discharge; if patient smoking, nurse provides 3 twenty minute face to face sessions over 8 weeks and offered nicotine patch therapy	254 coronary artery disease hospitalized patients	Smoking cessation rates increased from 42% at hospitalization to 53% at 3 month follow up (*P* = 0.05), but not significant at 1 year follow up	Good
Simon et al., 2004[101] United States Hospital	RCT 7 weeks 7 weeks, 3, 6 and 12 months	G1: 7 week course of Bupropion, 2 months transdermal nicotine replacement therapy, 1 visit with counselor (30-60 minute 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 3, 6, and 12 months The addition of 7-week treatment with Bupropion did not significantly increase quit rates over NRT and counseling	Fair
Swan et al; 2003 and 2003[102,103] United States Practice/ provider settings	RCT 12 months 3 and 12 months	All participants received Bupropion SR for 7 weeks G1: 150 mg Bupropion SR, brief counseling call day after quit date, personalized intervention materials, and access to 24 hour automated support line G2: G1 except 300 mg Bupropion SR G3: 150 mg Bupropion SR, self-help materials, support materials for family and friends, an in-depth telephone counseling session, 4 brief telephone counseling calls, and access to toll free quitline for 1 year G4: G3 with 300 mg of Bupropion SR	1524 adults	Abstinence significantly greater at both 3 months and 1 year for those receiving intensive counseling and higher dose of bupropion (G4) vs (G1, G3) and (G3) at higher dose with brief counseling The 300 mg dose was associated with more adverse events	Fair

counseling, self-help materials, and follow-up contact either in person or by telephone, and all interventions were compared with usual care of brief advice to quit smoking, related self-help materials, or both. In the trial for women admitted to hospital with cardiovascular or peripheral vascular disease, the nicotine patch was offered (if not contraindicated) to those women who were smoking more than 19 cigarettes per day and who had not succeeded after trying to quit at least once.[119]

One hospital-based study examined the effects of three smoking cessation counseling interventions for inpatients. Interventions included modified usual care, brief advice, and brief advice plus more extended counseling during and after hospitalization.[112] Pharmacological aids were not provided. Inpatients in four hospitals were randomly assigned to each condition and followed up at 7 days and 12 months after discharge. Another hospital-based intervention involved smoking cessation and relapse prevention among women admitted to the hospital with cardiovascular or peripheral vascular disease.[119] Neither of these hospital-based interventions increased biochemically verified abstinence rates at 12 months postdischarge, although self-reported abstinence rates were significantly higher for the most comprehensive intervention group.[112]

In the combined-setting study of diabetic patients seen in primary clinics and hospitals compared with a control group, those receiving nurse-managed assistance in quitting were, at 6-month followup, significantly more likely to quit smoking.[119] This work, biochemically validated, produced quit rates of 17.0 percent for the intervention group and 2.3 percent for the control group ($P = 0.001$). Among those who did not quit, the intervention significantly decreased the mean number of cigarettes smoked per day (for the experimental group, 20.0 at baseline and 15.5 at followup; for the control group, 19.7 and 18.1, respectively, at the two measurements; $P < 0.001$).

The two different interventions for adults in private practices showed no significant differences in quit rates at 12-month followup.[105,121] One of these studies also showed no significant differences in quit rates at 3 months or in continuous abstinence between 3- and 12-month followups.[121] The other study found no significant differences in biochemically confirmed quit rates between intervention and control groups at 6-month followup, 6-month sustained abstinence, or 12-month followup.[105]

The three studies in this section among hospitalized patients are also included in a separate section of this report about interventions among hospitalized patients.[112,119,120]

Single pharmaceutical therapy. Five studies examined the effect of a single pharmaceutical treatment on smoking cessation.[100,101,106,107,114] Three studies evaluated the effect of bupropion, one studied the effect of nicotine gum and of different doses of nicotine gum, and one the comparative efficacy of transdermal nicotine and nicotine nasal spray. Two studies were based in hospitals: one accepting adults age 20 and over[101] and the other involving adults employed by the hospital.[106] Three studies were population-based and enrolled only adults.[100,107,114] One study examined efficacy of bupropion use in the indigenous Maori population in New Zealand.[114]

A 6-month, multicenter, parallel group, randomized, double-blind, placebo-controlled study compared 7-week treatment with bupropion SR (Zyban®) with placebo as an aid to smoking cessation in health care workers.[106] All participants were motivated to quit smoking and received behavioral counseling. Continuous smoking abstinence at week 7 was achieved by 43 percent in the bupropion group and 18 percent in the placebo group ($P < 0.001$). Side effects, although frequent, were simple and reversible in both groups and generally consistent with the findings of

previous studies. Dizziness, insomnia, and pruritus appeared more frequently in the bupropion group than in the placebo group.

A randomized blinded trial examined the efficacy of bupropion SR for smoking cessation among an outpatient population. Of the 244 participants, 121 received a 7-week course of bupropion and 123 received placebo.[101] All participants received 2 months of transdermal nicotine replacement therapy and 3 months of cognitive behavioral counseling. During treatment the investigators observed a trend toward increased quit rates among participants randomized to bupropion. The self-reported end-of-medication quit rates were 64 percent for the bupropion group and 57 percent for the placebo group ($P = 0.23$). The trend favoring bupropion persisted at 3 months of followup ($P = 0.12$) but was not apparent at 6 months and 1 year of followup (both $P = 0.78$). The 12-month quit rates, validated by either saliva cotinine or spousal proxy, were 22 percent in the bupropion group and 28 percent in the placebo group ($P = 0.31$). Based on biochemical validation, 19 percent of the bupropion group and 24 percent of the placebo group had quit smoking by 1 year ($P = 0.36$).

Holt et al. attempted to determine whether bupropion combined with smoking cessation counseling was effective for the indigenous Maori population of New Zealand.[114] At 3- and 6-month followup, 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 all time points. Bupropion was also safe and generally well tolerated, although three subjects did not complete treatment with bupropion because of a rash.

Garvey et al. used the Heaviness of Smoking Index, a subset of the Fagerstrom Test for Nicotine Dependence, to classify smokers planning a cessation attempt as low or high in nicotine dependence.[107] Subjects within each level of dependence were then randomly assigned to placebo, 2-mg, or 4-mg nicotine gum treatment. Subjects were also provided brief (5 to 10 minutes per visit) behavioral counseling during a 1-year period of followup. At 1 year postcessation, quit rates were 11.2 percent, 19.5 percent, and 18.4 percent for low-dependence smokers receiving placebo, 2-mg, and 4-mg gum, respectively (P linear trend = 0.20). For high-dependence smokers, quit rates at 1 year were 6.1 percent, 15.7 percent, and 20.7 percent for the placebo, 2-mg, and 4-mg gum conditions, respectively (P linear trend = 0.002). The interaction of nicotine-gum dose and dependence group was not significant ($P = 0.42$). The 2-mg and 4-mg doses did not differ significantly in effectiveness, although both doses were significantly more effective than placebo gum. Other variables related to abstinence at 1 year postcessation were a longer period of abstinence on a prior quit attempt, being married, higher education level, and having a nonsmoking spouse or significant other. Results indicate that nicotine gum is a significant aid to smoking cessation, more than doubling the odds of successful cessation compared with the odds for placebo gum users. The 4-mg dose provided a nonsignificant increase in cessation rates for high-dependence smokers.

Lerman et al. conducted a randomized, open-label clinical trial to evaluate the comparative efficacy of transdermal nicotine and nicotine nasal spray and identify predictors of treatment outcome in two university-based smoking cessation research programs.[100] Intervention consisted of behavioral group counseling and 8 weeks of therapy with nicotine nasal spray or transdermal nicotine. Abstinence rates for the transdermal nicotine and nicotine nasal spray groups were not significantly different at 6-month followup (15.0 percent vs. 12.2 percent, respectively; $P > 0.2$). 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.

Combined pharmacotherapies. Three studies examined the effect of combined pharmacotherapies on smoking cessation.[91,99,116]

In one, Bohadana and colleagues recruited subjects through a local newspaper and randomized them to either the intervention group (which received a nicotine inhaler and nicotine patch) or a control group (which received a nicotine inhaler and placebo patch).[91] Smoking at intake was defined as smoking 10 or more cigarettes per day for 3 or more years and an expired CO level of 10 ppm or more.

Abstinence rates at 6 weeks, measured as expired CO of 10 ppm or more, were significantly higher for those receiving the nicotine inhaler and the nicotine patch than for those receiving the nicotine inhaler and placebo patch (60.5 percent vs. 47.5 percent, $P = 0.09$).[91] At 6-month and 12-month followup, however, the groups did not differ significantly in continuous abstinence. One-year survival analysis showed a significant association between abstinence and treatment with nicotine inhaler plus nicotine patch ($P = 0.04$). In an examination of weight gain, subjects in the intervention group had gained less weight than the control group by week 2 ($P < 0.01$), but after 12 months, differences in mean weight gains were not significant. Mean nicotine substitution at week 6 was 60.1 percent in the intervention group and 24.6 percent in the control group ($P < 0.001$). At 12 months, the frequency of respiratory symptoms in abstinent subjects had fallen significantly compared with their baseline (for morning cough, $P < 0.001$; for morning phlegm, $P = 0.002$; for wheezing, $P < 0.001$; and for shortness of breath, $P < 0.001$). A trend toward improved lung function was observed but not significant at 12-month followup compared with baseline. Subjects in the control group reported significantly more intense withdrawal symptoms at week 1 ($P < 0.001$) and craving symptoms at week 6 ($P = 0.04$) than those in the intervention group. The most common adverse events were throat irritation (from the inhaler) and itching (from the patch).

Jorenby et al. recruited adult subjects through media advertisements.[116] They randomized those in the intervention group to three conditions: bupropion only, nicotine patch only, or both bupropion and nicotine patch. Subjects in the control group received placebo pills and a placebo patch. Smoking at intake was defined as smoking at least 15 cigarettes per day. Self-report of smoking status and expired CO were used to assess smoking status at 6- and 12-month followups.

The abstinence rates at 12 months were 15.6 percent in the placebo group compared with 16.4 percent in the nicotine patch group, 30.3 percent in the bupropion-only group ($P < 0.001$), and 35.5 percent in the group given bupropion and the nicotine patch ($P < 0.001$).[116] Abstinence rates were higher with combination therapy than with bupropion alone, but the difference was not statistically significant. By week 7, participants in the placebo group had gained an average of 2.1 kg. Weight gain in the other groups was 1.6 kg in the nicotine patch group, 1.7 kg in the bupropion-only group, and 1.1 kg in the combined treatment group ($P < 0.05$). Subjects in the combined therapy group had gained significantly less weight than those in the placebo group ($P < 0.05$) or the bupropion-only group ($P < 0.05$). Groups did not differ significantly in mean weight changes after week 7. Adverse events were rare and tolerable; they included insomnia and headache.

In the third trial, Killen and colleagues recruited participants by placing program announcements in local newspapers and examined the efficacy of a smoking cessation treatment that combined nicotine replacement therapy via a transdermal system (TNS) with the

antidepressant paroxetine (a selective serotonin reuptake inhibitor [SSRI]).[99] Smokers (N = 224) were randomized to one of three groups: (1) TNS and placebo; (2) TNS and 20 mg paroxetine; and (3) TNS and 40 mg paroxetine. Assignment to treatment was double-blind. TNS treatment was provided for 8 weeks; paroxetine or placebo was provided for 9 weeks.

Abstinence rates at weeks 4, 10, and 26 were as follows: (1) TNS and placebo: 45 percent, 36 percent, and 25 percent; (2) TNS and 20 mg paroxetine: 48 percent, 33 percent, and 21 percent; and (3) TNS and 40 mg paroxetine: 57 percent, 39 percent, and 27 percent.[99] The differences were not statistically significant. The combined treatment was more effective in reducing both craving and depression symptoms associated with smoking cessation. A subgroup analysis compared outcomes only among compliant participants. Abstinence rates at weeks 4, 10, and 26 were as follows: (1) TNS and placebo: 46 percent, 35 percent, and 24 percent; (2) TNS and 20 mg paroxetine: 64 percent, 43 percent, and 33 percent; and (3) TNS and 40 mg paroxetine: 74 percent, 51 percent, and 38 percent. The differences between paroxetine groups and the control group at week 4 were statistically significant.

Pharmacotherapy and psychological interventions. We identified six studies designed to examine the effect on cessation rates of interventions that had both pharmacotherapy and psychological counseling.[97,98,102-104,113] Four studies were population-based studies of adults; two studies included members of a large health care system.

The population-based trial examined the effectiveness of the combination of fluoxetine (another SSRI antidepressant) and cognitive behavioral treatment (CBT).[113] One and 3 months after the quit date, fluoxetine increased the likelihood of abstinence, as compared with placebo, among smokers with minor depression but not among those with little or no depression. As an adjunct to CBT, fluoxetine increased cessation by selectively benefiting medication-compliant smokers who displayed even subclinical levels of depression. Investigators were unable to predict cessation outcome on the basis of drug assignment, individual differences, or their interaction. Thus, they would not suggest that an interventionist could simply use the personal attributes they studied to predict which smokers might benefit from adjunctive fluoxetine before knowing something about whether a smoker is likely to adhere to an intensive treatment regimen involving medication plus CBT.

No evidence suggested that the more nicotine-dependent smokers derived special benefit from fluoxetine.[113] The moderating effect of depression on fluoxetine responsiveness was independent of the effect of nicotine dependence; this effect persisted even after the variance explained by nicotine dependence was removed. These findings suggest that adjunctive antidepressant treatment offers little selective benefit for highly nicotine-dependent smokers.

Carpenter et al. studied the efficacy of smoking reduction aided by nicotine replacement therapy compared to motivational advice or no treatment by using a telephone-only intervention among smokers not currently interested in quitting.[98] They randomized these smokers (N = 616) to receive (1) telephone-based reduction counseling plus nicotine replacement therapy plus brief advice to quit, (2) telephone-based motivational advice plus brief advice, or (3) no treatment.

Over 6 months, more smokers in the reduction-counseling arm (43 percent) and the motivational arm (51 percent) made a 24-hour quit attempt than smokers in the no-treatment arm (16 percent; $P \leq 0.01$).[98] The two active intervention groups, however, did not differ on this outcome variable ($P \geq 0.05$). Similarly, 18 percent, 23 percent, and 4 percent in each group were abstinent (7-day point prevalence) at 6 months ($P \leq 0.01$). Results indicated that smoking reduction using nicotine replacement does not undermine cessation; rather, it increases the likelihood of quitting to a degree similar to that from motivational advice.

Using a chronic disease model of smoking, Hall et al. undertook to determine the effects of long-term antidepressant and psychological treatment.[97] They randomly assigned 160 subjects who smoked at least 10 cigarettes a day to one of four treatment groups in a two-by-two design (nortriptyline [a tricyclic antidepressant] versus placebo by brief versus extended treatment). All subjects received 8 weeks of a transdermal nicotine patch, five group counseling sessions, and active drug or placebo treatment. Interventions for subjects in brief treatment ended at this point. Subjects in extended treatment continued taking nortriptyline or placebo to week 52 and received 9 monthly counseling sessions, with checkup telephone calls midway through each session. Subjects were assessed at baseline and weeks 12, 24, 36, and 52.

At week 52, point-prevalence abstinence rates with missing subjects imputed as smokers were 30 percent for placebo brief treatment, 42 percent for placebo extended treatment, 18 percent for active brief treatment, and 50 percent for active extended treatment.[97] With missing subjects omitted, these rates were 32 percent, 57 percent, 21 percent, and 56 percent, respectively. Differences were significant for the active extended condition at each of 24, 36, and 52 weeks.

In a randomized controlled trial, Macleod et al. investigated the effectiveness of telephone counseling as an adjunct to nicotine replacement therapy by transdermal patch in smoking cessation.[104] Smokers were randomized to either replacement therapy alone or replacement therapy plus telephone counseling (five sessions spaced according to a relapse-sensitive call schedule). 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 percent vs 25.1 percent; $P = 0.04$ at 3 months; and 30.1 percent vs 22.4 percent; $P = 0.01$ at 6 months). Similarly, 90-day continuous abstinence rates at 6 months were significantly greater for participants receiving counseling (26.7 percent v 18.6 percent; $P = 0.004$).[104]

Two studies from the same research team examined characteristics associated with more clinically relevant smoking endpoints following treatment with bupropion SR in a large health care system.[102,103] In both studies, the researchers randomized smokers to receive one of four 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. The Swan, Jack, et al. study focused on predictors of outcome;[102] the Swan, McAfee, et al. study focused on group differences.[103]

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 24 percent higher for those who received the tailored mail program than those enrolled in the proactive telephone-counseling program (OR, 1.24; 95% CI, 1.06-1.47).

Strategies to Improve the Success Rate for Quit Attempts for Special Populations

Synthesis of prior systematic reviews. *Hospitalized patients.* In a meta-analysis of four studies meeting selection criteria and relevant to the analysis comparing augmented smoking cessation treatment with usual care for hospitalized patients, Fiore et al. found that smoking cessation treatments have been shown to be effective for hospitalized patients.[5] Augmented smoking cessation interventions among hospitalized patients increased rates of smoking abstinence. Because the meta-analysis was limited to four studies, the investigators made no

attempt to categorize the augmented treatment with respect to type or intensity. For reference only, the augmented interventions in the analyzed studies included elements such as self-help via brochure or audio/videotape, chart prompts that reminded physicians to advise smoking cessation, pharmacotherapy, hospital counseling, and postdischarge counseling telephone calls.

In the Rigotti et al. review of interventions for smoking cessation in hospitalized patients, intensive intervention (inpatient contact plus followup for at least 1 month) was associated with a significantly higher quit rate than control (Peto OR, 1.82; 95% CI, 1.49-2.22, six trials).[63] Interventions with less than a month of followup produced no significant benefit (Peto OR, 1.09; 95% CI, 0.91-1.31, seven trials). They found no evidence to judge the effect of very brief interventions (<20 minutes) delivered only during the hospital stay. Longer interventions delivered only during the hospital stay were not significantly associated with a higher quit rate (Peto OR, 1.07; 95% CI, 0.79-1.44, three trials). Although the interventions increased quit rates irrespective of whether nicotine replacement therapy was used, the results for replacement therapy were compatible with other data indicating that it increases quit rates.[63]

Pregnant women. Prior reviews included studies with substantial variation in the intensity of the intervention and the extent of reminders and reinforcement through pregnancy. All three reviews concluded that participants in intervention conditions experienced significant reduction in continued smoking in late pregnancy.[5,37,61]

Racial and ethnic minorities. A prior review of interventions specifically designed for particular racial or ethnic groups demonstrated the efficacy of a variety of smoking cessation interventions for minority populations. The resultant recommendation is that members of racial and ethnic minorities should be provided treatments shown to be effective in the *Treating Tobacco Use and Dependence* guideline.[5]

Synthesis of current literature. We identified 13 studies not covered by prior reviews dealing with special populations; 10 studies dealt with hospitalized patients,[112,115,119,120,123-128] two studies dealt with pregnant women,[122,129] and one with indigenous Maori.[114] We described one of these studies in the self-help portion of this chapter and two in the counseling portion, but, because they dealt with hospitalized patients, we included them here as well.[115,119,120] Of these, we rated four articles as poor quality (three for hospitalized patients[126-128] and one for pregnant women[129]) and do not discuss them further in this section. Detailed data on all studies can be found in Evidence Table 5.

Hospitalized patients by diagnosis. Three studies focused on improving cessation rates among hospitalized patients with specific smoking-related diagnoses.[119,120,123] One study involved smoking cessation and relapse prevention among women admitted to the hospital with cardiovascular or peripheral vascular disease,[120] one included diabetic smokers,[119] and one involved patients under the age of 78 years admitted for myocardial infarction, unstable angina, or care after coronary bypass surgery performed at other hospitals.[123] All interventions included nurse counseling, self-help materials, and follow-up contact either in person or by telephone, and all interventions were compared with usual care of brief advice to quit smoking and/or related self-help materials. In the trial for women admitted to hospital with cardiovascular or peripheral vascular disease, the nicotine patch was offered (if not contraindicated) to those women who were smoking more than 19 cigarettes per day and who had not succeeded after trying to quit at least once.[119]

All three of these hospital-based interventions failed to increase biochemically verified abstinence rates at 12 months after discharge. One, however, showed significant differences in self-reported abstinence at 12-month followup.[123]

Hospitalized patients by intensity of intervention. Four studies examined the effect of varying the intensity of smoking cessation intervention among hospitalized patients.[112,115,124,125] One study involved patients recently discharged from intensive care units (ICUs).[115] This intervention included (1) verbal encouragement to remain nonsmoking at ICU discharge and at 8-week and 6-month clinic follow-up visits, (2) instructions for patient's immediate family not to smoke in the same room as the patient, and (3) a 6-week self-help ICU rehabilitation manual for the patient and his or her relatives that emphasized the importance of remaining abstinent and provided practical tips for smoking cessation along with other general tips. In the study of recently discharged ICU patients, those receiving the intervention were much less likely to return to smoking after discharge from the ICU than control patients who received only the first component of the intervention. Investigators could not determine whether the smoking cessation advice in the ICU rehabilitation package or the whole package in general was responsible for the high quit rate.[115] Including an exercise program in the package may have enhanced the likelihood of quitting smoking.

Reid et al. evaluated the efficacy of a stepped-care approach to smoking cessation treatment among smokers with coronary artery disease (CAD).[125] Stepped care refers to the practice of initiating treatment with low-intensity intervention and then exposing treatment failures to successively more intense interventions. Smokers hospitalized with CAD were provided a brief cessation intervention. The participants then were assigned randomly to either a more intensive stepped-care treatment (counseling and nicotine patch therapy) or no additional treatment.

In the second study of this type, Ratner et al. designed an intervention to help smokers abstain from smoking before surgery, maintain abstinence postoperatively, and achieve long-term cessation.[124] Their intervention included counseling and nicotine replacement therapy. Finally, one study examined the effects of three smoking cessation counseling interventions for hospital patients: (1) modified usual care, (2) brief advice, and (3) brief advice plus more extended counseling during and after hospitalization.[112] Pharmacological aids were not provided. Inpatients in four hospitals were randomly assigned to each condition and followed up at 7 days and 12 months postdischarge.

None of these studies showed significant differences in 12-month abstinence. In two studies, significant differences in abstinence emerged for the short term (i.e., 3 months and 6 months). In the stepped-care intervention study, treatment increased smoking cessation rates from 42 percent to 53 percent during a 3-month follow-up period *(P* = 0.05).[125] In the Ratner et al. study, treatment group participants (73.0 percent) were more likely to abstain from smoking before surgery than were controls (53.0 percent) (X^2 [1, N = 228] = 8.89; *P* = 0.003), and they were also more likely to be abstinent 6 months after surgery (31.2 percent vs. 20.2 percent) after controlling for covariates in a logistic regression analysis.[124]

Pregnant women. A three-group randomized controlled trial was conducted from 1996 to 2001, with 583 women and their partners randomized to usual care (UC), a woman-only (WO) intervention, or a partner-assisted (PA) intervention.[122] Followups occurred at 28 weeks of pregnancy and 2-, 6-, and 12-months postpartum. Women in the UC condition received provider advice to quit and a self-help guide. The WO group received UC components plus a late-pregnancy relapse prevention kit (booklet and gift items) and six counseling calls (three in pregnancy and three postpartum) initiated by a health advisor. Women in the PA group received the WO intervention, and their partners received telephone counseling and a support guide emphasizing skills to help the woman build and maintain her confidence to quit smoking. Partners who smoked also received cessation aids and related counseling.

Intent-to-treat analyses showed no significant differences by condition in women's reports of abstinence at any followup.[122] In late pregnancy, more partners were abstinent in the PA condition (15 percent) than in the UC condition (5 percent) ($P = 0.02$).

Racial and ethnic minorities. In a study of whether bupropion combined with smoking cessation counseling was effective in treatment of tobacco use in indigenous Maori in New Zealand, the investigators found quit rates similar to those observed in other trials of bupropion and no special problems related to bupropion use.[114]

KQ 3. Implementation of Proven Population-Level Tobacco Use Cessation Strategies

Understanding and implementing evidence-based interventions remain major challenges for public health and clinical practice. Adoption and implementation of population-level tobacco use cessation strategies are no exception. Here we summarize current research on the efficacy of community and health care systems interventions to increase the implementation of such strategies. As elsewhere, we present information from prior systematic reviews and then summarize current literature. We start first with population-based strategies and then consider strategies based in provider settings and health care systems.

Population-Based Strategies

Tobacco users are more likely to quit using tobacco if they are engaged in community-wide, comprehensive programs that use multiple channels to engage individuals.[7,130] Comprehensive evidence-based programs usually include cessation services, policy initiatives such as smoke-free environments, increases in the unit price of tobacco products, worksite initiatives to increase cessation, and mass media education campaigns.[7] Cessation services range broadly: widespread mass media campaigns to encourage quitting, provision of printed self-help materials, and intensive group or individual-based cessation therapies offered in-person or over the telephone or Internet.[131]

Synthesis of prior systematic reviews. A Cochrane review was the only previous report that evaluated the effectiveness of community-wide interventions to increase the implementation of proven population-level strategies for tobacco use cessation. The report defined a community intervention as a coordinated, multidimensional program aimed at changing adult smoking behavior, which involves several segments of the community and is conducted in defined geographical areas, such as town, city, county, or other administrative district. The aim was to identify factors in the design, implementation, or evaluation of such programs that may have influenced the smoking behavioral outcomes. The review included 32 studies that met inclusion criteria and two additional studies that compared more intensive with less intensive interventions but not with an "untreated" community.

The authors examined changes in smoking prevalence using cross-sectional follow-up data in 27 studies. For all adults, the net decline in smoking prevalence ranged from –1.0 percent to +3.0 percent per year in 10 studies.[36] Analyses for women showed a net decline ranging from –0.2 percent to +3.5 percent per year (11 studies); those for men indicated a net decline ranging from –0.4 percent to +1.6 percent per year (12 studies). The authors were unable to provide estimates for changes in cigarette consumption or quit rates because their included studies reported such

measures in different ways and, in the case of quit rates, over different time periods. In sum, little convincing evidence exists that community interventions reduce smoking among adults.

Synthesis of current literature. We identified three new studies that met inclusion criteria (Table 12). Two randomized trials aimed to deliver effective strategies to large numbers of smokers at a low cost.[131,132] A pretest-posttest controlled group study investigated the effects of community intervention on smoking behavior and its determinants.[133]

Table 12. Community strategies to increase the implementation of proven population-level tobacco use cessation strategies

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Borland et al., 2003[131] Australia Population-based	RCT 6 months 3, 6, and 12 months baseline	G1: Offered self-help "Quit Pack"; 3 computer-generated tailored letters G2: Offered self-help "Quit Pack"; 3 computer-generated tailored letters; callback counseling service C1: Offered printed, self-help "Quit Pack"	528 adolescents, young adults, and adults	No difference in smoking prevalence at 12-month followup	Good
Maguire et al., 2001[132] United Kingdom Community-based	RCT 3 months 3, 6, 9, and 12 months	G1: Initial interview with pharmacist; smoking cessation contract; NRT offered if appropriate; leaflet; weekly followup for 4 weeks, then monthly followup for 3 months C1: Normal pharmaceutical service (including the provision of NRT, as appropriate) provided by pharmacist	484 adults	Significantly more participants in G1 had a validated (urinary cotinine) nonsmoking status at 12 months (G1: 14.3% C1: 2.7%; $P \leq 0.001$)	Fair
Ronda et al., 2004[133] Netherlands, Western Europe Community-based	Pretest-posttest control	G1: Regional mass Media-led smoking cessation campaign; local activities organized by local interested working groups C1: Older mass media-led smoking cessation campaign, no local activities	8,939 adults	No significant differences between interventions regarding smoking status and determinants of smoking behavior	Fair

C, comparison group; G, intervention group(s); NRT, nicotine replacement therapy; RCT, randomized controlled trials.

One RCT (rated good) examined the effectiveness of a computer-tailored advice program for callers to a reactive telephone help line service in Australia. The RCT assessed whether the computer-tailored advice enhanced a series of callback telephone counseling sessions as an alternative and complementary effort to proactive telephone callbacks.[131] This strategy was designed not only to reach larger numbers of smokers but also to test whether varying the intensity of the intervention and personalizing cessation assistance influenced cessation. Slightly more of the participants who received a combined intervention, namely, the computer-tailored

advice plus callback telephone counseling, made an attempt between baseline and 3-month followup than did the other two groups (computer-tailored advice only; control group receiving no extra help).[131] Significantly more people in the combination program who tried to quit in fact succeeded. The difference in point prevalence between the groups declined over time. It was not significant at the 12-month followup because of a nonsignificant trend among the groups that did not receive callbacks to start quitting.

Use of nicotine replacement therapy varied across the groups.[131] The group receiving only computer-tailored advice reported significantly lower use rates than the other two groups (i.e., the control and the group that received the combination intervention). The investigators analyzed the potential effect of replacement therapy on smoking status at 3 months using logistic regression. Nicotine replacement significantly improved outcomes (OR, 2.04; 95% CI, 1.22-2.73; $P < 0.001$), as did callback telephone counseling (OR, 1.84; 95% CI, 1.36-3.02; $P < 0.001$); computer-tailored advice had no effect (OR, 1.11; 95% CI, 0.72-1.72; $P = 0.63$).

The results indicate the questionable value of computer-tailored cessation materials, but they are largely consistent with other research showing an association between the greater likelihood of quitting smoking and the use of nicotine replacement therapy or callback counseling. The ineffectiveness of the computer-tailored advice program was most probably attributable to the fact that the program did not meet the needs of smokers who were already motivated to quit and actively seeking help.[131] No evidence suggested that combining the two interventions (i.e., the computer advice and telephone counseling) was effective because, in an earlier trial of the callback service, the quit rates were marginally higher than those observed in this study.[131]

The other trial (rated fair), seeking to deliver effective strategies to large numbers of people, evaluated whether a structured smoking cessation program based in community pharmacies in Northern Ireland and London would result in a higher smoking cessation rate compared with ad hoc advice from pharmacists.[132] The intervention package, "Pharmacists' Action on Smoking" (PAS), used a one-to-one counseling format with structured followup; the intervention was compared with brief, unstructured advice. Study site pharmacies displayed a poster on smoking cessation throughout the study; television, radio, and newspaper media were used to advertise the project to the general public. Smoking cessation was promoted to those using the pharmacy for nonmedical reasons, those asking for advice on minor ailments, and those being dispensed medicine by prescription.

Significantly more subjects assigned to the PAS intervention had abstained for 12 months (cotinine-confirmed) than those not assigned to the PAS intervention: 14.3 percent vs. 2.7 percent ($X^2 = 16.2$; $P < 0.001$).[132] Use of nicotine replacement therapy was similar in both groups initially, but data were insufficient to estimate the contribution of either replacement therapy or counseling about replacement therapy use (or both) to overall cessation rates. Pharmacy type and size had no impact on the 12-month cessation rates.

The pretest-posttest control group design with two posttests (rated fair) evaluated the effects of a regional Dutch Heart Health Community intervention on smoking behavior and its determinants.[133] The community intervention included a regional mass media-led smoking cessation campaign ("Congratulations!") using radio commercials, advertisements, and messages in papers, billboards, posters, and postcards in waiting rooms and public buildings. Smaller local activities arranged by representatives of local organizations supplemented these regional efforts. The investigators hypothesized that this combination of regional and local strategies would be more effective than a national mass media-led smoking cessation campaign consisting of various

television programs, an information line, nonsmoking courses, mailings to various organizations, billboards in bus shelters, brochures, posters, and other materials.

The researchers found no significant differences between the intervention region and the control region on smoking behavior and its determinants at either 24 months or 36 months after baseline.

Provider and Health Care System-Based Strategies

Interventions in health care systems focus on two main approaches. One approach involves changing provider behavior relative to offering tobacco treatment services through provider education alone or with feedback and assessment. Another approach involves changing health care systems so that health care providers will be more likely to offer effective strategies either proactively or in response to client demand.[37]

Synthesis of prior systematic reviews. Two reviews provide information on this issue in terms of interventions based in settings other than full communities. One report is from the Task Force on Community Preventive Services;[7] the other is the 2000 update of the 1996 AHCPR guideline.[5]

Zaza et al. reviewed six interventions that health care systems can use to increase cessation of tobacco use by their members.[7] They reported "strong" evidence of effectiveness for provider reminder systems with provider education, with or without client education, and for multicomponent interventions that include client telephone support. Provider reminders with provider education include efforts to educate and prompt providers to identify and intervene with tobacco-using clients and to provide supplementary educational materials when appropriate. "Sufficient" evidence of effectiveness enabled the Task Force to recommend use of health care provider reminders alone and reductions in patient out-of-pocket costs. Provider reminders can carry various types of information and can be delivered by a variety of methods, including chart stickers, vital sign stamps, medical record flowsheets, and checklists. Lowering patient out-of-pocket costs reduces financial barriers that impede access to effective cessation therapies. Finally, the authors reported "insufficient" evidence of effectiveness to recommend provider education alone and provider feedback and assessment.

To facilitate adoption of effective tobacco treatment in health care settings, the AHCPR guideline update used meta-analyses to identify six effective systems strategies.[5] These included (1) implementing a tobacco user identification system in every clinic; (2) providing education, resources, and feedback to promote provider intervention; (3) dedicating staff to provide tobacco dependence treatment and assessing the delivery of this treatment in staff performance evaluations; (4) promoting hospital policies that support tobacco dependence services; (5) including tobacco dependence treatments (both counseling and pharmacotherapy) identified as effective as paid or covered services for all subscribers or members of health insurance packages; and (6) reimbursing clinicians and specialists for delivery of effective tobacco dependence treatments and including those interventions among the defined duties of the clinicians.

Synthesis of current literature. Twelve new studies met all inclusion criteria (Table 13).[134-145] Of these studies, three were RCTs;[140,142,144] four, cluster RCTs;[134,138,139,145] four, cross-sectional designs,[135,136,141,143] and one, a time series design.[137]

Four randomized trials, three rated fair quality and one rated good, investigated efforts to train providers in effective strategies.[134,140,142,144] One study also trained general medicine residents.[134] Eight studies describing interventions conducted in health care systems to improve use of effective cessation strategies met all inclusion criteria and received quality ratings of

Table 13. Strategies to increase implementation of population-level tobacco use cessation: provider-based and health care settings

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Cornuz et al., 2002[134] Switzerland, Western Europe Practice/provider settings	RCT with cluster randomization 3 months 1 year	G1: Active learning training program for residents; received the control training 4 months later C1: Traditional didactic training program on management of dyslipidemia; received the intervention training 4 months later	251 young adult and adult patients 35 residents	Those patients seen by intervention group residents more likely to be abstinent for at least 1 week at 1-year followup (P = 0.005)	Fair
Goldstein et al., 2003[141] United States Practice/provider settings, community-based	Cross-sectional NR 6, 12, 18, and 24 months	G1: Physicians provided "4 As" to patients G2: Smokers provided with computer-generated, stage-tailored cessation information at home G3: Physician delivered "4 As" to patients, and patients received computer-generated, stage-tailored smoking cessation information at home C1: No intervention	2,346 adults	At 2-year followup, patients who received the "4 As" were significantly more likely to quit smoking (P = 0.006)	Fair
Joseph et al., 2004[143] United States Practice/provider settings	RCT 2 days 6 and 12 months	G1: Organizational support, 2 day training sessions, smoking cessation medication C1: NR	5,678 adults	No effect on change scores between groups reporting whether their physician asked about smoking or provided counseled	Fair

"4 As" approach to tobacco-cessation counseling: (1) ask about tobacco use; (2) advise to quit; (3) assist with quitting; and (4) arrange for followup; C, control group; FP, family practitioner; G, intervention group; GP, general practitioner; NR, not reported; RN, registered nurse; WIC, Women, Infants, and Children program

Table 13. Strategies to increase implementation of population-level tobacco use cessation: provider-based and health care settings (continued)

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Katz et al., 2004[142] United States Practice/provider settings Community-based	RCT 2 months Immediate	G1: Study personnel worked with intake clinicians to implement guideline intervention; clinicians completed survey prior to implementation; After clinic visit, study personnel interviewed patients to evaluate whether they received cessation counseling C1: Intake clinicians completed survey just before tutorial session at end of intervention period, but had no help with guideline implementation	1,221 adult patients 72 clinicians	Intervention group RNs were the most likely to ask about smoking, assess willingness to quit, advise patients to quit, and assist patients in quitting (*P* = NR)	Fair
Katz et al., 2004[144] United States Practice/provider settings	RCT 10.5 months 2 and 6 months	G1: Multicomponent office based intervention including a tutorial for intake clinicians on the AHRQ Guideline, performance feedback, offer of free NRT, and proactive counseling C1: Staff received general information on the AHRQ Guideline	2,163 adult patients	Significantly more patients from practices who received the intervention were more likely to be asked by their clinician about their smoking status, willingness to quit, given literature about quitting, assisted in setting a quit date, engaged in a discussion about pharmacotherapy, or remain abstinent	Good
Pbert et al., 2004[139] United States Practice/provider settings	RCT with cluster randomization 10 months End of pregnancy, 1, 3, and 6 months postpartum	G1: Clients visited community health centers and WIC offices that received provider training, an office reminder system, and establishment of program boards to coordinate the transfer of documentation among clinics C1: Usual care	550 adult pregnant women	Women in the intervention group more likely than those in the control to be abstinent at the end of pregnancy (G1: 26%; C1: 12%; OR: 2.57; *P* = 0.05) and 1 month postpartum (G1: 26%; C1: 11%; OR: 3.01; *P* = 0.04) No effect remained at 3- and 6-month followup	Fair

Table 13. Strategies to increase implementation of population-level tobacco use cessation: provider-based and health care settings (continued)

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Pieterse, 2001[140] The Netherlands, Western Europe Practice/provider settings	RCT with simple randomization NR 1 and 12 months	G1: Brief physician counseling; self-help manual; follow-up sessions C1: Usual treatment—no counseling or advice on smoking except when initiated by the patient or when indicated by the contact reason	530 young adults, adults	At 12 months, smoking abstinence rates were greater among those in the intervention compared with controls (G1: 13.4%; C1: 7.3%; OR = 1.51, CI: 1.1, 2.1; $P < 0.05$), as were consecutive abstinence rates (G1: 8.2%; C1: 3.1%; OR = 3.04, CI: 1.7, 5.6l; $P < 0.001$)	Fair
Piper et al., 2003[145] United States Practice/provider settings	RCT NR 12 months	G1: Smoking added to vital sign stamp C1: Usual vital sign stamp without smoking	1,611 adult smokers	Significant increase (31%) in asking behavior of physicians in the smoking plus vital sign clinics ($P = 0.0002$); no difference in abstinence rates	Fair
Russos et al., 1999[135] United States Practice/provider settings	Cross-sectional 2 years 2 years postbaseline	G1: Orthodontists given antitobacco materials, training session on tobacco prevention, written antitobacco prescriptions and reimbursement for distribution, quarterly visits and calls; office staff asked to make office tobacco-free C1: Orthodontists given no training, materials, or visits, nor asked to change their offices or practices	126 adults	In a typical week more clinicians in G1 vs. C1 provided prevention counseling to patients (Mean: 25.4% vs. 3%, Mann-Whitney U = 696.5, z = -7.0, $P < 0.01$) and at least some cessation counseling (91% vs. 72%, $X^2 = 8.4$, $P < 0.01$)	Fair
Slama et al., 1999[136] France, Western Europe Practice/provider settings	Cross-sectional NA 1 and 12 months	G1: NA C1: NA	372 adult patients 2,680 general practitioners	None of the GPs' smoking-related attitudes and reported behaviors were significantly related to their participation in the study or to their patients' rates of smoking cessation at 1 or 12 months	Fair

Table 13. Strategies to increase implementation of population-level tobacco use cessation: provider -based and health care settings (continued)

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Smith et al., 2002[137] United States Hospital	Time series 3 months 1 year	G1: During hospitalization: physician advice on smoking cessation, bedside education and counseling with nurse, take-home materials, NRT if requested or indicated, 4 nurse-initiated postdischarge phone counseling calls C1: NA	1,077 adults	Including only those who were reached at 12 months, 49% reported being smoke-free for the previous 7 days. Including the 211 who were not reached at 12 months (intent to treat) and counting them as smokers, self-reported smoking cessation rate was 35%	Fair
Young et al., 2002[138] Australia Practice/provider settings	RCT with cluster randomization 4 months 6 months postbaseline	G1: Family physicians received three academic detail visits, resources for FPs, resources for practices. and resources for patients C1: Similar intervention to G1 in terms of intensity and format, but focused on cervical screening	1,788 adult patients 60 family practitioners	Improvements between baseline and posttest in patient recall of FP advice about nicotine replacement patches and gum were significantly greater in the intervention than the control group (P = 0.0056 and P = 0.0002, respectively)	Fair

fair.[135-139,141,143,145] Six of these studies used some variation of an academic detailing approach (i.e., personal educational visits to clinicians in their own practice setting) to increase system support for cessation interventions.[135,138,139,141,143,145] One study examined the effect of physician attitudinal and behavioral variables on participation and effectiveness of general practitioners in offering a minimal smoking cessation intervention.[136] The group effectiveness study evaluated how a previously proven effective smoking cessation intervention is integrated into standard hospital practice.[137]

Provider-based interventions. Researchers in one study designed training programs to help general practitioners and their practice assistants[140] and general medicine residents.[134] The aim was to help providers acquire and apply skills to help their patients quit smoking. Two other studies implemented AHCPR strategies[5] in practice and internal medicine clinics to facilitate adoption of effective tobacco treatment in health care settings.[142,144]

Both training programs included skills training in counseling approaches tailored to smokers' readiness to quit smoking and instruction in the use of written self-help materials for patients. General practitioners' office assistants were also trained to apply the randomization and

informed consent procedures.[140] To evaluate the effects of the training, Pieterse et al. randomized eligible smokers into two groups.[140] One group received brief (10-minute) counseling sessions with the physician that are based on the stages of change model, a self-help manual, and follow-up sessions led by practice assistants; the other group received usual care consisting of no counseling or advice on smoking except when initiated by the patient or when indicated by the contact reason (in which case, counseling was limited to straightforward stop-smoking advice and possibly referral to local municipal health organizations).

At 1-month followup, smoking abstinence rates were greater among those in the intervention group than among controls (OR, 2.56; 95% CI, 1.8-3.8).[140] This relationship held at the 12-month followup (OR, 1.51; 95% CI, 1.1-2.1). Continuous abstinence was also greater among intervention group subjects than among controls (OR, 3.04; 95% CI, 1.7-5.6).

In evaluating training for general medicine residents, Cornuz et al. stratified residents by clinic either in an intervention group trained in smoking cessation or in a control group trained in dyslipidemia.[134] The control group received training in the intervention 4 months later, after the 3-month patient recruitment period had ended. Eligible patients identified as smokers were randomly assigned to intervention (i.e., residents trained in smoking cessation) or control clinics (i.e., residents trained in managing dyslipidemia).

According to smokers' self-reports, trained residents used all counseling strategies significantly more often than control residents.[134] These strategies included assessing motivation to quit (29 percent vs. 19 percent, $P = 0.05$), offering help to quit (23 percent vs. 7 percent, $P = 0.003$), discussing benefits of cessation (21 percent vs. 12 percent, $P = 0.05$) and obstacles to cessation (16 percent vs. 6 percent, $P = 0.01$), giving a brochure (14 percent vs. 1 percent, $P < 0.001$), discussing strategies to prevent relapse (15 percent vs. 6 percent, $P = 0.01$), and setting a quit date (8 percent vs. 2 percent, $P = 0.02$). Compared with control residents, trained residents expressed significantly higher self-confidence (mean scores of 7.7 vs. 5.2; $P = 0.002$) and also a nonsignificantly higher level of self-perceived effectiveness in smoking cessation counseling (mean scores of 6.8 vs. 5.4; $P = 0.09$) 3 months after training.[134] At 12-month followup, 1-week smoking abstinence was significantly higher in the intervention group than in the control group (13 percent vs. 5 percent, cluster-adjusted OR, 2.8; 95% CI, 1.4-5.5). The proportion of smokers willing to quit was significantly higher in the intervention group than in the control group (94 percent vs. 80 percent; $P = 0.007$). Daily cigarette consumption tended to be lower in the intervention than in the control group, but the groups did not differ significantly. The groups also did not differ significantly in the proportion of smokers in the precontemplation stage or the proportion of smokers who moved forward one stage, applying the principles of educational outreach to improve clinical decisionmaking.

Katz et al. tested the effectiveness of a multimodality intervention to implement the AHCPR Smoking Cessation Clinical Practice Guideline in six family practice and two internal medicine clinics.[144] The intervention consisted of a tutorial for intake clinicians that instructed them on how to assess the patient's smoking status and how to provide brief smoking cessation messages to each smoker with feedback on performance, real-time reminders (i.e., modified vital sign stamp), onsite pharmacotherapy, and proactive telephone counseling.

Face-to-face interviews were conducted with clinic patients immediately after their office visit to assess how the clinic staff had performed guideline-recommended activities. In addition, clinic patients were contacted by telephone by study personnel, blinded to treatment group, and asked about their smoking habits at 2 and 6 months following the exit interview. Clinic patients

who reported not smoking at 6 months were mailed kits for saliva collection to verify biochemically self-reported abstinence.[144]

During the intervention period, more patients at intervention clinic sites were asked about their smoking status (OR, 3.1; 95% CI, 1.2-8.2; $P = 0.02$) and their willingness to quit smoking (OR, 6.4; 95% CI, 3.7-10.8; $P < 0.001$), were given literature about quitting (OR, 21; 95% CI, 8.8-49; $P < 0.001$), were assisted with setting a quit date (OR, 33; 95% CI, 11-100; $P < 0.001$), or were engaged in a discussion about pharmacotherapy (OR, 3.9; 95% CI, 2.5-6.3; $P < 0.001$). Among patients treated during the intervention period, those at intervention clinic sites were more likely than those at control sites to report being abstinent at the 2-month mark (16.4 percent vs. 5.8 percent, adjusted OR, 3.3; 95% CI, 1.9-5.6; $P < 0.001$) and the 6-month mark (15.4 percent vs. 9.8 percent; adjusted OR, 1.7; 95% CI, 1.2-2.6; $P = 0.009$) and to report continuous abstinence (10.9 percent vs. 3.8 percent). Although planned collection of confirmatory salivary cotinine tests of self-report cessation had very low response rates, the confirmed abstinence rates at 6 months showed no difference between intervention clinics and controls.[144]

A secondary analysis[142] of data from the same RCT of guideline implementation determined whether intake clinicians (registered nurses [RNs] and less costly personnel (licensed practical nurses [LPNs] and medical assistants [MAs]) are similar when performing smoking cessation activities that AHCPR guidelines had recommended.[5] Using patient exit interviews, the investigators obtained information on differences in performance among RNs compared with MAs, RNs compared with LPNs, and LPNs compared with MAs. Patients were queried whether their intake clinician asked about their smoking, assessed their willingness to quit, gave them advice about quitting, and assisted them in quitting.

Performance of all guideline-recommended counseling activities was significantly greater for all types of nursing personnel at test sites than at control sites.[142] MAs were significantly less likely to assess willingness to quit (adjusted OR, 0.4; 95% CI, 0.2-0.8, $P = 0.005$); they also tended to offer advice and assistance in quitting less often than RNs. Similar findings were observed for LPNs assessing willingness to quit (adjusted OR, 0.5; 95% CI, 0.3-1.0; $P = 0.03$). After accounting for personal beliefs, self-efficacy, and role satisfaction in cessation counseling, subset analysis in subjects with complete survey data revealed that being seen by an MA was no longer associated with statistically significant differences in performance. These results indicate that MAs and LPNs were less likely than RNs overall to perform actions recommended by the AHRQ smoking cessation recommendations.

Health care systems interventions. Practice sites for academic detailing interventions included community health centers, clinics in the Women, Infants, and Children (WIC) program, orthodontists' offices, primary care clinics, and family physician practices. Specific elements of an academic detailing approach varied across the six studies, but included

- An in-service training for staff members on how to asses and document smoking status as a part of regular collection of vital signs;[145]
- A 1.5-hour workshop, antitobacco materials, reimbursement for provision of antitobacco prescriptions, and quarterly check-up visits;[135]
- Provider training to deliver a smoking intervention based on national clinical practice guidelines tailored to the woman's stage of change and delivered through three channels (obstetric, pediatric, and WIC providers);[139]

- An office practice management system to routinely screen for smoking status, prompt/remind providers to intervene, document the encounter, distribute materials and arrange followup;[139]
- Establishment of program boards to coordinate the transfer of documentation among clinics, including periodic meetings with representatives from all clinics;[139]
- Two to three day site visits designed to communicate with Directors, Pharmacy Service Chief, smoking cessation coordinators and primary care nurses about barriers to implementation of AHCPR Smoking Cessation Guidelines;[143]
- Audit, feedback, and academic detailing for family physicians;[138] and
- Four or five physician-centered office visits in the intervention counties to encourage physician adoption of a smoking cessation strategy based on the "4As" model from the National Cancer Institute (NCI) and distribution of a copy of the NCI manual *How to Help Your Patients Stop Smoking*.[141]

Studies examined whether significant effects were achieved on clinician uptake and use of cessation strategies, on cessation rates among patients served by these clinicians, or both. Investigators used various approaches to assess clinician uptake and use of cessation guidelines and other evidence-based strategies, including exit, telephone, and other interviews of patients, medical record audit, and mail or telephone provider surveys. Study designs included three randomized trials with cluster randomization,[138,145] two cross-sectional[139] studies,[135,143] and a community-based quasi-experimental study.[141]

A multifaceted, practice-based intervention involving audit, feedback, and academic detailing to improve family physicians' use of evidence-based smoking cessation strategies enrolled 60 family physicians from 39 practices.[138] Their provision of smoking cessation advice was measured by patient recall, medical record audit, and self-report. Improvements between baseline and posttest in patient recall of physician advice about nicotine replacement patches and gum were significantly greater in the intervention group ($P = 0.0056$) than in the control group ($P = 0.002$).[138] Substantial increases occurred in patients' recall of assessment of smoking status and family physicians' use of quit dates, behavioral advice, and written materials in the intervention group, but these changes were not significantly greater than those in the control group. Notation of patient's smoking status and smoking cessation advice in medical records remained suboptimal in both groups.

Providers in community health centers and WIC offices received training to deliver a smoking intervention based on national clinical practice guidelines.[139] The program included (1) provider training tailored to the woman's stage of change and delivered through three channels (obstetric, pediatric, and WIC providers); (2) an office practice management system to screen routinely for smoking status, prompt/remind providers to intervene, document the encounter, distribute materials, and arrange followup; and (3) establishment of program boards to coordinate the transfer of documentation among clinics, including periodic meetings with representatives from all clinics. Providers in control clinics provided usual care. Five community health centers were randomized to intervention or usual care. Subjects were pregnant or postpartum women who were current smokers or smokers who had quit during pregnancy.

The intervention and usual care groups differed significantly in 30-day abstinence rates at the end of pregnancy among women who had not quit spontaneously upon learning of their pregnancy (26 percent vs. 12 percent; OR, 2.57; $P = 0.05$).[139] This effect remained at 1 month postpartum but was lost at 3- and 6-month postpartum followups.

Staff members in outpatient primary care clinics who usually take vital signs for each patient received in-service training on how to assess and document smoking status as part of the regular collection of patient information.[145] On exiting the clinic, patients were asked questions about their smoking habits and smokers were asked to participate in a follow-up telephone interview in 1 year. These later interviews revealed no statistically significant difference between either the intervention or control clinics for point-prevalence abstinence from baseline to the intervention phase. Chi square analysis indicated that abstinence was independent of being asked about smoking, receiving advice to quit, being prescribed nicotine replacement therapy, or having a follow-up appointment.

Orthodontists in private practice offices participating in a controlled trial to decrease the incidence of tobacco use among adolescents were enrolled in a cross-sectional interview study to determine the rate and determinants of tobacco prevention and cessation counseling to youth.[135] The experimental group received a 1.5-hour workshop, antitobacco materials, reimbursement for provision of antitobacco prescriptions, and quarterly check-up visits. Control group clinicians did not receive training materials or visits.

Orthodontists in the experimental group were more likely than those in the control group to ask their patients whether they use tobacco (4.8 percent vs. 2.9 percent; $P < 0.01$), to provide at least some cessation counseling to their patients who smoked (91 percent vs. 70 percent; $X^2, 8$; $P < 0.01$), and to report mostly positive reactions from tobacco users for cessation counseling ($X^2, 7.8$; $P < 0.05$).[135] Demographic, office, and clinic practice variables were not associated with cessation counseling. Higher rates of cessation counseling were associated (all $P < 0.05$) with asking patients whether they used tobacco, belief that counseling is important, belief that clinicians should receive counseling training, intention to attend training, and disagreement that counseling is not part of their job description.

The study that tested implementation of the tobacco guideline randomized 20 Veterans Affairs Medical Centers to an intervention or control group.[143] A multicomponent intervention was designed to increase three specific guideline recommendations: (1) documentation of tobacco use status in medical records, (2) delivery of cessation intervention to all smokers, and (3) liberal use of pharmacotherapy for smoking cessation. In a 2-day training meeting, the three target strategies were presented to physicians, nurses, psychologists, and pharmacists. The training recommended using electronic medical records to identify smokers, giving smoking cessation treatment within the primary care setting rather than using referral-based care, and removing restrictions to prescriptions of smoking cessation aids. Site visits by an interventionist provided academic detailing on barriers to implementation strategies.[143]

Cross-sectional surveys were conducted at baseline and 1 year later (i.e., after the intervention) among a sample of randomly selected patients who had seen their primary care provider within 6 weeks. A cohort of current cigarette smokers identified at baseline also completed a follow-up survey 1 year after the intervention. At the 1-year point, medical records showed a significant effect on smoking status documentation (intervention medical records were more likely to document smokers than were those of the control group, 67 percent vs. 60 percent, $P = 0.0007$). The groups did not differ in quit rates, providers asking about smoking status, or being counseled to quit smoking.

In a community-based quasi-experimental study, Goldstein et al. delivered an academic detailing intervention to physicians in intervention counties during a 15-month period. The multicomponent office-based intervention aimed to increase primary care physicians' adoption, implementation, and maintenance of the NCI "4As" as a smoking cessation strategy. The

intervention included four or five physician-centered visits and distribution of a copy of the NCI manual *How to Help Your Patients Stop Smoking*. The program was implemented through personal educational visits to clinicians in their own practice settings.[141]

Among smokers reporting a physician visit during the study period, the investigators reported a borderline significant effect at 24-month followup for those residing in intervention areas compared with those residing in control areas (OR, 1.35; 95% CI, 0.99-1.83; $P = 0.057$).[141] Patients of experimental group physicians reported that about 60 percent of their doctors talked to them about smoking and advised them to quit; the figure was about 55 percent for control group physicians (X^2, 13.8; $P = 0.000$ [sic]).[141] In a subgroup analysis, after controlling for confounding factors, Goldstein et al. also reported that, among smokers who visited an enrolled physician, those residing in physician intervention counties were significantly more likely than those residing in control counties to quit smoking at 24 months (adjusted OR, 1.80; 95% CI, 1.16-2.75, $P = 0.008$). Stage of change at baseline was the only other significant predictor of smoking cessation at 24 months (adjusted OR, 2.75; 95% CI, 1.89-3.98; $P = 0.000$ [sic]).

One interview-based study (rated fair) examined the effect of physician attitudinal and behavioral variables on participation and effectiveness of general practitioners (GPs) to offer a minimal smoking cessation intervention.[136] Attitudinal variables included (1) individual GP assessments of the influence of GPs in general, and of themselves in particular, on prevention efforts aimed at both smokers and other patients and (2) assessments of the potential that modern medicine has to affect disease outcome through screening and treatment. Behavioral variables included individual reports of knowing their own cholesterol level, being careful about diet, exercising regularly, and watching their weight. Matched pairs of smoking and nonsmoking GPs were invited to participate in a regional smoking cessation intervention.

Among the GPs who initially accepted, a significantly higher proportion of GP nonsmokers than GP smokers participated in the study (54.1 percent vs. 45 percent, X^2, 5.147; $P < 0.05$).[136] Nonetheless, those GP smokers who did participate achieved results similar to those of nonsmokers when comparing the success or lack of success in their patients' reports of quitting smoking. The smoking status of GPs was not significantly related to either point prevalence smoking status at 1 and 6 months or to sustained abstinence. These findings suggest that when minimal advice has an effect, that effect can be attributed more to the systematic nature of the intervention provision than to the attitudes or reported practices of the provider offering the advice.

A group effectiveness study (rated fair) evaluated how an RCT smoking cessation intervention, previously proven effective, was integrated into standard hospital practice.[137] Although this study had no comparison group, it provides useful, detailed data about continuation of a smoking cessation program. The intervention examined a nurse-managed smoking cessation program for general hospitalized patients, which continued for 3 years after trial completion. The intervention included physician advice, bedside education and counseling by a nurse specially trained in smoking cessation techniques, take-home materials (i.e., a videotape, workbook, and relaxation audiotape), nicotine replacement therapy if requested or indicated, and four nurse-initiated, postdischarge telephone counseling calls.

Of the patients identified as smokers, 50 percent enrolled in the program, 18 percent wanted to quit on their own, 20 percent did not want to quit, and 10 percent were ineligible.[137] The 12-month self-reported cessation rate (7-day point prevalence) was 35 percent if patients lost to followup were considered smokers and 49 percent if they were not. Patients hospitalized for cancer, cardiovascular, or pulmonary reasons were most likely to participate, and they had the

highest self-reported cessation rates (cancer: 63 percent, cardiovascular: 57 percent, and pulmonary: 46 percent).

KQ 4. Effect of Smokeless Tobacco Product Marketing and Use on Population Harm from Tobacco Use

In our systematic review of the effects of smokeless tobacco product marketing and use on population harm from tobacco use, we specifically examined three issues: (1) whether substituting smokeless tobacco for smoking leads to less smoking-related harm on a population basis, (2) whether smokeless tobacco marketing leads to greater use or substitution of smokeless tobacco for smoking (or both), and (3) whether data on harms and harm reduction associated with smokeless tobacco are used to model the potential health effects of substituting smokeless tobacco for smoking. As elsewhere, we present information from prior systematic reviews and then summarize current literature.

Effects of Smokeless Tobacco Product Marketing and Use

Adolescents and young adults continue to be a strategically important market segment for the tobacco industry.[15] During 2001, the largest tobacco manufacturers spent $236.7 million on smokeless tobacco advertising and promotion, using images that portray the attractiveness of tobacco products.[18] Growth in sales of smokeless tobacco moist snuff has been attributed to advertising and marketing campaigns that encourage young nonusers to experiment with low-nicotine starter products. Once adolescents or young adults begin to use smokeless tobacco, the tobacco companies' intent is to move new users to higher nicotine brands as nicotine dependence progresses.[2] An estimated 7 percent of high school students are current users of smokeless tobacco; males are the primary consumers.[20] Adolescents who use smokeless tobacco are more likely than nonusers to become smokers.[15]

Recently, tobacco companies have begun to market their smokeless tobacco products as less harmful alternatives to smoking tobacco, emphasizing that smokeless tobacco does not carry the same risks to others that are associated with smoking (i.e., secondhand and environmental tobacco smoke).[46] We believe it is too early to determine whether these harm reduction approaches to smokeless tobacco marketing are effective in increasing product use; however, we have included this issue in our literature search for KQ 4.

Synthesis of past literature reviews. Two types of smokeless tobacco are sold in the United States: chewing tobacco (i.e., loose leaf tobacco, plug, or twist) and snuff (i.e., finely ground tobacco that can be dry, moist, or in sachets).[18,19] Smokeless tobacco can lead to nicotine addiction and dependence.[17] Evidence from the Surgeon General and others has linked smokeless tobacco causally with oral leukoplakia and oral cancers.[2,39] Since 1964, the Surgeons General reports have continuously examined the role cigarettes and smokeless tobacco play in developing cancers of the oral cavity and pharynx. As research has progressed, conclusions indicate that all forms of tobacco use (i.e., cigarettes, pipes, cigars, snuff, chewing tobacco, betel, and other smoked and smokeless products) can cause malignancies in any part of the oral cavity and pharynx except the salivary glands.[1,2,6] Specific risks associated with the use of smokeless tobacco products are advanced periodontal disease, tooth decay, leukoplakia, stomach and pancreatic cancers, and heart disease.[1]

Treating nicotine addiction (from cigarettes, pipes, cigars, and smokeless tobacco) will help prevent most of the approximately 30,200 new cases of cancer and 7,800 deaths from these cancers that occur annually in the United States. Eliminating smokeless tobacco use will prevent 12,300 new cases of esophageal cancer alone and 12,100 deaths from esophageal cancer annually.[1]

Limited research indicates that increases in smokeless tobacco prices will reduce the use of smokeless tobacco, particularly by adolescents and young adults. Nonetheless, the tax on smokeless tobacco is well below that on cigarettes. Although increases in cigarette prices may reduce smoking among youth, increases may also boost the likelihood of smokeless tobacco use.[2]

Recommendations from the updated AHCPR tobacco cessation guideline advise treating users of smokeless tobacco with the same counseling cessation interventions recommended for smokers.[5] Studies of pharmacotherapies to address nicotine dependence on tobacco have not provided sufficient evidence showing long-term abstinence among users; specifically, gum and nicotine patches have not increased abstinence rates.[5] Because oral lesions caused by smokeless tobacco use are common, dental clinicians are in a suitable position to use minimal interventions to reduce smokeless tobacco use.[2,5] Recently, behavioral interventions by dental clinicians using oral examinations with feedback about the mucosal changes associated with smokeless tobacco use have had positive effects on abstinence (OR, 2.41; 95% CI, 1.79-3.24).[57] This finding suggests that dental health clinicians are in an opportune position to deliver brief but efficacious interventions to smokeless tobacco users.

Prior systematic reviews did not address issues relevant to KQ 4. Past reviews focused on risks associated with the use of smokeless tobacco and on the potential offered by smokeless tobacco cessation treatments. Information on tobacco product marketing is more likely to be disseminated in editorials, summary articles, and newspaper articles that were excluded from this review.

Synthesis of current literature. Our review of smokeless tobacco product marketing and use found no studies evaluating whether substituting smokeless tobacco for smoking results in less smoking-related harm; we also did not identify any studies indicating that any researchers have used data on harm and harm reduction associated with smokeless tobacco to model the potential health effects of substituting smokeless tobacco for smoking. We found two studies (both rated fair) that assessed whether smokeless tobacco marketing leads to greater use of these products or to substitution of smokeless tobacco for smoking (Table 14).[146,147] Both studies were population-based, used a cross-sectional design, and recruited only adolescent boys or young adult males.

In the larger study (N = 3,996 responders; response rate 62 percent), adolescent and young adult males 11 to 19 years of age provided information on their smoking and smokeless tobacco use behavior through responses on the Teenage Attitudes and Practice Survey (TAPS-I and -II) in 1989 and 1993.[147] The investigator used responses on these US-wide surveys to assess 4-year initiation rates of smokeless tobacco use and cigarette smoking in relation to each other; the investigator also examined switching between products.

In a multiple logistic regression analysis, which was adjusted for age and race, males who had been regular users of smokeless tobacco were more than three times as likely as never-users of smokeless tobacco to become smokers (OR, 3.45; 95% CI, 1.84-6.47). Current smokers were not different from never-smokers in the rate of initiating current regular use of smokeless

Table 14. Characteristics and results of studies assessing the effects of smokeless tobacco marketing

Author Year Setting	Design	Survey	N	Results	Quality Rating
Choi et al., 1995[146] California Population-based	Cross-sectional	Youth Attitudes and Practice Survey	2,814 adolescents, young adult males	Among adolescent boys, recall of smokeless tobacco advertisements was associated with smokeless tobacco use: OR, 7.5; 95% CI, 3.1-18.1	Fair
Tomar et al., 2003[147] United States Population-based	Cross-sectional	Teenage Attitudes and Practice Survey (TAPS-I and -II)	3,996 adolescents, young adult males	Significantly more users than nonusers of smokeless tobacco became smokers during 4 years of followup: OR, 3.45; 95% CI, 1.84-6.47	Fair

CI, confidence intervals; OR, odds ratio.

tobacco (OR, 1.45; 95% CI, 0.5-4.22). Among males who were regular smokeless tobacco users but not smokers at baseline, 44.8 percent continued to exclusively use smokeless tobacco at followup, 25.5 percent switched to smoking at followup, 14.3 percent continued to use smokeless tobacco while also smoking at followup, and 15.2 percent were no longer using tobacco. Of the smokers at baseline who were not users of smokeless tobacco, 78.7 percent were still smokers 4 years later, 0.8 percent switched to using smokeless tobacco exclusively, 3.6 percent continued to smoke but also used smokeless products, and 16.9 percent stopped using tobacco altogether.[147]

The other study (N = 2,814) assessed susceptibility to smokeless tobacco advertising in terms of risk factors in a study among adolescent and young adult males in California.[146] This analysis used the Youth Attitudes and Practice Survey (conducted in 1990, 1992, and 1993); the majority of the analysis was based on data from 1993. The investigators contacted a stratified random sample of young adults and adolescents 12 to 17 years of age through random-digit dialing and interviewed them to assess trends in smokeless tobacco use. The researchers specifically identified risk factors that distinguished youth who used or were at risk of using smokeless tobacco. Risk factors included current tobacco use, exposure to tobacco advertising and other smokeless tobacco users, susceptibility to use smokeless tobacco, level of rebelliousness, peers' use of drugs or alcohol, and peer norms.

Findings from the 1993 survey documented that the highest rate of smokeless tobacco use occurred among subjects 16 and 17 years of age (6.6 percent; 95% CI, 4.1-9.1). Exposure to smokeless tobacco advertisements was twice as high among males 16 to 17 years of age than among those 12 to 13 years of age (43.8 percent [95% CI, 38.8-48.8] and 21 percent [95% CI, 17.4-24.6], respectively). Recall of smokeless tobacco advertisements was significantly associated with smokeless tobacco use (AOR, 7.5; 95% CI, 3.1-18.1; $P < 0.001$). In addition, cigarette smokers were at greater risk of being smokeless tobacco users than youth who did not smoke (AOR, 3.3; 95% CI, 1.9-5.7; $P < 0.001$).[146]

KQ 5. Effectiveness of Prevention and Cessation Interventions in Populations with Co-Occurring Morbidities and Risk Behaviors

Our final systematic review investigated smoking prevention and cessation interventions in populations with co-occurring morbidities and risk behaviors. For this report, we define a person with co-occurring disorders as one who has a psychiatric condition and a nicotine addiction. Psychiatric conditions include depression, anxiety, personality disorders, traumatic stress disorder, attention deficit disorder, eating disorders, disruptive behavioral disorders, and schizophrenia. We also identify risk behaviors as behaviors that trigger or exacerbate tobacco use, such as alcohol abuse and other chemical dependencies.

As with other sections, we present information on previous systematic reviews as the background or context for recommendations to date. We then examine specific studies identified over and beyond those reviews.

Populations with Psychiatric Conditions

People with psychiatric conditions are twice as likely to smoke as the general population and to smoke more heavily than other smokers.[30] As many as 30 percent of smokers seeking cessation treatment have a history of depression.[5] Smoking cessation rates reported for the psychiatric population are lower than rates reported for the nonpsychiatric population.[30]

People with psychiatric conditions may use nicotine to self-medicate. Neurobiological and psychosocial factors reinforce the use of nicotine in populations with co-occurring disorders. Traditional antipsychotics used for certain psychiatric conditions may result in increased smoking, whereas patients taking atypical antipsychotics may smoke less.[148] Smoking improves processing of auditory stimuli in patients and may lessen negative symptoms by increasing dopamine in the prefrontal and frontal cortex.[148] Smoking is also an integral part of psychiatric culture because it provides a daily pastime for patients who may otherwise have few activities to pursue.[30] With new smoking bans enforced in health care facilities, more information on the outcomes of smoking cessation strategies tailored to these specific populations is needed.

Synthesis of prior systematic reviews. Approaches to increase quit rates among individuals with psychiatric conditions include medications, educational strategies, and cognitive behavior modifications.[30] Smoking behavior in psychiatric populations remains a challenge, with health concerns and costs similar to those for nonpsychiatric populations. Although psychiatric populations have lower smoking cessation rates than nonpsychiatric populations, in the absence of relevant RCTs on smoking cessation for populations with psychiatric comorbidities, experts agree that clinicians should use smoking cessation treatments recommended for the general population, such as pharmacotherapies and counseling.[5,30]

Synthesis of current literature. We found six studies related to KQ 5; all relate to cessation efforts.[113,149-153] We found no studies on prevention per se*;* as this question is phrased, the populations of interest are already smoking. Table 15 presents information on five of these six studies. One study[153] was graded as poor because of postrandomization of exclusions and other major flaws, so it is not discussed further. Detailed information is presented in Evidence Table 9

Table 15. Tobacco cessation interventions for persons with co-occurring morbidities and risk behaviors

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Studies in Psychiatric Populations					
Brown et al., 2001[150] United States Population-based	RCT 6 weeks 1, 6, and 12 months	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 the main analysis, smoking abstinence did not differ when CBT tailored for depression was added; in a secondary analysis CBT tailored for depression had significant interactions with both heavy smoking and recurrent depression	Fair
Brown et al., 2003[151] United States Psychiatric hospital	RCT Variable, dependent upon the length of stay 1,3,6,9, and 12 months	G1: In-person motivational interviewing sessions, offer of nicotine patch, postdischarge telephone counseling (MI) C1: Brief in-person advice, on cessation, pamphlet and shorter course of nicotine patch (BA)	191 hospitalized adolescents for psychiatric disorders	7-day point prevalence rates At 1 month • MI arm: 11% • BA arm: 11% At 6 months • MI arm: 13.3% • BA arm: 8.5% At 12 months • MI arm: 14% • BA arm: 9.9% *P* = NS Anxiety disorders increased odds for quit attempts in adolescents with psychiatric disorders (AOR, 1.99; 95% CI, 1.08-3.71)	Fair
Hitsman et al., 1999[113] United States Population-based	RCT 10 weeks 1 week; 1, 3, and 6 months	G1: Individual behavioral therapy; fluoxetine 30mg; quit date set, compliance level at 150ng/ml G2: Same as G1 except fluoxetine is a 60mg dose and compliance level set at 300ng/ml C1: Same as G1 except received placebo	253 adults	At 1 and 3 months, for treatment-compliant patients, fluoxetine had a positive association with degree of depression and likelihood of abstinence (OR, 1.35; 95% CI, 1.00-1.81)	Fair

Table 15. Tobacco cessation interventions for persons with co-occurring morbidities and risk behaviors (continued)

Author Year Setting	Design Exposure Followup	Intervention	N	Results	Quality Rating
Studies in Substance-Addicted Populations					
Joseph et al., 2004[149] United States Residential substance use disorder treatment program	RCT 10 weeks 3, 6, 9,12, and 18 months	G1: Individual behavioral therapy; recommended nicotine patches (21 mg for 6 weeks, 14 mg for 2 weeks, and 7 mg for 2 weeks) for smokers; combination of patches and nicotine gum for smokers of >20 cigarettes per day C: Temporary control group with treatment delayed for 6 months	499 substance use disorder adults	At both 3 and 6 months, smoking abstinence rates were significantly greater in the treatment groups than the temporary control group ($P < 0.000$ and $P = 0.02$, respectively)	Good
Joseph, 1993[152] United States Hospital	Prospective cohort study 3 weeks 1 year 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 a substance abuse treatment program	Patients who want to quit smoking At 3-week followup • Prepolicy: 24% • Postpolicy: 61% ($P < 0.001$) Patients who quit smoking At 1-year followup • Prepolicy: 3% • Postpolicy: 8% ($P < 0.05$)	Fair

AOR, adjusted odds ratio; C, control group; CBT, cognitive behavioral therapy; G, intervention group(s); ng/ml, nanogram per milliliter; NS, not significant; OR, odds ratio; RCT, randomized controlled trials.

(Appendix C).[§] Of the studies discussed for KQ5, we rated one as good and the other four as fair.

Three studies addressed smoking cessation interventions for populations with co-occurring morbidities.[113,150,151] These RCTs, all rated fair, were conducted in the United States. One study implemented a smoking cessation intervention in a psychiatric hospital;[151] the others were population-based interventions.[113,150] One trial included adolescents and the other two enrolled adults; the sample sizes ranged from 179 to 253.

Brown and colleagues compared the efficacy of a standard CBT smoking cessation treatment with standard smoking cessation treatment combined with CBT for depression.[150] Through newspaper, radio, and television advertisements, the study recruited regular smokers (i.e., smoked cigarettes for at least 1 year and currently smoke 10 cigarettes each day) between ages

[§] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/tobusetp.htm.

18 and 70 years with a history of major depressive disorder (MDD) determined by structured interviews using the DSM-III-R. The 179 participants enrolled in the study received eight group counseling sessions over 6 weeks and standard CBT. Participants in the treatment group received "The Coping with Depression Course," which served as the basis for the CBT.[150]

Self-report of smoking status was collected and verified by expired CO at each treatment session from the quit date to the end of treatment; follow-up data were collected by telephone at 1, 6, and 12 months. No statistical differences were identified in 7-day point prevalence abstinence rates at 1, 6, and 12 months for the standard CBT (30.1 percent, 24.7 percent, and 24.7 percent, respectively) compared with the depression-based CBT (39.5 percent, 24.4 percent, and 32.5 percent, respectively). In the final steps of the generalized estimating equations (GEE) analysis, significant interactions occurred between treatment and heavy smoking (OR = 3.73; $P = 0.02$) and between treatment and recurrent depression (OR = 3.62; $P = 0.02$).[150]

A second study from Brown and colleagues randomly assigned adolescent smokers between 13 and 17 years of age who had been hospitalized for psychiatric and substance use disorders into either a motivational interviewing (MI) or a brief advice (BA) tobacco cessation intervention.[151] The MI arm consisted of two in-person, 45-minute motivational interviews during hospitalization.[151] Participants in the MI arm received comprehensive manuals about relapse prevention and coping skills for mood management. Additionally, two courses of free transdermal nicotine patch therapy were offered to medically eligible participants. At the end of the MI intervention, participants received up to six postdischarge telephone counseling sessions, and their parents received up to four brief telephone counseling sessions. BA participants received 5 to 10 minutes of advice to quit smoking by one of the student therapists, a copy of the "I Quit!" self-help pamphlet, and (for those who were eligible) a one-time offer of a transdermal nicotine patch treatment regime.

The MI arm had 116 participants and the BA arm had 75 participants. The population was primarily female (62.3 percent) and white (94.8 percent). The mean age of participants was 15.4 years, and 68.6 percent met the Diagnostic and Statistical Manual for Mental Disorders, Fourth Edition (DSM-IV) criteria for nicotine dependence. Psychiatric disorders included mood, anxiety, disruptive behavior, attention deficit, and substance-related disorders. The investigators assessed nicotine dependence at 1, 3, 6, 9, and 12 months. Smoking abstinence, measured by self-report, was confirmed through biochemical verification using saliva cotinine.[151]

To assess whether MI would lead to more and longer quit attempts, reduced smoking, and more abstinence from smoking, Brown et al. employed hierarchical linear modeling, GEE analyses, and logistic regression.[151] The findings did not show higher quit attempts for those receiving MI than those receiving BA (mean quit attempts = 1.1 vs. 1.3, P = not significant [NS]). Seven-day point prevalence abstinence at 1, 6, and 12 months was not significantly different between the groups (see Table 15 for point prevalence rates). The mean number of days for the longest quit attempt was 48.2 days for the MI group and 60.9 days for the BA group; however, this difference was not significant.

Two findings were associated with significantly less smoking among adolescent psychiatric patients.[151] Examination of covariates revealed that having an anxiety disorder increased the odds for quit attempts (AOR, 1.99; 95% CI, 1.08-3.71); in the hierarchical linear model, higher discharge self-efficacy scores were associated with less smoking during followup ($b_1 = -0.02$, standard error = 0.007; $P = 0.007$). MI and BA were equally ineffective smoking cessation interventions for this population.

Hitsman et al. hypothesized that smokers with greater depressive symptoms and those with elevated weight concerns would be more likely to achieve tobacco abstinence when receiving fluoxetine (combined with CBT) than when receiving a placebo (and CBT).[113] The first arm involved nine 1-hour, individual CBT sessions plus 30 mg fluoxetine for a total of 10 weeks. Participants were required to set a quit date within 2 weeks of drug treatment initiation. Participants quit smoking at the third CBT session, and medication stopped at the ninth CBT session, at which time the 6-month follow-up period began. Patients with fluoxetine levels less than or equal to 150 ng/ml were considered compliant. The second arm was the same as the first arm except that the fluoxetine dose was 60 mg, and fluoxetine blood levels less than or equal to 300 ng/ml were considered compliant. The third arm of the trial was also the same as the first except that participants received a placebo.

Participants were considered to be smoking if expired CO was greater than 8 ppm and saliva cotinine values were greater than 10ng/ml. Level of depression, nicotine dependence, weight concerns, and self-efficacy about quitting were also assessed. Baseline measures were similar across all treatment groups. Hitsman et al. applied predictive models using logistic regression with a hierarchical approach to variable selection to analyze the data. Separate hierarchical logistic regression using intent-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.[113]

An interaction between fluoxetine treatment and the depression score occurred at 1- and 3-month followup for treatment-compliant patients only (n = 169). Participants treated with fluoxetine had a positive association between degree of depression and likelihood of abstinence (OR, 1.35; 95% CI, 1.00-1.81); for controls, the opposite was true, and increasing depression scores were associated with decreasing likelihood of abstinence. The fluoxetine effect was greater for individuals with depression scores in the upper quartile of the depression scale (Hamilton Rating Scale for Depression [HRSD], 3; OR, 2.0; 95% CI, 0.85-4.7) than for individuals in the lower quartile of the depression scale (HRSD, 1; OR, 1.10; 95% CI, 0.38-3.19). At 3 months, the interaction effect was sustained; fluoxetine selectively benefited smokers with higher initial levels of depression (OR, 1.39; 95% CI, 1.02-0.89) and patients receiving fluoxetine showed a positive association between degree of depression and likelihood of abstinence (highest quartile HRSD = 3; OR, 1.44; 95% CI, 0.53-3.91). Smoking characteristics predicting treatment compliance were nicotine intake at baseline, saliva cotinine (X^2, 11.4; $P < 0.001$), and expired CO (X^2, 5.3; $P < 0.05$).[113]

Populations with Substance Addictions

Smoking rates for alcohol and drug users are well above those for the average population, exceeding 70 percent.[5] The risk of death is significantly higher for individuals with concurrent addictions of alcohol and nicotine than for individuals who abuse only alcohol or tobacco. Consequently, alcoholics are thought to be more likely to die from cigarette-related diseases than from alcohol-related diseases.[154]

The best way to approach smoking cessation treatment with people who have chemical addictions remains controversial. Additionally, some in the substance abuse treatment community argue (on the basis of untested assumptions) that smoking cessation treatment threatens the process of alcohol rehabilitation.[154] Others claim that the opportunity to engage this population in smoking cessation treatment may be lost by delaying treatment until after sobriety.[24]

Synthesis of prior systematic reviews. Multimodal strategies using nicotine replacement therapy in conjunction with psychosocial intervention strategies are effective in treating tobacco addiction in patients with alcohol and other substance abuse problems.[9] Fiore et al. report that people with chemical and nicotine dependency should receive counseling and pharmacotherapy to assist with smoking cessation.[5] Although these types of interventions had positive short-term effects for stopping smoking, maintaining long-term abstinence was not successful.[9] Evidence is clear that smoking cessation treatment does not interfere with recovery from chemical dependency.[9] This finding eliminates obstacles to providing this population with concurrent treatment for substance abuse and nicotine dependency.

Synthesis of current literature. Three studies examined smoking cessation treatments for alcohol and substance abusers; we excluded one study from this discussion because of a quality rating of poor.[149,152,153] The other two studies, both conducted in the United States, received a good[149] and a fair[152] rating. One study used a prospective cohort study design;[152] the other was a RCT.[149] Both enrolled adults in substance use disorder programs; the samples size ranged from 706 to 499.

To examine long-term smoking cessation outcomes, Joseph evaluated the feasibility of a smoke-free policy and a nicotine treatment program implemented in a drug and alcohol treatment hospital.[152] Patients admitted to the treatment facility were consecutively enrolled in the study. In 1988, before implementation of the smoke-free policy, patients were not provided with specific information about smoking or cessation. Patients in the facility when the smoke-free policy changed (i.e., those admitted to the hospital between May and July 1988) were excluded from the study. After implementation of the smoke-free policy, patients were required upon admission to acknowledge the smoke-free policy, sign a contract agreeing to abstain from nicotine during their treatment period, and agree to attend a smoking cessation program specifically designed for substance use patients. The program included (1) didactic lectures on the pharmacology of nicotine, (2) films, and (3) a discussion group.

Joseph used a one-page, standardized, self-administered questionnaire to assess smoking status and motivation to quit at admission and again during the third week of hospitalization.[152] Structured telephone interviews at 1 year after hospitalization assessed substance use other than nicotine. The prepolicy patients (n = 156) completed posthospitalization telephone interviews at 16.2 months, and postpolicy patients (n = 163) at 10.7 months. Approximately 55 percent of the sample was lost to followup. The telephone interview assessed the long-term outcome of the patient's chemical dependency. Improvement in chemical dependency was defined as less or no use of the substance for which patients were treated at the time of hospitalization. Other outcomes were smoking status, motivation to quit, and use of substances other than nicotine.

At 3-week followup, the 24 percent of patients in the prepolicy group and 61 percent in the postpolicy group "want[ed] to quit" smoking ($P \leq 0.001$).[152] 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 percent vs. 9 percent, $P < 0.001$). Postpolicy patients cut down significantly more on the number of cigarettes smoked while in the hospital than did the prepolicy patients (93 percent vs. 46 percent, $P < 0.001$). At the 1-year follow-up interview, 8 percent of the postpolicy patients and 3 percent of the prepolicy patients had quit smoking ($P < 0.05$). The groups did not differ significantly at the 1-year followup for nonnicotine substance use.

Joseph and colleagues compared the effects of treatment for nicotine dependence and intensive treatment for alcohol dependence, delivered concurrently, with the same nicotine

dependence treatment delayed by 6 months.[149] Eligible participants included both men and women between the ages of 21 and 75 who met the criteria for alcohol dependence or abuse according to the DSM-IV and who smoked more than five cigarettes each day for a year. Participants with no interest in quitting were excluded from the study.

The nicotine dependence intervention included a combination of behavioral and pharmacological treatments. A 1-hour individual counseling session and up to three followup sessions conducted in person or by telephone were offered to participants. Participants 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. The intervention was identical in both treatment arms but delayed in one, which effectively established a temporary control group.[149]

Biochemically validated self-reports were collected for both smoking and alcohol outcomes. Seven-day point prevalence abstinence rates 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 a simple likelihood ratio chi-square test and intent-to-treat analysis, the 7-day point prevalent smoking abstinence rates at 3 months were 15.5 percent in the concurrent treatment group and 4.4 percent in the delayed group ($P < 0.0001$). At 6 months, abstinence rates were 10.5 percent in the concurrent treatment and 5.2 percent in the delayed treatment group ($P = 0.02$); the delayed group, however, had not received the intervention at 3 and 6 months. Thereafter, at 9 and 12 months, the treatment groups did not differ significantly. The rate of prolonged smoking abstinence at 18 months for both groups was similar: 8.8 percent for concurrent treatment and 8.9 percent for delayed treatment. However, the participation rate in the concurrent treatment was significantly higher than in the delayed treatment (78.5 percent vs. 64.5 percent, $P = 0.005$; OR = 2.01; 95% CI, 1.35-2.99).

The alcohol abstinence outcomes at 6, 12, and 18 months for 6-month alcohol abstinence was lower in the concurrent treatment group (41 percent, 33 percent, and 41 percent, respectively) than in the delayed treatment group (56 percent, 42 percent, and 48 percent; $P = 0.004$, $P = 0.11$, and $P = 0.01$, respectively).

Chapter 4. Discussion

This chapter reviews the quality of the literature and strength of the evidence base for selected outcomes relating to tobacco prevention, smoking cessation intervention, and smokeless tobacco marketing. The confidence that readers can have in our findings, conclusions, and recommendations is contingent on the quality of the research reviewed and the overall robustness of the evidence. Key question (KQ) 6, addressed in this chapter, concerned limitations in the literature and gaps in the knowledge base that point to needed future research. Our information and suggestions pursuant to this question will be especially pertinent to participants at the National Institutes of Health (NIH) State-of-the-Science Conference on Tobacco Use on June 12–14, 2006.

Quality of Literature and Strength of Evidence

As described in Chapter 2 and documented in the evidence tables (Appendix C[§§]), we selected articles for this review using rigorous criteria and assessed them using a component quality rating scale of "good," "fair," and "poor." The prior systematic reviews that we used for several key questions or parts of questions were all of good or fair quality.

We also evaluated the strength of the body of evidence based on the suitability and quality of execution of the study design, the amount of evidence available, and the coherence or consistency of available evidence. The strength-of-evidence categories were strong, sufficient, and insufficient. The suitability of the study design for assessing effectiveness is based on how well the study design protects against potential threats to validity.[56] Concurrent comparison groups, prospective measurement of exposure, multiple outcome measurements conducted over time, and assessment of exposure that precedes assessment of outcome are ways to avoid potential threats to validity. Suitability of the study design was contingent on whether the study had concurrent comparison groups, no comparison group but multiple prepost measurements, or single prepost measurements and was assessed as greatest, moderate, or least, respectively. For assessing the quality of study execution (see Chapter 2), we considered the following areas that posed possible threats to validity: (1) study population, (2) intervention descriptions, (3) sampling, (4) exposure and outcome measurement, (5) data analysis, (6) interpretation of results, (7) followup, (8) bias, and (9) confounding. We evaluated studies based on limitations in one or more of these areas. The number of studies needed to assess the strength of the body of evidence is variable and depends on the suitability and execution of the studies.

KQ 1. Effective Population- and Community-based Interventions to Prevent Tobacco Use in Adolescents and Young Adults

Population-based tobacco prevention interventions. Two studies implemented population-based tobacco prevention interventions.[73,79] Thomson et al. examined the effects of statewide youth tobacco access ordinances in Massachusetts and had one result in the expected direction.[79] Residents of towns with fewer free-standing tobacco product displays were less likely to perceive tobacco as easy to purchase. The study found an association between increased attempts

[§§] Appendixes cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/tobusetp.htm.

to purchase tobacco and being older and male, but the study did not determine whether adolescents in towns with more tobacco access ordinances and regulations had less tobacco initiation. The second population-based study conducted within families was time intensive and required many resources to implement,[73] but it was successful at reducing tobacco initiation for a subset of the population (i.e., non-Hispanic whites). These two studies alone provided little evidence to draw conclusions about population-based tobacco prevention interventions.

Prior systematic reviews reported strong evidence of effectiveness for two approaches to tobacco use prevention among adolescents and young adults: (1) increasing the unit price of tobacco products, and (2) mass media campaigns run concurrently with other interventions such as increased excise taxes or school- and community-based tobacco prevention programs.[7] We found no other research to add to existing evidence on increasing unit price for tobacco products or on mass media campaigns alone or in conjunction with other tobacco prevention efforts.

Sufficient evidence of effectiveness was determined for tobacco prevention strategies that mobilize community support in conjunction with restricting tobacco product distribution, regulating the mechanisms of sale, enforcing access-to-minors laws, and educating and training merchants.[7] The findings from the Massachusetts study on statewide youth tobacco access ordinances augments the already sufficient evidence of effectiveness for tobacco prevention strategies that coordinate community-wide interventions to regulate and enforce access-to-minors laws.[79]

Community-based tobacco prevention interventions. Ten studies implemented school-based tobacco prevention programs.[68-72,74-76,81,82] The studies had adequate sample sizes and used appropriate cluster analysis for school-level data. Limitations of school-based tobacco prevention studies include high attrition rates, lack of long-term follow-up assessments, and inconsistent definitions of smoking status and abstinence.

Programs done over a single school year provided mixed results. At the end of the interventions or shortly afterwards, two studies, one using classroom instruction and the other using personalized letters, reduced tobacco initiation.[68,71] Two other studies, however, both using classroom instruction (with one incorporating extracurricular activities and parent involvement), were effective only for boys.[75,81]

Interventions done over multiple school years, which provide longer or repeated exposure to prevention treatment, also produced mixed results. Two studies significantly reduced tobacco initiation rates,[72,74] one study reduced tobacco uptake for boys but not girls,[70] and two other studies had no effect.[76,82] No school-based study reported long-term effects.

Past systematic reviews report limited support for community- and school-based tobacco prevention programs for reducing tobacco initiation.[34,64] Long-term effects (i.e., greater than 2 years) have not been found with school-based interventions. Although educational strategies conducted together with population and community tobacco prevention efforts have postponed tobacco initiation,[2] this result was not evident in our studies. Existing evidence is sufficient to demonstrate that tobacco prevention measures conducted in school settings have positive short-term effects on preventing adolescents from initiating tobacco use.[68,70-72,74,75,81] Without definitive findings, evidence is insufficient to draw conclusions on the effectiveness of school-based programs to produce long-term effects. These results are consistent with past reviews that suggest school-based prevention strategies show limited effectiveness over the long run.[34]

Provider-based tobacco prevention interventions. The only provider-based study we reviewed found no intervention effects.[80] Therefore, existing evidence is insufficient to determine whether tobacco prevention conducted in provider settings is effective for preventing

tobacco use among adolescents. Past systematic reviews have not evaluated provider-based tobacco prevention strategies in health care settings.

Gaps in Tobacco Prevention Literature

Population-based tobacco prevention interventions. With the exception of tobacco industry and product restriction, earlier systematic reviews had extensively evaluated tobacco prevention strategies and provided intervention recommendations that included increasing tobacco product prices, enforcing tobacco laws and regulations, and conducting mass media education campaigns. Our review identified two population-based studies (only one related to past reviews and recommendations). Population-based tobacco prevention research lacks tobacco industry and product restriction interventions. More research is needed on the effects of price increases in combinations with other strategies. Too few studies of good and fair quality report on the effects of enforcing tobacco youth access laws and regulations aimed at retailers, and many studies do not use reduced initiation as the outcome variable. More rigorous research on the enforcement of youth access laws and regulations and their impact on smoking initiation among adolescents and young adults is needed to help build the evidence base.

Limited information is available on the effectiveness of implementing several population-based interventions simultaneously. Implementing tobacco prevention strategies that we know are effective concomitantly may greatly influence the uptake of tobacco use among adolescents and young adults.

Community-based tobacco prevention interventions. The body of evidence for school-based tobacco prevention is large; our review found several recent school-based tobacco prevention studies. Improving this body of evidence entails producing more rigorous research through adequate use of randomization, using control groups without contamination or confounding issues, achieving low attrition rates, and consistently using operationally defined outcome variables. The lack of long-term effects of school-based programs is problematic, so sustainability of effects remains unknown.

Additionally, we found no research about comprehensive interventions that include combining school-based prevention programs with other effective interventions such as media campaigns or enforcement of tobacco youth access laws and regulations. More research on community-based tobacco prevention interventions is needed, because our review found no other community-based interventions beyond what has been reported in prior systematic reviews.

Provider-based tobacco prevention interventions. Virtually no evidence is available to report on provider-based tobacco prevention for adolescents. Provider-based tobacco prevention may be practical only for dental or orthodontic practices, where many adolescents have repeated visits. Research in this area has focused on measuring implementation, content of counseling, and frequency of counseling, but studies did not report on our outcome variable for KQ 1 (i.e., reduced initiation of tobacco use).[135] Additional evidence is needed to assess whether provider settings are a viable place to implement tobacco prevention for this age group.

KQ 2. Effective Strategies for Increasing Consumer Demand for and Use of Proven Individually Oriented Cessation Treatment

Multicomponent strategies to increase the number of users who attempt to quit.

Telephone counseling. Findings from recent reviews show that proactive telephone counseling is effective in increasing tobacco use cessation for adults, especially when combined with other

counseling formats. We identified three studies of fair quality that focused on telephone counseling with related print materials.[84-86] These studies, on their own, yielded insufficient and inconsistent evidence to draw conclusions about the efficacy of telephone counseling. Two trials reported significant increases in cessation in the short term among those using telephone counseling;[85,86] one trial reported no difference in either abstinence at each followup or in continuous abstinence.[84] When considered within the context of recent systematic reviews and meta-analyses, results from two studies in our review were consistent with that body of evidence; each demonstrated a positive effect of telephone counseling along with relevant printed materials on quitting smoking.[85,86]

We found only two studies targeting youth and young adults with telephone counseling. Both showed that telephone counseling for youth and young adults resulted in quit rates comparable to those for adults. The small number of studies led us to conclude that, although promising, the evidence is currently insufficient to draw conclusions with regard to the effect of telephone counseling on adolescents and young adults.

We found no study evaluating other multiple formats for increasing the number of users who attempt to quit. One study that evaluated counseling enhanced by providing information on genetic susceptibility to lung cancer showed a short but unsustained effect on cessation rates. Results of studies evaluating persistence of effect in the long term were inconsistent.

Numerous design and measurement issues complicate the interpretation of study findings for this portion of the review. Smokers were defined in various ways in these studies; no two studies applied the same definition. The trials evaluated very different interventions; they also used different measures of smoking status and abstinence and different follow-up intervals. The five studies using continuous abstinence as an outcome, however, did consistently define it as abstinence at all reporting periods.

Strategies to improve the success of quit attempts. Our review included studies evaluating the efficacy of cessation strategies such as self-help, counseling, single pharmaceuticals, combined pharmacotherapies, and pharmacotherapies combined with psychological counseling. Three studies were determined to be of good quality; all others were fair. Our findings for self-help strategies were consistent with those of earlier reviews. We found insufficient evidence of the efficacy of self-help strategies given the small number of new studies and discrepancies across their reported effects. In the one study that showed an effect, we could not estimate the independent effect of practical tips for smoking cessation compared with other components of the intervention such as tips on exercise.[115] These findings were consistent with those of other recent reviews showing the marginal efficacy of self-help when offered without any person-to-person intervention.

Our review of counseling showed mixed results. Two studies reported increased abstinence with counseling treatment; three showed no effect. This evidence is insufficient on its own to make a recommendation differing from those of prior reviews indicating that even brief individual cessation counseling is efficacious.

In our review of pharmaceutical approaches to increasing the success of quit attempts, we reviewed five studies, all of fair quality. Three studies evaluated the effect of bupropion, one studied the effect of nicotine gum and of different doses of nicotine gum, and one examined the comparative efficacy of transdermal nicotine and nicotine nasal spray.

Findings are consistent with those of prior reviews showing that nicotine gum is a significant aid to smoking cessation, more than doubling the odds of successful quitting. No differences in dose response (2 mg vs. 4 mg) for nicotine gum were found in one study.

Results were mixed for bupropion. Two studies showed a significant benefit of bupropion compared with placebo at 6-month assessment. Patients ready to quit participated in one study;[106] participants at all stages of readiness in an indigenous population group were enrolled in another.[114] In the final study, bupropion use in outpatients regardless of stage of readiness to quit showed a nonsignificant trend in favor of abstinence in the short term (3 months) but not at longer periods (e.g., 6 and 12 months).[101] These mixed findings for bupropion are insufficient on their own to warrant a change in findings from previous reviews concluding that bupropion is a first-line pharmacotherapy for smoking cessation.

In a trial evaluating the comparative efficacy of transdermal nicotine and nicotine nasal spray, abstinence rates for the two groups were not significantly different at 6-month followup (15.0 percent vs. 12.2 percent, respectively; $P > 0.2$).[100] These results are consistent with estimates of significant effect for transdermal nicotine and nicotine nasal spray found in prior reviews. Smokers with low to moderate dependence levels, who were not obese, and who were white achieved higher abstinence levels with transdermal nicotine. By contrast, smokers who were highly dependent, obese, or members of minority groups achieved higher abstinence rates with nasal spray.[100] These findings provide useful information for those offering these pharmaceuticals to their patients.

Three studies assessed the efficacy of combined pharmaceutical therapy. Two of these studies showed a significant increase in long-term cessation (i.e., 12 months) compared with one pharmacotherapy alone. One of these studies was consistent with prior reviews showing that a combination of nicotine patch with a self-administered form of nicotine replacement therapy was more effective than a single form of replacement therapy. The other study showed the significant benefit of bupropion alone and in combination with the nicotine patch over the long term (12 months) compared with placebo. The third study showed no overall benefit of the patch and paroxetine combined, but did demonstrate significant differences between paroxetine groups and placebo in the short term (4 weeks).

We identified six studies combining pharmacotherapy and psychological interventions; interventions varied by type of pharmacotherapy and by content, format, and intensity of counseling. Five of these studies demonstrated a significant improvement in abstinence in treatment groups receiving combination pharmacotherapy and psychological interventions. These studies provide sufficient evidence of the efficacy of combined pharmacotherapy and psychological interventions and add to findings from previous reviews that pharmacotherapy either alone or in combination with counseling is effective.[5,30] The single study on fluoxetine is not sufficient to add it to the list of efficacious pharmacotherapies.

Strategies to improve the success of quit attempts for special populations. Nine studies evaluated strategies to increase the success of quit attempts among special populations. Three studies focused on hospitalized patients in different diagnostic categories;[119,120,123] four examined the impact of varying the intensity of interventions for hospitalized patients;[112,115,124,125] one dealt with pregnant women[122] and one with the indigenous Maori population in New Zealand.[114]

Hospitalized patients. When considering interventions for hospitalized patients by diagnosis, two studies of fair quality and one of good quality found results similar to those in prior studies; that biochemically validated abstinence rates at 12 months postdischarge, although reported as higher for the intervention group, were not statistically significant.[119,120,123] In one study, significant differences at 12 months in compliant patients did not hold with intent-to-treat analysis.[123] Overall, studies in our review were in agreement with findings of the Rigotti, et al.

review showing that there was no strong evidence that clinical diagnosis affected the likelihood of quitting.[63]

Four studies considered whether cessation varied with counseling intensity for hospitalized patients.[112,115,124,125] All three studies compared an intensive intervention (defined as inpatient contact plus followup for at least 1 month) with usual care and/or a less intensive intervention. One study showed significant differences in self-reported, but not biochemically validated, abstinence at 12-month followup. Two studies showed significant increases in abstinence at 3- or 6-month assessments but not at 12-month assessments. One study found a significant increase in abstinence but was unable to attribute it directly to the intervention.

Pregnant women. One study using enhanced counseling to prevent postpartum relapse, telephone counseling during and after pregnancy, and partner assistance in quitting demonstrated no significant improvement in abstinence.[122]

Ethnic groups. In a study of whether bupropion combined with smoking cessation counseling was effective in treatment of tobacco use in indigenous Maori in New Zealand, the investigators found quit rates similar to those observed in other trials of bupropion.[114] They also reported no data to suggest that the Maori encountered any special problems related to bupropion use.

Gaps in the Literature for Increasing Demand for and Use of Cessation Treatments

Very few studies examined the relative population impact of proven cessation interventions. For example, information on how proactive telephone counseling support compares with a face-to-face intervention would be useful; similarly, whether nicotine replacement therapy is offered in either of these (or other) situations would be useful for those designing combination interventions. Little is known about differential rates of success of and enrollment in various programs and how each may either offset or enhance the other. These research questions are especially important given the move toward provider referral to quit-line services.

We found no studies comparing the specific aspects of telephone counseling with each other. Issues about the number and timing of calls and the role of feedback to the caller's primary provider have not been studied sufficiently.

We did not identify sufficient studies of the role of mass media in increasing use of cessation services among specific subsets of the population. Research on specific messages and their effectiveness in reaching and motivating target audiences such as adolescents, young adults, and persons with low income and educational status could improve the impact of such interventions.

We found very few studies examining the effectiveness of multiple intervention formats, of combination pharmacotherapy, or of adjuncts other than pharmacotherapy to individual counseling in increasing the success of smoking cessation interventions. Similarly, very few studies examined differences in either withdrawal symptoms or side effects associated with continuation or success of pharmacotherapy. Persistence of effect on smoking status over time was reported by only two studies; larger, prospective trials are likely needed to increase the evidence base for this issue. Finally, very few studies focused on ways to reach or treat special populations such as adolescents and young adults.

KQ 3. Effective Strategies for Increasing the Implementation of Proven Population-Level Tobacco Use Cessation Strategies, Particularly by Health Care Systems and Communities

Population-based implementation strategies. We found insufficient evidence to suggest that community-based interventions increase implementation of proven cessation strategies. Three studies, one of good quality and two of fair quality, focused on very different strategies and populations and produced inconsistent results.[131-133] Positive results were shown only in a trial using community-based pharmacists to discuss smoking cessation with smokers coming to their pharmacies for a variety of services.[132] The positive results observed with pharmacist-led interventions suggest that further research into how pharmacists might be engaged in and support community-based strategies would be useful.

Provider- and health care system-based tobacco use cessation strategies. One prior systematic review reported "strong" evidence of effectiveness for provider reminder systems with provider education, with or without client education, and for multicomponent interventions that include client telephone support; "sufficient" evidence of effectiveness for provider reminders alone and reductions in patient out-of-pocket costs; and "insufficient" evidence of effectiveness to recommend provider education alone and provider feedback and assessment.[7]

A meta-analysis identified six systems strategies to facilitate adoption of effective tobacco treatment in health care settings: (1) implementing a tobacco user identification system in every clinic; (2) providing education, resources, and feedback to promote provider intervention; (3) dedicating staff to provide tobacco dependence treatment and assessing the delivery of this treatment in staff performance evaluations; (4) promoting hospital policies that support and provide tobacco dependence services; (5) including tobacco dependence treatments (both counseling and pharmacotherapy) identified as effective as paid or covered services for all subscribers or members of health insurance packages; and (6) reimbursing clinicians and specialists for delivery of effective tobacco dependence treatments and including those interventions among the defined duties of the clinicians.

Four studies showed that provider training improved provision and uptake of smoking cessation strategies.[134,142,144] When examining the effect of these changes on smoking abstinence, two studies reported significant increases in abstinence compared with control, and one reported no differences at 6-month followup after biochemical verification of self-reported abstinence.[144] Our review supports the efficacy of provider-based strategies to increase the implementation of proven cessation strategies, but falls just short of providing sufficient evidence that these improvements in implementation will increase cessation.

In our review of interventions carried out in health care systems, we found sufficient evidence that academic detailing approaches improved provider delivery of effective smoking cessation treatments. Family physicians and other providers in office-based private practices, public clinics, hospitals, and orthodontist offices improved their knowledge and use of effective strategies as a result of personal educational visits in their own practice setting that included education, audit, and feedback.

The evidence was insufficient, however, to suggest that these improved treatment practices lead to significant, long-term increases in cessation among those being treated. Too few studies reported quit rates for the population served. Those studies reporting quit rates showed no consistent effects on cessation in the long term. One study found significant improvement in cessation in the short term; this occurred among pregnant women.[139] This finding is especially

important given the immediate positive health outcomes associated with quitting in the short term for a pregnant woman and her fetus.

No evidence was found to conclude that provider attitudes and smoking behavior have an effect on uptake and use of effective interventions. The only study to test this relationship found no effect.[136]

Evidence was also insufficient to suggest that interventions proven effective in earlier trials could be sustained as a part of routine care. Only one study examined this important aspect of improving the odds of maintaining an effective program.[86] The investigators found that successfully implementing a proven strategy after completion of the original trial is possible; they also determined that the sustained program produced quit rates comparable to those observed in the trial and that success was more likely among cancer, cardiovascular, and pulmonary patients.

Gaps in the Literature for Increasing Implementation of Cessation Strategies

We found inconsistencies in the literature evaluating academic detailing as an approach to improving implementation of cessation strategies. Additional studies are needed that use a standard definition of academic detailing, that observe changes not only in practice patterns but also in related smoking cessation outcomes, and that systematically assess the impact of academic detailing across and within practice types. At a minimum, all subsequent studies should incorporate all proven components of an academic model, such as provider reminder systems.

We found only one study describing how provider attitudes and smoking behavior affected provider use of effective interventions. Similarly, we found only one study examining the factors affecting incorporation of effective interventions into usual care. Many studies reported on implementation strategies to improve smoking cessation services in practice settings, but few studies collected data on whether these system-based improvements translate into increased quit rates.

KQ 4. Effect of Smokeless Tobacco Product Marketing and Use on Population Harm From Tobacco Use

Smokeless tobacco product marketing and use. Two studies with quality ratings of fair focused on smokeless tobacco use.[146,147] They investigated (1) how smokeless tobacco use affects smoking behaviors and (2) how exposure to smokeless tobacco advertising affects use. Tomar reported that smokers were more likely to quit smoking than become users of smokeless tobacco.[147] More importantly, users of smokeless tobacco were significantly more likely than nonusers of tobacco to become smokers.[147] One study does not provide sufficient evidence to draw conclusions on whether smokeless product marketing results in substituting smokeless tobacco for smoking.

Our review found one study that indicates smokeless tobacco marketing may lead to greater use at least for adolescents.[146] Choi et al. found that exposure to advertising increased adolescents' susceptibility to smokeless tobacco. One predictor of current use of smokeless tobacco is exposure to smokeless tobacco advertising, resulting in a sevenfold increase in current

use.[146] Again, one study does not provide sufficient evidence to determine whether tobacco marketing increases smokeless tobacco use.

Prior systematic reviews did not address issues relevant to KQ 4. Past reviews focused on risks associated with the use of smokeless tobacco and on the potential offered by smokeless tobacco cessation treatments.[1,2,5]

Gaps in Smokeless Tobacco Product Marketing and Use

Smokeless tobacco product marketing and use. The gaps in research on smokeless tobacco product marketing and use are substantial. No studies addressed two of three concerns presented in this review: (1) whether substituting smokeless tobacco for smoking results in less smoking-related harm on a population basis, and (2) whether data on harms and harm reduction associated with smokeless tobacco are used to model the potential health effects of substituting smokeless tobacco for smoking. Additional evidence is necessary to determine how smokeless tobacco use affects smoking behaviors and how exposure to smokeless tobacco advertising affects use.

KQ 5. Effectiveness of Prevention and of Cessation Interventions in Populations with Co-Occurring Morbidities and Risk Behaviors

Tobacco cessation for persons with co-occurring morbidities. Three studies evaluated smoking cessation for persons with psychiatric conditions.[113,150,151] Hitsman et al. hypothesized that smokers with greater depressive symptoms would be more likely to achieve abstinence when receiving fluoxetine combined with cognitive behavioral therapy (CBT) than when receiving a placebo and CBT.[113] Brown et al. compared standard CBT with CBT tailored for depression for adults with a history of major depressive disorder (MDD).[150,151] A second study by Brown and colleagues treated adolescent smokers hospitalized for psychiatric and substance use problems with either motivational interviewing or brief advice tobacco cessation interventions.[151] Two of the three studies[113,151] used some form of pharmacotherapy. Hitsman et al. achieved significant results in an adult population, but Brown et al. did not in an adolescent population.[113,151] Counseling paired with CBT produced smoking cessation rates for people with a history of MDD but depression-based CBT did not significantly increase smoking cessation rates over standard CBT for this population.

Consistent with prior reviews, pharmacotherapy was effective.[5,30] Participants treated with fluoxetine had a higher likelihood of abstinence than did participants treated with placebo, and fluoxetine benefited smokers with higher initial levels of depression.[113] The effects of counseling and CBT are also congruous with the prior reviews, but depression-based CBT does not statistically increase abstinence rates above standard CBT abstinence rates.[150] Neither motivational interviewing nor brief advice tobacco cessation interventions were effective for adolescents hospitalized for psychiatric and substance use problems.[151] Prior reviews did not report effective smoking cessation interventions for adolescents in this population.

Our review of the effect of smoking cessation interventions for persons with co-occurring morbidities supports prior reviews. Nonetheless, because we found only a limited number of studies and inconsistent results, it does not provide sufficient evidence to make further recommendations about the effectiveness of smoking cessation interventions in populations with psychiatric conditions.

Tobacco cessation for persons with substance abuse addictions. Two studies investigated smoking cessation among alcohol and substance abusers.[149,152] Joseph evaluated the feasibility of

a smoke-free policy and a nicotine treatment program implemented in a drug and alcohol treatment hospital.[152] In another study, Joseph et al. investigated the effects of concurrent versus delayed smoking cessation intervention in substance use and abuse treatment centers.[149] These studies used some form of counseling or classroom smoking cessation instruction with pharmacotherapy; compared with control groups, these approaches produced significant results. Joseph et al. found no difference in smoking cessation rate between concurrent and delayed interventions, a point that suggests that the intervention is effective for smoking cessation regardless of when it is implemented. However, alcohol abstinence was negatively affected (i.e., lower) in the concurrent treatment group compared with the delayed treatment group.[149]

Consistent with prior systematic reviews,[9] pharmacotherapy and psychological counseling significantly influence abstinence rates compared with control interventions in this population. The evidence is not consistent regarding the impact of smoking cessation treatment on non-nicotine substance use.[149,152] Although the two studies reported significant short-term effects for smoking cessation, only one study reported long-term (i.e., 12-month) abstinence rates. More than 50 percent of the participants were lost to followup in this study.[152] The studies support findings from past reviews on the positive short-term effects of such interventions;[30] however, the body of evidence in our review is insufficient to point to further recommendations.

Gaps in the Literature for Effectiveness of Prevention and of Cessation Interventions in Populations with Co-Occurring Morbidities and Risk Behaviors

The gaps in this evidence base remain significant for these populations. We found no research publications on tobacco prevention for populations with co-occurring morbidities and risk behaviors. Although the term co-occurring suggests that these populations are already smoking, tobacco prevention efforts, typically directed at adolescents, need to consider testing prevention strategies tailored for psychiatric and substance-addicted populations.

Additional studies need to determine whether smoking cessation treatment should be done at the same time as, at the beginning, or at the end of treatment for psychiatric and substance-addicted populations. Research to rule out any possibility of adverse effect from concurrent treatment regimes of psychiatric or substance use conditions and nicotine addiction is necessary to move forward with smoking cessation treatment for this population. More research explaining interaction effects among depression and smoking cessation interventions is needed.

Several studies allude to negative perceptions and attitudes of treatment center staff as barriers to treating nicotine addiction simultaneously with psychiatric conditions, especially, with substance abuse problems. Research exploring the legitimacy of these statements should be pursued. We believe the current opportunity to contribute to this area of tobacco research is extensive.

Limitations of Evidence Base

Inadequate Randomization and Concealment Allocation

Randomization procedures were rated inadequate in more than 25 percent of the randomized controlled trials (RCTs) we reviewed. Few studies used methods that ensured a chance

assignment of participants in the treatment and control groups. Preset plans, alternation method, and hospital numbers were used in randomization schemes. Many studies failed to report how investigators achieved randomization. Only 25 percent of the RCTs reported adequate concealment allocation.

Deficient Study Designs

In the absence of RCTs, particularly for studies on the effects of smokeless tobacco marketing on use and population harm, we accepted cross-sectional and cohort study designs. RCTs are the ideal, but, in some instances, more suitable study designs were appropriate for answering the KQs. Other study design deficiencies concerned control groups, recruiting, and power analyses. In about one-quarter of the studies, the control group was not adequately described. Studies lacked descriptions of comparison or control groups. A small number of studies employed convenience and volunteer samples, and studies rarely reported a power analysis.

Refusal and Attrition Rates

Both refusal rates and attrition rates for tobacco cessation studies are quite high. Participants not ready to stop tobacco use will not participate, and those who do participate often drop out of studies because of noncompliance. Other issues contributing to refusal and attrition rates were parental refusal (i.e., tobacco prevention studies), relocation, discharge from hospital, and side effects of drugs. Investigators used intent-to-treat analysis in about two-thirds of the studies.

Construct Validity Problems

Some intervention studies assessed tobacco use behaviors with a single item (e.g., “Have you smoked in the past 7 days?”). A single question measuring tobacco use may not provide adequate information about the key construct, tobacco use. Multiple items measuring tobacco use help to determine whether the behavior measured is actually the intended behavior.

Studies often used a single version of the prevention or cessation intervention in comparison with a control group. This creates a “mono-operation bias,” in which the results of the study reflect only the particular version of the intervention and not the actual construct. Implementing a single version of a program, in a single place at a single point in time, may not capture the full breadth of the concept of the program. Arguably, the results of the study reflect only the peculiar version of the intervention implemented, not the actual construct proposed.

Reliability of Results

Biochemical verification was rarely used for tobacco prevention studies with adolescents. Randomized controlled trials, particularly pharmacotherapy studies, used biochemical verification such as expired carbon monoxide or salivary cotinine to verify self-reported tobacco use. Low response rates for expired carbon monoxide or salivary cotinine were reported. Although the reliability of self-reported data is assumed to be adequate for population-based studies on other topics, such data will typically underrepresent smoking status. Studies that used biochemical verification of smoking status did not routinely report statistics on discrepancies between self-report and biochemical verification. Often, investigators who used surveys and

questionnaires to assess tobacco use, self-efficacy regarding quitting, perceived quitting intentions, and other variables did not document whether they (or others) had tested the instrument for reliability or other psychometric properties.

Inconsistent Terminology

Studies lacked consistent and clear definitions of tobacco use. The definition of nonsmokers in KQ 1 ranged from "never smoked even one cigarette or a puff of one" to "no smoking in past 30 days" or "past 12 months" to "no intention of smoking in high school." The definition of cigarette smoking in the other KQs ranged from "10 cigarettes per day on average over last year" to "having smoked greater than 100 cigarettes during a subject's lifetime" and "having smoked at least 1 cigarette in the last week." This degree of variation in the dependent variable in smoking cessation studies makes comparing effect sizes across studies challenging if not impossible.

Characteristics of Poor-Quality Studies

Table 16 documents the principal reasons for rating studies that we included and reviewed as poor quality. Only KQ 4 had all good or fair studies; KQ 2 had the highest number of poor studies. Problems with studies varied considerably, but we note in particular problems with study design (including selection of participants), lack of reporting of basic data (baseline; group comparisons), and attrition.

Future Research Recommendations

Our review highlighted several gaps in the literature that could be addressed by future research and by improvement in methods. Future research should address the issues highlighted below.

KQ 1. Effective Population- and Community-based Interventions to Prevent Tobacco Use in Adolescents and Young Adults

Population-based tobacco prevention programs. Future research in population-based tobacco prevention for adolescents and young adults needs to examine tobacco industry and product restrictions. In particular, how laws that regulate the content, labeling, promotion, and advertising of tobacco products affect adolescent and young adult tobacco use warrants greater attention. However, before tobacco prevention research in this area can move forward, changes in legislation are required. Continued research on whether enforcing tobacco youth access laws and regulations, when they are implemented community wide, can significantly reduce tobacco use support is important to build this body of evidence.

Other research using various combinations of population-based interventions may show that their effectiveness is greater than using interventions independently. Most important, future population-based studies on price increases, tobacco youth access laws and regulations, mass media campaigns, or tobacco industry and product restriction need to use control or comparison groups in their study designs to measure the impact that the intervention strategies have on the uptake of tobacco use among adolescents and young adults.

Table 16. Characteristics of studies rated poor quality

Intervention Design* Sample Size	Reasons for Rating
Key Question 1	
Group counseling, social support[77] RCT 450	All methods (e.g., randomization, sampling) not well delineated No baseline data reported analytical methods not well described
Video, classroom instruction[78] RCT 3,038	No baseline data reported No treatment versus comparison data reported Post randomization exclusions
Key Question 2	
Self-help materials[129] RCT 918	High attrition rate No intention-to-treat analysis No power analysis Baseline differences
Self-help, computer-based program, telephone counseling, group counseling, social support, media campaign, individual counseling by health professional[111] Quasi-experiment 538	Intervention group volunteer sample Control group care not reported Exposure to intervention low Findings not generalizable† High attrition
Self-help, individual counseling by health professional, social support[118] Cohort study 110	Self-selected sampling technique Baseline differences regarding motivation to quit Incomplete reporting of data
Self-help, group counseling[108] Before/after study 119	Self-selection of intervention Small group sample sizes High attrition rate No report of comparison of groups Findings not generalizableH
Individual counseling, Acupuncture[92] RCT 141	High attrition rate Completers analysis
Pharmaceuticals[110] RCT 1,384	High rate of noncompliance High overall rate of attrition
Pharmacotherapy[93] RCT 134	Removed study participants perceived not to be motivated (similar to a “run-in period”) Attrition moderately high Limited reporting on adverse events Randomization not described
Pharmacotherapy[126] RCT 245	Attrition rate not reported Allocation to groups predictable No adverse events reported Poor randomization
Pharmaceuticals, group counseling[117] RCT 5,887	Large differences in baseline comparisons between white and black participants negate any conclusions from findings
Pharmacotherapy, cognitive behavioral counseling[96] RCT 150	Randomization not reported No power analysis High attrition rate No adverse events reported
Pharmacotherapy, cognitive behavioral counseling[127] RCT 248	High attrition rate Randomization not reported No adverse events reported No power analysis

Table 16. Characteristics of studies rated poor quality

Intervention Design* Sample Size	Reasons for Rating
Pharmacotherapy, self-help, counseling[128] RCT 137	High attrition rate Lacked power Significant baseline differences not reported
Telephone quit line[94] Cohort study 1594	High attrition rate Confounded by "additional support" Baseline data not reported for Proactive Treatment group No reliability or validity measures for instruments Inclusion/exclusion criteria not reported
Telephone counseling, group meetings[95] RCT 756	No true control group Randomization not reported Population not described Inclusion/exclusion criteria not reported Intention-to-treat analysis not reported
Key Question 3	
Video, telephone counseling, individual counseling by health professional, group counseling, social support, pharmaceuticals[155] Before/after study 299	Sampling not explained No control group Limited generalizability†
Self-help, individual counseling by health professional, telephone counseling, video[156] RCT 1,173	Inadequate allocation of concealment and blinding Contamination of usual care group Attrition not reported
Key Question 5	
Group counseling, pharmaceuticals[153] RCT 3,976	Sampling technique not reported Study criteria changed after one-third of participants recruited; post-randomization Attrition not reported Adverse events not reported No systematic measure of nicotine replacement therapy use among participants

* RCT, randomized controlled trial.
† Generalizability is noted but did not figure directly in the quality rating.

Community-based tobacco prevention programs. More community-based research that integrates an array of strategies such as community empowerment, dissemination of health education materials, media advocacy, youth antitobacco activities (e.g., contests, peer leadership programs), and letters to schools, parents, and tobacco retailers is urgently needed. Although sufficient evidence exists on the positive short-term effects of school-based tobacco prevention programs, more (and better-designed) studies demonstrating positive long-term effects will improve understanding of how best to prevent adolescents from initiating tobacco use. The approaches to tobacco prevention need to be comprehensive (e.g., combining school-based interventions with community mobilization, media campaigns, and enforcement of tobacco youth access laws and regulations). In general, the body of evidence for community-based tobacco prevention requires more rigorous research through adequate use of randomization, use of control groups without contamination or confounding issues, low attrition rates, and consistent and universal utilization of operationally defined outcome variables.

Provider-based tobacco prevention programs. Future research using providers as a conduit for tobacco prevention education should assess whether such settings are a viable place to implement tobacco prevention for adolescents and young adults. Because dental clinicians

may be better suited for tobacco prevention, particularly in the case of smokeless tobacco use and for younger subjects, additional research in these settings is warranted.

KQ 2. Effective Strategies for Increasing Consumer Demand for and Use of Proven Individually Oriented Cessation Treatment

Increasing the number of users who attempt to quit. Additional research will further our understanding of how to increase consumer demand for and use of individually oriented cessation treatment. The role of mass media in driving individuals to quit-line and other cessation services should be examined. Audience research on the effectiveness of specific messages in reaching and motivating target audiences such as adolescents, young adults, and persons with low income and educational status can inform and increase the impact of mass media. For expanding the use of quit-line or other telephone support services, future research should compare specific components of telephone counseling and their relative impact on enrollment and continuation in these services as well as their impact on individual motivation to quit and smoking status. Future research could investigate issues related to suitability and appropriateness of the services such as the number and timing of calls, the role of feedback to the caller's primary provider, and the participants' satisfaction with cessation services.

The relative population impact of various proven cessation interventions should also be examined. One example is to determine how proactive telephone counseling support compares with in-person intervention, regardless of whether nicotine replacement therapy is offered. Documenting whether differential rates of success and enrollment offset or enhance each other on a population basis will also be an important addition to the knowledge base. These research questions are especially important given the move toward provider referral to quit-line services.

Strategies to improve the success rate for quit attempts. To improve the success rate of cessation services, well-designed studies should examine the effectiveness of multiple intervention formats, of combination pharmacotherapy, and of adjuncts other than pharmacotherapy in comparison with individual counseling for all smokers and for special populations of smokers. Adjuncts to counseling could include patient incentives, biomarker feedback, and other approaches designed to increase the likelihood of quitting. Future studies should also examine ways to reduce withdrawal symptoms and cravings among those attempting to quit using tobacco products. Research on ways to minimize the side effects associated with use of various individual pharmacotherapies and combined pharmaceutical regimes is also needed. Identifying ways to increase the persistence of effect on smoking cessation over time also warrants further study.

KQ 3. Effective Strategies for Increasing the Implementation of Proven Population-Level Tobacco Use Cessation Strategies, Particularly by Health Care Systems and Communities

Population-based implementation strategies. Some evidence, albeit inconsistent, suggests that interventions at the community level increase the implementation of tobacco use cessation strategies at the population level. Well-designed investigations should examine ways to reach out to smokers in the general population and to special populations such as adolescents and young adults with messages that motivate smokers and nonsmokers to become aware of, promote, and use existing cessation services.

Provider- and health care system-based tobacco use cessation strategies. Future research to improve strategies that providers and health care systems might employ should focus on well-designed studies of effective ways to change not only provider practice patterns but also related smoking cessation outcomes. To provide more awareness about what does and does not work with academic detailing, studies should assess the impact of academic detailing across and within practice types. At a minimum, future studies should incorporate all proven components of an academic model such as provider reminder systems.

Either within or separate from the academic detailing research, studies should explore how provider attitudes and smoking behavior affect provider use of effective interventions. Research is also needed to understand how other institutional barriers might hamper the adoption of effective strategies in health care settings and among providers. Better appreciation of the factors that affect incorporation of effective interventions into usual care is critical. More studies are also needed to understand how implementation of effective interventions by providers and/or health systems translates into increased abstinence from smoking.

KQ 4. Effect of Smokeless Tobacco Product Marketing and Use on Population Harm From Tobacco Use

Smokeless tobacco marketing and use. The field of smokeless tobacco marketing and use is wide open for new research. Future research should investigate whether new tobacco industry marketing strategies are increasing use of smokeless tobacco, and, if so, whether the observed increase applies differentially to specific user populations. Of special importance is examining possible links between point-of-purchase tobacco promotion and advertising and increased use of smokeless tobacco among adolescents and young adults. We see many opportunities to build evidence in the area of smokeless tobacco product marketing; we advise researchers to advance this research with rigorous study designs.

Robust research has established links between use of smokeless tobacco and certain cancers.[1] For that reason alone, future research should move away from investigating whether smokeless tobacco is a viable substitute for smoking and toward developing strategies to reduce its use. Research should continue to pursue possible treatments (i.e., counseling, pharmacotherapy) to assist or complement efforts aimed at smokeless tobacco cessation.

KQ 5. Effectiveness of Prevention and of Cessation Interventions in Populations with Co-Occurring Morbidities and Risk Behaviors

Populations with psychiatric comorbidities and risk behaviors. Specifying the best approaches for smoking cessation treatment in populations with co-occurring morbidity and risk behaviors remains controversial. Because populations with these additional ailments and risk behaviors smoke at higher rates than others,[9,30] successfully accomplishing therapy may require pharmacotherapy and tailored treatments.[9,113]

Investigators need to examine the effects of pharmacotherapy, particularly antidepressants alone or in combination with counseling, not only for people with a history of depression but also for people currently diagnosed with clinical depression. Additional pharmacotherapy studies using antidepressants such as fluoxetine alone or in combination with other nicotine replacement therapy will help determine whether rates of smoking cessation in psychatric and substance abuse populations can be improved (relative to those in the general population).[9]

Comprehensive research on concurrent versus delayed treatment for smoking cessation and chemical dependency is warranted in light of recent inconsistent results regarding adverse effects on sobriety or other drug use.[9,149,152] Investigators need to determine the benefits gained from higher participation rates with concurrent treatment against the cost of the adverse effects and the lost opportunity to engage this elusive population with delayed smoking interventions.

Finally, barriers to smoking cessation treatment in patients with other health problems, such as contraindications of pharmacotherapy, and the validity of concerns on the part of clinicians about hindering sobriety should also be investigated.

Methods Recommendations

Apart from the topics recommended above, we emphasize the need for investigators to use markedly better and more rigorous methods for all new research into tobacco prevention, control, and cessation. Essential scientific and technical improvements cut across many aspects of study design and conduct. Among the more critical are the following:

- Improved study designs using rigorous research methods such as control or at least adequate comparison groups, adequate randomization procedures, and tobacco use as the dependent variable for specific tobacco prevention strategies;
- Consistent definitions and measurement of baseline smoking status, abstinence, and continuous abstinence;
- Clear descriptions of interventions and comparison and control groups;
- Use and reporting of psychometrics of reliable and valid assessment instruments;
- Consistent definition of academic detailing;
- Use of biochemical validation of self-reported smoking status as appropriate;
- Use of intent-to-treat analysis; and
- Better methods of addressing drop-out and attrition, reporting power calculations, and taking loss to followup more into account in statistical analyses.

Finally, we note the absence of important documentation of study design, conduct, and other details in much of the literature reviewed. We hope that both investigators and those publishing their studies can find a way to provide more detail on methods, study populations, interventions, and the like, if not in published form then through web-based media.

Conclusions

This review updates the literature found in previous systematic reviews. In most instances, the evidence in our review was consistent with that in those publications. On its own or in combination with findings from earlier reviews, the information from newer work is insufficient to draw new conclusions or conclusions different from those that prior reviews offered.

The new studies examining tobacco prevention for adolescents and young adults in our review found short-term effects for school-based interventions but no evidence to draw conclusions for long-term effects. Insufficient new evidence exists on population-, community-, and provider-based interventions for reducing tobacco initiation among adolescents and young adults.

Findings from studies in our review, although insufficient in number and quality to draw conclusions on their own about the effectiveness of multicomponent strategies such as telephone counseling, are consistent with previous reviews indicating the efficacy of these approaches.

Studies in our review of strategies to improve the success of quit attempts were consistent with previous reviews. Fundamentally, self-help strategies alone are not efficacious; counseling, pharmacotherapies either alone or in combination, or pharmacotherapies combined with psychological counseling all increase the likelihood of successful quitting.

When considering interventions for special populations, we found results both consistent and inconsistent with prior reviews. When evaluating interventions with hospitalized patients by diagnosis, studies in our review agreed with findings of a prior review showing that there was no strong evidence that clinical diagnosis affects the likelihood of quitting.[63] Results of our review were inconsistent with two prior reviews indicating that hospitalized patients were more likely to quit smoking as intensity of the intervention increased.[5,63] Although some studies in our review found significant gains in abstinence in the short term, all studies showed an absence of effect at 12-month assessment. The findings of our review remain consistent with those of prior reviews showing that counseling does increase the likelihood of abstinence among pregnant smokers. Investigators found quit rates for indigenous Maori in New Zealand to be similar to those observed in other trials of bupropion.[114]

Consistent with earlier findings, we also found insufficient evidence of effectiveness for population-based interventions to increase implementation of proven cessation strategies. Sufficient evidence in our review indicated that implementing provider-based interventions, such as training, and health systems-based interventions, such as academic detailing, improved provider delivery of cessation treatment, but the information was insufficient to conclude that implementing these approaches leads to higher quit rates.

We found no evidence on how smokeless tobacco product marketing affects population harm and only insufficient evidence on whether smokeless tobacco product marketing increases use and leads users to substitute smokeless tobacco for smoking.

Our review found no evidence for tobacco prevention in populations with co-occurring morbidities and risk behaviors. Consistent with other reviews, we found some support for pharmacotherapy and/or counseling, but the evidence was insufficient in number and quality to draw conclusions about the effectiveness of smoking cessation interventions in comorbid populations. Taken as a whole, this clearly illuminates the need for better studies to close these gaps.

We documented numerous gaps in the existing knowledge base and deficiencies in the design and conduct of currently available studies and recommend a variety of research initiatives to overcome these limitations.

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Appendix A
Search Strategies by Database

Appendix A. Search Strategy

#1	Search "Tobacco Use Cessation"[MeSH] OR "Smoking Cessation"[MeSH] OR "Smoking/prevention and control"[MeSH]	17017
#2	Search "Smoking"[MeSH] AND "Primary Prevention"[MeSH]	479
#3	Search #1 OR #2	17275
#4	Search #1 OR #2 Limits: Adolescent: 13-18 years, Adult: 19-44 years, Middle Aged: 45-64 years, English, Humans	7383
#5	Search ("Community Networks"[MeSH] OR "Community Health Services"[MeSH] OR "Community Health Planning"[MeSH] OR "Community Health Aides"[MeSH] OR "Community Health Nursing"[MeSH] OR "Community Health Centers"[MeSH] OR "Community Mental Health Services"[MeSH] OR "Community Medicine"[MeSH] OR "Community Mental Health Centers"[MeSH])	345024
#9	Search ("Randomized Controlled Trial"[Publication Type] OR "Randomized Controlled Trials"[MeSH]) OR "Single-Blind Method"[MeSH] OR "Double-Blind Method"[MeSH] OR "Random Allocation"[MeSH]	310410
#10	Search #4 AND #5 AND #9	402
#11	Search ("Consumer Satisfaction"[MeSH] OR "Consumer Participation"[MeSH]) OR "Health Services Needs and Demand"[MeSH]	84543
#12	Search #4 AND #11	129
#13	Search "Health Plan Implementation"[MeSH] OR "Diffusion of Innovation"[MeSH] OR "Patient Education"[MeSH]	52494
#14	Search #4 AND #13	334
#15	Search "Tobacco, Smokeless"[MeSH]OR "spit tobacco" OR "chewing tobacco" OR "dip tobacco" OR "oral tobacco"	1893
#16	Search #4 AND #15	160
#17	Search ("Marketing"[MeSH] OR "Social Marketing"[MeSH]) OR "Choice Behavior"[MeSH] OR "Advertising"[MeSH]	39557
#18	Search #4 AND #17	402
#19	Search "Comorbidity"[MeSH] OR ("Risk-Taking"[MeSH] OR "Risk Factors"[MeSH]) OR ("Depressive Disorder"[MeSH] OR "Depression"[MeSH]) OR "Bipolar Disorder"[MeSH] OR "Attention Deficit Disorder with Hyperactivity"[MeSH] OR "Stress Disorders, Post-Traumatic"[MeSH] OR "Diabetes Mellitus"[MeSH] OR "Hypertension"[MeSH] OR "Heart Diseases"[MeSH] OR "Asthma"[MeSH] OR "Obesity"[MeSH]	1406831
#20	Search #4 AND #19	1742
#21	Search #20 AND #9	250

Cochrane and the CCTR

(smoking or tobacco) AND (tobacco or quit) AND community

Reviews = 3

Trials = 89

Psychological Abstracts

(smoking or tobacco) AND (cessation or quit) AND community = 79

Sociological Abstracts

((smoking or tobacco)and(cessation or quit)) and ((community)and(intervention or Program or plan)) = 48

Cumulative Index for Nursing and Allied Health

(smoking AND (cessation OR quit)) AND community AND trial = 36

1237 unduplicated records

Appendix B
Sample Review Forms/
Quality Rating Forms

Title Abstraction Form

1. Original research (no editorials, letters to the editor) published in English after 1980 or a Cochrane review?

- ☐ Yes
- ☐ No
- ☐ Cannot determine

2. Study located in any of the following countries: USA, Canada, United Kingdom, Western Europe, Australia, New Zealand

- ☐ Yes
- ☐ No
- ☐ Cannot determine

3. Addresses one or more of the following (check all that apply):

- ☐ Population and Community based interventions for preventing tobacco use (KQ1)
- ☐ Strategies for increasing consumer demand for and use of individually oriented cessation treatments (KQ2)
- ☐ Strategies for increasing the implementation of population-level cessation strategies (KQ3)
- ☐ Effects of smokeless tobacco product marketing and use on population harm (KQ4)
- ☐ Effectiveness of interventions in populations with co-morbidities and risk behaviors (KQ5)
- ☐ Future research (KQ6)
- ☐ Cannot determine by the title or abstract
- ☐ None of the above

4. Study design is one of the following:

- ☐ RCT (n>30)
- ☐ RCT (n=?)
- ☐ Meta-analysis

- ☐ Observational Study (n=?)
- ☐ Observational Study (n>100)
- ☐ Case series
- ☐ Case report
- ☐ Cannot be determined
- ☐ Observational Study (n<99)
- ☐ Model or simulation study
- ☐ None of the above designs (Flag this response)
- ☐ Cochrane systematic review

5. If an **RCT** is excluded because of **small sample** size check here:

☐ Yes

6. Use for background ? If Yes, check here and **flag** article.

☐ Yes

Full Text Review Form

1. Is this article

a) referenced in a systematic review, or an editorial or comment?

b) Cochrane systematic review or meta analysis?

- ☐ Yes
- ☐ No

2. Study is located in any of the following countries:

USA, Canada, United Kingdom, Western Europe, Austrailia, New Zealand

- ☐ Yes
- ☐ No

3. The study is one or more of the following:

- ☐ KQ1 - Population and community based interventions for preventing tobacco use in adolescents and young adults (RCTs published Jan 2000 & later only) or refers to tobacco industry and product restriction (1980 to present)
- ☐ KQ2 - A 6mo or longer intervention designed to increase the number of tobacco users (i.e. adults/diverse pops) who seek individually-oriented treatments or increase use of proven intervention strategies {i.e., counseling, behavorial, & Pharmo} (published Jan 1999 & later only)
- ☐ KQ3 - A 6 mo or longer study of strategies to increase the implementation & use of proven pop-level tobacco cessation interventions, particularly those in communities & healthcare settings (published Jan 1999 & later only)
- ☐ KQ4 - Influence of smokeless tobacco marketing on initiation & use, and the effects on population harm
- ☐ KQ5 - 6 mo or longer study of effectiveness of cessation interventions in pops with co-morbidities & risk factors
- ☐ KQ6 - Future research
- ☐ None of the above

4. Study design is one of the following:

- ☐ RCT (n>30)

- ☐ Cohort Study (n>100) - Smokers & non-smokers followed over time to compare outcomes
- ☐ Case Control (n>100) - Subjects who have a certain condition are compared with people who don't
- ☐ Cross Sectional (n>100) - Like case-control studies, but more than two categories (such as just "smoker" & "non-smoker")
- ☐ None of the above (please flag if meta-analysis or systematic review)
- ☐ Cochrane Systematic review or meta analysis

5. If an RCT is excluded because of sample size <30, please check here and flag:

- ☐ Yes

6. Use for background? If yes, please check & flag (write background in flag box)

- ☐ Yes

Abstraction Form for Systematic Review or Meta-analysis

1. Is this a systematic review of meta-analysis?

- [x] Systematic Review
- [ ] Meta-analysis

2. Author et al, date

3. Geographic Area

- [ ] United States
- [ ] Canada
- [ ] United Kingdom
- [ ] Western Europe
- [ ] Australia
- [ ] New Zealand

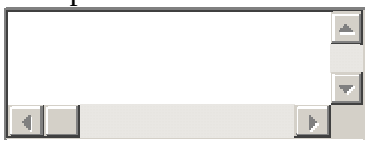
4. Funding Source

5. Aim of Review

6. Time Period Covered

7. Inclusion Criteria

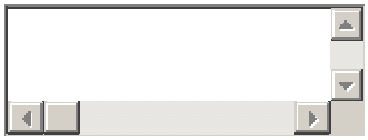
8. Population



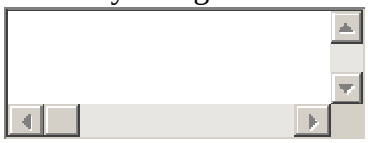
9. Characteristics of studies (Interventions)

10. Method of Review

11. What studies are included in the Meta analysis?



12. Study Design



13. Main Results

14. Adverse Events

☐ No

☐ Yes

☐ Not Applicable

15. Quality Rating

☐ Good

☐ Fair

☐ Poor

Comments:

Abstraction Form for Articles

1. Abstractor Initials

2. If the article should have been excluded in level 2 exclude and provide reason in text box...otherwise include.

☐ Exclude Enter Reason

☐ Include

3. Key Question

☐ KQ1

☐ KQ2

☐ KQ3

☐ KQ4

☐ KQ5

☐ KQ6

4. Author/Year

5. Geographic Area

☐ United States

☐ Canada

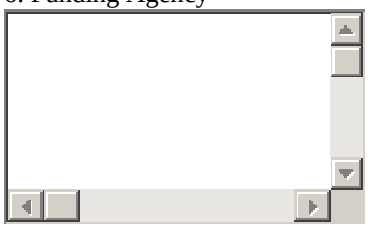
☐ United Kingdom

☐ Western Europe

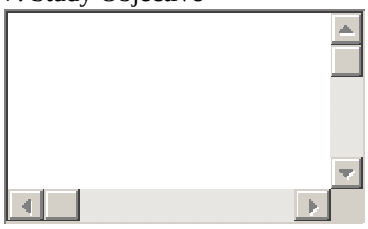
☐ Australia

☐ New Zealand

6. Funding Agency



7. Study Objective



8. Population

☐ Adolescents,

☐ Young Adults,

☐ Adults,

☐ Men (only),

☐ Women (only),

☐ Pregnant women,

☐ African Americans,

☐ American Indians,

☐ Latino,

☐ Low SES,

Describe

9. Risk Behavior(s)

10. Psychiatric condition(s)

11. Study Setting

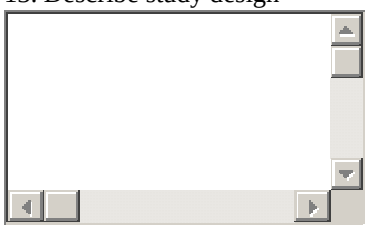
- ☐ School-based
- ☐ Community-based
- ☐ Population-based
- ☐ Hospital
- ☐ Worksite
- ☐ Practice/provider settings

Describe

12. Study Design

- ☐ RCT with simple randomization
- ☐ RCT with systematic randomization
- ☐ RCT with stratified randomization
- ☐ RCT with cluster randomization
- ☐ Cohort Study
- ☐ Case Control
- ☐ Before and after study
- ☐ Time series
- ☐ Control trial
- ☐ Cross-sectional

13. Describe study design



14. Sampling Technique

15. Sample Size

- ☐ Total sample
- ☐ I1
- ☐ I2
- ☐ I3
- ☐ C1

16. Inclusion Criteria:

17. Exclusion Criteria:

18. Intervention Methods

- ☐ Self-Help
- ☐ Individual Counseling by Health Professional
- ☐ Individual Counseling by non Health Professional
- ☐ Group Counseling
- ☐ Telephone Counseling
- ☐ Computer-based Program
- ☐ Social Support
- ☐ Video

- [ ] Media Campaign
- [ ] Pharmaceuticals
- [ ] Parent involvement
- [ ] Extra-curricular activities
- [ ] Classroom instruction
- [ ] Community-Activities

Describe

19. Intervention

I1

I2

I3

C1

20. Method of Assessment

21. Definition of Smoking

☐ Cigarettes

☐ Smokless tobacco

☐ NR

22. Baseline Data

23. Statistical Analysis

24. Data verification

25. Results

Dependent Variables

Outcome measures

26. Adequate Randomization

☐ Yes

☐ No

☐ NR

27. Attrition Rates

28. Quality Rating

- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Comments

Quality Review Form for RCT Studies

1. Is this a drug study?

- [x] Yes
- [ ] No

2. Was randomization adequate?

- [ ] Yes
- [ ] No
- [ ] Not Randomized
- [ ] NR

3. Was allocation of concealment adequate?

- [ ] Yes
- [ ] No
- [ ] Not randomized
- [ ] NR

4. Are the groups similar at baseline?

- [ ] Yes
- [ ] No
- [ ] NR

5. Was the eligibility criteria specified?

- [ ] Yes
- [ ] No

6. Was blinding adequate?

- [ ] Yes

- [ ] No
- [ ] Yes, but method not described
- [ ] NR
- [ ] NA

7. The outcome assessor (Researcher) was blind to the study participants.

- [ ] Yes
- [ ] No
- [ ] Yes, but method not described
- [ ] NR

8. Are participants blind to the study treatment?

- [ ] Yes
- [ ] No
- [ ] Yes, but method not described
- [ ] NR

9. Reporting of crossovers, adherence, and contamination.

- [ ] Yes
- [x] No

10. Was attrition less then 25%? Please report percentage.

☐ Yes

☐ No

☑ Not Reported

Percentage

11. Was the differential attrition less than 15%?

☐ Yes

☐ No

☑ NR

Percentage

12. Was a power analysis calculated for the study?

☐ Yes

☐ No

☐ NR

13. Did the study use Intention To Treat analysis (impute missing responses)?

☐ Yes

☐ No

14. Did post randomization of exclusions occur in the study?

☐ Yes

☐ No

☐ Unable to determine

☐ NR

15. What is the quality rating for this study? Please provide a rational in the comment box.

- ☐ Good
- ☐ Fair
- ☐ Poor

comments:

Quality Assessment for External Validity

16. The control group standard of care was described?

- ☐ Yes
- ☐ No

Comments:

17. Is the study population representative of the population of interest?

- ☐ Yes
- ☐ No

Comments:

Quality Assessment for Adverse Events

The next questions are for drug studies only.

18. Non-bias selection?

☐ Yes

☐ No

☐ Not clear

19. Low overall attrition at follow-up (less than 25%)?

☐ Yes

☐ No

☐ Not clear

20. The adverse events were pre-specified and defined?

☐ Yes

☐ No

☐ Comments:

21. Ascertainment techniques (instruments) were non-biased and adequately described?

☐ Yes

☐ No

Comments:

22. Statistical analysis of potential confounders?

☐ Yes

☐ No

Comments:

23. Was there adequate duration of follow-up (at least 6 months)?

☐ Yes

☐ No

Comments:

24. What is the overall adverse event assessment quality?

☐ Good

☐ Fair

☐ Poor

Comments:

Quality Review Form for NonRCT Studies

Study quality is evaluated using six categories (Descriptions, Sampling, Measurement, Analysis, Interpretation of Results, and other). Some problems with a study can be included under several of the categories. Use your best judgement to list the problems under the most appropriate category.

Answer the questions based on the quality of execution of the study's design.

Always provide comments for limitations.

External Validity (Generalizability of the Study Results)

1. Was the study population well described? (Study should describe both intervention and comparison populations and all relevent characteristics such as age, gender, SES)

- ☐ Yes
- ☐ No
- ☐ NR
- ☐ Limitations

2. Was the intervention well described? (What was done?, how was it delivered?, who was targeted?, and where it was done?)

- ☐ Yes
- ☐ No
- ☐ NA
- ☐ NR
- ☐ Limitations:

3. Did the authors specify the sampling frame or universe of selection for the study population?

- ☐ Yes
- ☐ No
- ☐ NR
- ☐ NA
- ☐ Limitations:

4. Did the authors specify the screening criteria for study eligibility?

- ☐ Yes

☐ No

☐ NR

☐ NA

☐ limitations:

5. Was the population that served as the unit of analysis the entire eligible population or a probability sample?

☐ Population

☐ Probability Sample

☐ Limitations:

6. Are there other selection bias issues not identified above? (This might include a very low participation rate (or a high refusal rate), a volunteer sample (as opposed to a convenience sample selected by the investigators), an inappropriate control or comparison group, or extremely restricted sampling inappropriate for measuring the effectiveness of the intervetion being studied.

☐ Yes

☐ No

☐ NA

☐ Limitations:

Internal Validity and Reliability

7. Did the authors attempt to measure exposure to the intervention? (observation, interviews, self administered questionnaire, Record review, lab test)

- ☐ Yes
- ☐ No
- ☐ NA
- ☐ Limitations: ____

8. Was the exposure variable valid? (i.e., measured exposure in different ways, consistency checks for self-reports)

- ☐ Yes
- ☐ No
- ☐ NA
- ☐ limitations: ____

9. Was the exposure variable reliable? (meausres of internal consistency were used, Cronbach's alpha, inter rater reliability)

- ☐ Yes
- ☐ No
- ☐ NA
- ☐ Limitations: ____

10. Were the outcome and other (or predictor) variables valid?

- ☐ Yes
- ☐ No
- ☐ NA
- ☐ NR
- ☐ Limitations: ____

11. Were the outcome and other (or predictor) variables reliable?

- ☐ Yes
- ☐ No

- [ ] NA
- [ ] NR
- [ ] Limitations:

12. Did the authors conduct appropriate statistical testing by: (Select all that apply)

☐ Conducted statistical testing when appropriate.

☐ Reported which statistical test were used.

☐ Controlled for design effects in the statistical model.

☐ Controlled for repeated measures in populations that were followed over time.

☐ Controlled for differential exposure to the intervention.

☐ Used a model designed to handle mult-level data when they included group-level and individual covariates in the model.

Describe other problems with the data analysis.

13. Was the attrition greater then 25% (if a survey, please write in the response rate)?

☐ Yes

☐ No

☐ NA

☐ Survey response rate

14. Did the author assess whether the unit of analyses were comparable prior to exposure to the intervention?

☐ Yes

☐ No

☐ NA

15. Did the author correct for controllable variables or institute study procedures to limit bias apporpriately (e.g., randomization, restriction, matching, stratification, or statistical adjustment)?

☐ Yes

☐ No

☐ NA

16. Based on your overall impression of the study please rate quality of article. Important issues: who are the participants and how are they selected, are good instruments used to measure the results, are the results analyzed using appropriate methods. Finally can the results be replicated and are the outcomes generalizable...if not, this study may have a fatal flaw.

Good studies (an outstanding study, one to two minor limitations)

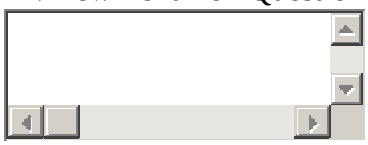
Fair studies (limitations but mostly minor limitations)

Poor studies (the study had fatal flaws in sampling, assessment measures, or statistical analysis)

- [ ] Good
- [ ] Fair
- [ ] Poor

- [ ] Comment

17. New Text Box Question



Quality Review Form for Systematic Reviews and Meta-analysis

1. Is this a systematic review or meta-analysis?

- ☐ Systematic Review
- ☉ Meta-analysis

2. Is the systematic review based on a focused question of research?

- ☐ Yes
- ☐ No
- ☐ Not reported

3. Are the eligibility criteria for the studies clearly described?

- ☐ Yes
- ☐ No
- ☐ Not reported

4. Did the search strategy employ a comprehensive, systematic literature search?

- ☐ Yes
- ☐ No
- ☐ Not reported

5. Did at least 2 people independently review studies?

- ☐ Yes
- ☐ No
- ☐ Not reported

6. Did the authors use a standard method of critical appraisal before including studies?

- ☐ Yes
- ☐ No

☐ Not reported

These questions are for meta-analysis only

7. Was publication bias assessed?

☐ Yes

☐ No

☐ Not reported

8. Was heterogeneity assessed and addressed?

☐ Yes

☐ No

☐ Not reported

9. Did statistical analysis maintain trials as the unit of analysis?

☐ Yes

☐ No

☐ Not reported

10. What is the quality rating for this study? Please provide rational for response.

☐ Good

☐ Fair

☐ Poor

☐ Rational:

Appendix C
Evidence Tables

Glossary

#	number
%	percent
2x	2 times or twice
3x	three times or thrice
ACS	American Cancer Society
ALSAC	American Lebanese Syrian Associated Charities
ANOVA	Analysis of Variance
AOR	adjusted odds ratio
ASH	Action on Smoking and Health database
ASSIS	Applied Social Sciences Index and Abstracts
b	regression coefficient
b/w	between
BA	Brief Advice
C	Control group
Calif	California
CBT	cognitive behavioral therapy
CD	cardiovascular disease
CDC	Centers for Disease Control
C-DISC	Clinical Data Interchange Standards Consortium
Chi sq	Chi square
CI	confidence intervals
CNS	central nervous system
CO	carbon monoxide
COPD	Chronic Obstructive Pulmonary Disease
CSAHS	Central Sydney Area Health Services
CT	computed topography
CVD	CD
d.f.	degrees of freedom
DARE	Drug abuse resistance education
Dec	December
DHSS	Department of Health and Social Services
DSM-IV	Diagnostic and Statistical Manual – Fourth Edition
dz	diagnosis
et al.	et alia
FEV	forced expiratory volume
FP	family physician
FTQ	Fagerstrom Tolerance Questionnaire
FVC	forced vital capacity
g	grams
G	Group
GEE	generalized estimating equations
GLIMMIX	General Linear Model for Mixture Distributions
GP	general practitioner
GSTM1	glutathione s-transferase, MU-1

HDRS	Hamilton Depression Rating Scale
HMO	Health Maintenance Organization
HPS	health promoting schools
HPS	Health Promotion School
hr(s)	hour(s)
HRSD	Hamilton Rating Scale for Depression
HS	high school
HSPP	Hutchinson Smoking Prevention Project
ICU	intensive care unit
IG	immunoglobins
ITT	intent to treat
kg	kilogram
LCS	Lung Cancer Substudy
LHS 1, 2, or 3	Lung Health Study
LPN	licensed practical nurse
MA	medical assistant
mg	milligram
MI	Motivational Interviewing
mo(s)	month(s)
N	number
NA	not applicable
NCCTG	North Central Cancer Treatment Group
NCI	National Cancer Institute
ng/ml	nanograms per millileter
NHLBI	National Heart, Lung, and Blood Institute
NHS	National Health Services
NIAS	National Institute Against Smoking
NIDA	National Institute on Drug Abuse
NNS	nicotine nasal spray
NP	nicotine patch
NR	not reported
NRT	nicotine replacement therapy
NS	not significant
NSW	New South Wales
OR	odds ratio
P	p-value
pg	page
ppm	parts per million
PTSD	posttraumatic stress disorder
RCT	randomized controlled trial
RN	registered nurse
RR	relative risk
RS	Spearman's Rank Correlation
SAS	statistical package
SD	standard deviation
SEQ	Self-Efficacy Questionnaire

SES	socioeconomic status
SI	smoking intervention
SLF	Smoke Free Leitrim
SLT	social learning theory
SPSS	Statistical Package for the Social Sciences
ST	smokeless tobacco
SE	Standard error
t	time
TN	Tennessee
TTM	Transtheoretical Model
txt	treatment
UCSF	University of Calif San Francisco
UK	United Kingdom
US	US
VA	Veterans Administration
v.	versus
w/	with
WIC	Women, Infants, and Children
wk(s)	week(s)
X^2	Chi sq
yr(s)	yr(s)

Evidence Table 1. Effective population-based interventions

Study Characteristics	Study Design	Sample Design and Definitions
Author: Ennett et al., 2001 **Geographic area:** US **Funding agency:** National Institute on Drug Abuse **Study setting:** Population-based	**Research objective:** To identify mediators through which the Family Matters Program influenced adolescent smoking and drinking **Population:** • Adolescents • 12 to 14 yr olds and their families **Study type:** RCT w/ simple randomization **Inclusion criteria:** Families had to have an adolescent age 12 to 14 yrs old and live in contiguous 48 states **Exclusion criteria:** NR	**Sampling plan:** • Probability sample of families throughout 48 contiguous States of US entered into a randomized trial • Partcipants identified through random-digit dialing • Eligible families screened • Offered opportunity to participate in study and told that they had a 50/50 chance of receiving Family Matters program • 1,316 adolescent–parent pairs agreed to enrolled in study • Pairs completed baseline interviews by telephone, matched w/ another pair by date and time of completion, and then randomly assigned either to receive Family Matters or to serve as controls **Sample size:** Total: 1,316 adolescent-parent pairs **G1:** NR **C1:** NR **Definition of smoking:** Cigarettes • Non-user: never smoked, not even a puff • User: smoked even a puff

Evidence Table 1. Effective population-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Telephone counseling w/ parents **Intervention:** **G1:** Family Matters consists of successive mailings 4 mailings over 14 mos of 4 booklets to parents of 12- to 14-yr-old adolescents and telephone discussions b/w parents and health educators after each mailing **C1:** NR **Method of assessment:** 3- and 12-month followup via telephone interview w/ parent/guardian and adolescent **Baseline data:** Fewer non-Hispanic Whites in G1 than in C1	**Statistical analysis:** • Repeated measures logistic regression w/ GEE using a one sided tail test • Mediation analysis follows approach outlined by Baron and Kenny to assess whether extent to which change in behavioral outcomes as a result of Family Matters program is accounted for by change in proposed mediators **Data verification:** Self-report **Dependent variables:** • Smoking status • Global family mediators (supervision, support, communication and involvment) • Substance specific mediators (expected consequences, parental attitude, parental encouragement, parent substance use, rules about use, monitoring, availability, nonfamily influences)	• Adolescents in C more than 1.5 times likely to smoke at follow up than family matters group (OR = 1.59, P = 0.008, lower bound CI, 1.19) • Program parents significantly more likely to discuss peer and media influences (b = -.76, P < 0.01), set rules about smoking (b = -0.46, P < 0.01) • Non Hispanic white participants only, program parents significantly more likely to encourage their children not to smoke (b = -0.42, P < 0.01), improvements in parent involvement (b = -0.10, P < 0.05), and positive effect on adolescent's intentions to smoke (b = -0.15, $P \leq 0.01$) Mediating effects for full model: stricter parent supervision (b = 0.16, P < 0.01) and decreased parental use of tobacco (b = 0.60, P < 0.01) Expected consequences and intention to use (b = 1.82, and b = 0.85, P < 0.01) decreased smoking	**Quality rating:** Fair **Comments:** • No description of control intervention • Sample size for G1 and C1 NR **Adequate randomization:** Yes **Attrition rate:** 26%

Evidence Table 1. Effective population-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Thomson et al., 2004 **Geographic area:** US **Funding agency:** NCI, Flight Attendant Medical Research Institute **Study setting:** Population-based	**Research objective:** To test whether community-level youth access ordinances reduce adolescents' perceived access to tobacco, purchase attempts, and tobacco use **Population:** • Adolescents, 12 to 17 yrs **Study type:** Cross-sectional **Describe study design** • Representative sample of youth from across Massachusetts **Inclusion criteria:** • Age 12 to 17 • Resident of Massachusetts • Parental consent • Youth assent **Exclusion criteria:** • Youth report of resident town disagreed w/ ZIP code and phone exchange indicators • Towns having no identified youth	**Sampling plan:** • University of Massachusetts obtained a statewide random sample of households by random-digit dialing • Interview conducted w/ an adult resident to collect demographic data • Requested permission to interview all youth in household b/w ages 12 to 17 yrs • Screen interviewers completed 66% of sample and 6,006 eligible youths identified **Sample size:** • Total: 3,831 **Definition of smoking:** Cigarettes • Ever smoker: smoked or puffed cigarette in lifetime • Current smokers: smoked at least one cigarette inpast 30 days

Evidence Table 1. Effective population-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Parent involvment • Implementation of state wide youth tobacco access ordinances **Intervention:** **G1:** Community-level tobacco ordinances **C1:** NA **Method of assessment:** Phone survey	**Statistical analysis:** X2uare GEE **Data verification:** Self-report **Dependent variables:** • Youth perceived access to tobacco • Attempts to purchase tobacco • Tobacco use **Baseline data:** White: 78% Hispani**C1:** 9% Other: 13%	• 37% of youth perceived easy access to purchase tobacco • Less likely to perceive easy to purchase w/ ban on free displays AOR = 0.6, 95% (CI 0.5-0.9; *P* = 0.007) • Youth reported easy access in towns that required tobacco vendors to have a license OR = 1.3, 95% (CI 1.1 – 1.5, *P* = 0.009) • Increased perceived access associated w/ being older (*P* < 0.0001) and male, (*P* ≤ 0.002) • 33% of 512 youth who smoked a cigarette in past 6 mos reported purchasing cigarettes • Result associated w/ bans on free samples and single cigarette sales in unadjusted model only • Attempts to purchase cigarettes: AOR = NS for all ordinances • Tobacco use: NS in adjusted model	**Quality rating:** Fair **Comments:** Strengths: accounted for clustering in analyses Limitations: moderate participation rate; generic data on ordinance enforcement; cross-sectional data **Adequate randomization:** NR **Attrition rate:** 76% of eligible youth had parental consent

Evidence Table 2. Effective school-based interventions

Study Characteristics	Study Design	Sample Design and Definitions
Author: Ausems et al., 2004 **Geographic area:** Western Europe **Funding agency:** European Commission and the Dutch Cancer Foundation **Study setting:** School-based	**Research objective:** To compare effects on smoking prevention among Dutch first grade vocational school children using a newly developed computer-tailored (personalized messages/letters) out-of-school program, an existing in-school program, and a combined approach including both in-school and out-of-school programs **Population:** • Adolescents • Vocational school children in the Netherlands **Study type:** • RCT w/ cluster randomization • Six out of 8 area health departments agreed to participate, and within these areas local vocational schools invited to participate **Inclusion criteria:** Dutch vocational schools **Exclusion criteria:** NR	**Sampling plan:** • 19 schools already participating in Healthy Schools and Stimulant Program • Randomly assigned within regionally defined blocks to in-school and out-of school conditions • Remaining 17 schools randomlly assigned to out-of school or control conditions **Sample size:** **G1:** 9 schools **G2:** 8 schools **G3:** 10 schools **C1:** 9 schools **Definition of smoking:** Cigarettes • Never-smokers: students who have never smoked even one cigarette or a puff of one • Non-current smokers: students who have smoked in past, but not during past month • Current smokers: students who have smoked during past month

Evidence Table 2. Effective school-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Computer-based program • Classroom instruction • Computer generated letters **Intervention:** **G1:** In-school intervention: • Three lessons, each lasting about 50 min, student and teacher manuals available • Each lesson consisted of general introduction by teacher, reading text in workbook, classroom discussion, workbook task and additional task that summarized main points of lesson • First lesson explained ingredients of tobacco, and physical and mental reactions of smoking, while second discussed norms concerning smoking, and third emphasized pressures to smoke and skills that are helpful in resisting cigarettes	**Statistical analysis:** • All effect analyses done separately for posttests 1–2–3 • Since running large regression models w/ MIXOR might cause problems, model reduction first applied, using SPSS 9.0 to determine final models containing significant covariates and interaction terms for prediction of smoking at posttests 1–2–3 **Data verification:** Self-reports **Dependent variables:** Smoking rates, based on both smoking initiation among never-smokers and smoking continuation among ever-smokers **Baseline data:** • Smoking behavior: • Ever smoking: 59.7% • Current smoking: 19.5% • Mean age (yrs): 13.1 • Gender (%, male): 52.1 • Origin (w/ both parents Dutch): 73.0% • Religious (adhering to a religion): 61.4% • Family composition (w/ two parents): 82.1% • Father's occupation (paid job): 68.7% • Pocket money (%, > 6.8 euro): 23.5	• Twelve months after pretest (posttest 2), in-school intervention successful in preventing vocational school students from continuing to smoke, compared w/ students in control condition OR = 0.49; 95% CI 0.29–0.84 • Eighteen months after pretest (posttest 3), tailored out-of-school intervention successful in preventing smoking initiation, compared w/ students in control (OR = 0.42; 95% CI, 0.18–0.96) • Effect of combined approach not larger than sum of effects of in-school and out-of-school effects.	**Quality rating:** Fair **Comments:** • Refusal rate NR • Randomization description unclear regarding number of schools in txt groups • Out-of-school intervention poorly implemented (65% of personalized letters read by participants) **Adequate randomization:** Yes **Attrition rate:** School level • Posttest 1: 5.6% (2 schools) • Posttest 2: 8.3% (3 schools) • Posttest 3: 18.5% (NR) Student level: • Posttest 1: 17.3% • Posttest 2: 5.4% • Posttest 3: 24.6%

Evidence Table 2. Effective school-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Ausems et al., 2004 (continued)		

Evidence Table 2. Effective school-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
G2: Out of school intervention: • Three tailored letters w/ smoking prevention messages, sealed in envelopes and mailed to students' homes at 3-wk intervals; researchers signed letters and added telephone numbers; students' pretest smoking behavior not disclosed in letters; to prevent arguments in students' families, letters tailored to individual characteristics • Pretest questionnaire on attitudes, social norms, self-efficacy, smoking intention and smoking behavior used to create a database file containing personal information • Computer program combined database file w/ message file using decision rules that linked students' answers to personal messages; all messages thus selected combined in a letter format; letters illustrated w/ a picture puzzle and several cartoons; and competition included where students could win one of two CD vouchers **G3:** Combination of in- and out-of-school interventions **C1:** Control **Method of assessment:** • Questionnaire for students at 6, 12 and 18 months • After a pretest, teachers questioned about effectiveness of process			

Evidence Table 2. Effective school-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Aveyard et al., 2001 **Geographic area:** United Kingdom **Funding agency:** NR **Study setting:** School-based	**Research objective:** To re-evaluate whether addition of a TTM-based intervention to existing health education school curriculum would protect young people from becoming smokers and help those who smoked quit compared w/ unknown effect of existing health educationRe-evaluation employed different periods of followup and fully exploring effects of using an ITT analytical approach **Population:** • Adolescents, ages 13 to 16 • Living in West Midlands, UK **Study type:** RCT w/ cluster randomization **Inclusion criteria:** Yr 9 student (age 13 to 14) in participating school, assented and parents consented **Exclusion criteria:** • Parent or student refusal • Smoking status could not be assessed at followup(s)	**Sampling plan:** • Sampling description referenced from previous study (Aveyard et. al., 1999) • Once schools agreed to participate individuals randomly allocated to intervention or control • Arms balanced by ordering schools into five groups based on numbers of students in yr 9; allocated each school a number b/w 1 and n (maximum number in group) • Computer program generated n/2 random numbers b/w 1 and n, and schools allocated to intervention • One school allocated to intervention dropped out after randomisation and before baseline questionnaires administered All Yr 9 students (aged 13 to 14) in participating schools invited to participate **Sample size:** **G1:** 4,125 **C1:** 4,227 **Definition of smoking:** Cigarettes • Regularly smoking at least one cigarette per wk

Evidence Table 2. Effective school-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Computer-based program • Video • Classroom instruction **Intervention:** **G1:** During Yr 9, received • Three whole class lessons and three interactive computer sessions (including video clips of young people discussing their smoking) • Followed by questionnaires assessing stages of change, smoking uptake or cessation • Feedback on results of questionnaire, counseling about how to move forward in stages, and feedback on progress over time points **C1:** Standard lessons on smoking as part of English national curriculum, possibly up to three additional lessons on smoking (already available from teaching resources), which included quizzes and group work on health effects of smoking and different methods of persuading someone to quit smoking, all unrelated to TTM; no data collected on receipt of information **Method of assessment:** Self-report questionnaire administered at baseline, 1 yr and 2 yr followups	**Statistical analysis:** • Random effects logistical regression • Logistical regression • Bivariate analysis, • Frequencies • Kappa assessment • Sensitivity analysis **Data verification:** Self-report **Dependent variables:** • Movement in stage of change • Smoking status **Baseline data:** • NR, but stated no large differences b/w groups in these predictors of smoking at baseline • Predictors included: smoking status, stage of change, and potential confounders, i.e., risk factors for smoking in future	No evidence of change of stage at either 1 yr or 2 yr followup: G1 vs C1 • 1 yr AOR = 1.13, 95% (CI, 0.91 - 1.41); • 2 yr AOR = 1.25, 95% (CI, 0.95 - 1.64) No change in regular smoking at either follow up: • G1 vs **C1:** 1 yr AOR = 1.14, (95% CI, 0.93, 1.39) • 2-yr AOR = 1.06, (95% CI, 0.86, 1.31) Subgroup analysis by initial smoking status NS for benefit for prevention of smoking or smoking cessation	**Quality rating:** Fair **Comments:** 40% refusal rate; no details on baseline data; C exposure to other prevention programs not assessed **Adequate randomization:** Yes **Attrition rate:** Yr 1: **G1:** 11% **C1:** 10.7% Yr 2: **G1:** 14% **C1:** 16.9%

Evidence Table 2. Effective school-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Brown et al., 2002 **Geographic area:** Canada **Funding agency:** NHLBI **Study setting:** School-based	**Research objective:** To evaluate an extracurricular HS tobacco control intervention developed by teachers and students **Population:** • Adolescents • Cohort followed from 7-8th grade through 9-10th grade **Study type:** • RCT w/ cluster randomization and paired-matching • Matched pairs prior to randomization • Randomized within pairs to Intervention and Cs **Inclusion criteria:** • School board participated in prior elementary school smoking prevention study • At least 30 students from elementary school cohort projected to attend HS **Exclusion criteria:** NR	**Sampling plan:** 30 high schools Matched pairs prior to randomization by: • Size of school • Number of students projected to attend who participated in an elementary school study • Proportion of cohort students from elementary school study control condition **Sample size:** **G1:** 1,563 **C1:** 1,465 **Definition of smoking:** Cigarettes • Experimental smoker: smoked less than once a wk • Regular smoker: smoked weekly

Evidence Table 2. Effective school-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Extra-curricular activities • Mobilization of staff and students to involvement in anti-smoking activities **Intervention:** **G1:** Extracurricular activities: Quit and win contests, poster contests, displays, health fairs, smoking surveys • Average of 3.8 intervention activities in 9th grade and 3.5 activities in 10th grade • A teacher facilitated students, staff, and community members in planning and implementing prevention and cessation activities tailored to each intervention school to build committment and strengthen not smoking as a school social norm • Research staff provided consultation, conducted semiannual workshops for teachers and student leaders, developed resources for dissemination to all intervention schools, produced newsletters, and provided a $1000 per school annual budget **C1:** Usual care, details NR **Method of assessment:** Surveys completed by cohort at end of their 9th and 10th grade yrs; data collectors blind to txt status	**Statistical analysis:** Cluster-randomized designs (as discussed in Donner) and applied a procedure that uses a variance term appropriate to randomization of schools (Liang) **Data verification:** • Bogus CO breath samples collected to enhance validity of self-reported smoking behavior • Data collected from absent students by mail or phone, but no bogus CO samples collected **Dependent variables:** • Social model risk score • Elementary school risk score • Smoking status **Baseline data:** Baseline data similar except proportion of HS students in elementary school study intervention cohort : **G1:** 84% **C1:** 75% (*P* = 0.10)	Grade 10 smoking rates for never smokers: • Male regular smoking rates lower **G1:** 9.8% **C1:** 16.4% *P* = 0.02 Smoking rates despite baseline status (NS): • Females: **G1:** 28.3% **C1:** 24.8% *P* = NR • Males: **G1:** 21.1% **C1:** 26.4% *P* = NR • Overall: **G1:** 24.9% **C1:** 25.7% *P* = NR	**Quality rating:** Fair **Comments:** • Randomization technique incomplete • Control schools received “usual” care but not described • Some slight baseline data differences • Limited generalizability **Adequate randomization:** Yes **Attrition rate:** **G1:** 5% **C1:** 5%

Evidence Table 2. Effective school-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Crone et al., 2003 **Geographic area:** Western Europe **Funding agency:** None **Study setting:** School-based	**Research objective:** To assess effect of a peer pressure based antismoking intervention on adolescents in lower secondary (middle) school **Population:** • Adolescents • 1st grade of lower secondary education in the Netherlands (mean age 13) **Study type:** RCT w/ stratified randomization **Inclusion criteria:** • Adolescents in lower secondary education in the Netherlands **Exclusion criteria:** • If already participating in another study	**Sampling plan:** Community Health Sources • 48 school identified; 18 willing to participate; 8 additional schools recruited • Schools stratified by size and use of national drug education • Randomized to intervention or control by toss of coin by independent person **Sample size:** **G1:** 14 schools, 1,444 students **C1:** 12 schools, 1,118 students **Definition of smoking:** Cigarettes • Smoker: all students who experiment w/ smoking or who smoke weekly or daily

Evidence Table 2. Effective school-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Video • Classroom instruction • Competition by NIAS that reward class w/ < 10% smokers **Intervention:** **G1:** Three lessons on knowledge, attitudes, and social influence, followed by a class agreement not to start smoking or to stop smoking for next 5 months • Two extra video lessons on smoking and social influence were available as an optional extra during the 5 months • A competition administered by the NIAS that rewarded classes that had fewer than 10% smokers at the end of the 5 month period • A photography contest to pick best photos that expressed a non-smoking class **C1:** Used drug prevention program normally given to students (which intervention schools used as well) • Given option to use intervention program one yr after study **Method of assessment:** Surveys administered at baseline, at end of intervention, and at 1 yr followup	**Statistical analysis:** • Used multilevel techniques to account for clustering; • Compared intervention and Cs in terms of proportions of smokers before and after intervention and proportion who started smoking, controlling for differences at baseline • Performed ITT analysis **Data verification:** Self-report **Dependent variables:** Smoking status • Changes in attitude toward smoking • Perceived social influence • Self-efficacy • Intention to remain a smoker **Baseline data:** Males (%): **G1:** 49.5 **C1:** 60.9 *P* = < 0.001smoker Mean age: 13 yrs	Proportion increase at end of intervention: • Nonsmokers: **G1:** 9.6% **C1:** 14.2% OR 0.61 (95% CI, 0.41-.90) • Smokers: **G1:** 2.6% **C1:** 7.9% OR = 0.62 (95% CI, 0.43 - 0.90) Perceived social pressure: • More likely to be smokers OR = 2.21 (95% CI, 1.53 - 3.18) • Effects at one yr followup: NS	**Quality rating:** Fair **Comments:** • Refusal rate (62.5%) • Not generalizble • Significant differences in baseline data • Very high attrition but used ITT **Adequate randomization:** Yes **Attrition rate:** Schools: Overall attrition: 11.5% (3/26) **G1:** 7.1% (1/14) **C1:** 16.7% (2/12) Student attrition: Overall: 63.3% (1,621/2,562) **G1:** 61.4% (887/1,444) **C1:** 63.9% (714/1,118)

Evidence Table 2. Effective school-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Ellickson et al., 2003 **Geographic area:** US **Funding agency:** NIDA, the BEST Foundation for a Drug-Free Tomorrow; the Conrad N. Hilton Foundation **Study setting:** School-based	**Research objective:** To evaluate revised Project ALERT drug prevention program across a variety of Midwestern schools and communities **Population:** • Adolescents, 7th and 8th graders in South Dakota (Urban and rural communities) **Study type:** RCT w/ stratified randomization **Inclusion criteria:** • Middle schools in South Dakota • Parental consent obtained **Exclusion criteria:** NR	**Sampling plan:** • 48 school clusters (high schools and their feeder middle schools) • Schools organized in 3 strata by community size and type (city, town, rural) • Blocks of school clusters consisted of 3 clusters from same stratum located in same geographic region of state., within each block, 1 school cluster randomly assigned to each experimental condition • Results are combined through 8th grade for this study w/ one C **Sample size:** **G1:** 34 middle schools, 2,553 students **C1:** 21 middle schools, 1,723 students **Definition of smoking:** Cigarettes • Cigarette use: ever, past month, and weekly

Evidence Table 2. Effective school-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Classroom instruction **Intervention:** **G1:** 11 lessons in 7th grade and 3 lessons in 8th grade that, using interactive teaching methods, they sought to change students' beliefs about drug norms and social, emotional, and physical consequences of using drugs, to help students identify and resist pro-drug pressures from parents, peers, media, and others, and to build resistance self-efficacy; followed by booster lessons in 9th and 10th grades **G2:** 11 lessons in 7th grade and 3 lessons in 8th grade that, using interactive teaching methods, they sought to change students' beliefs about drug norms and social, emotional, and physical consequences of using drugs, to help students identify and resist pro-drug pressures from parents, peers, media, and others, and to build resistance self-efficacy; not followed by any booster lessons **C1:** Did not receive experimental program; schools could continue other prevention curricula already in place **Method of assessment:** Students completed surveys at baseline and 18 months later	**Statistical analysis:** • Adjusted for multiple baseline covariates, including covariates for school geographic location and enrollment size to account for blocking • Used Bayesian model to impute missing data for covariates; a generalized estimating equation that assumed a linear model for natural logarithm of the odds of use and constant correlation among responses from students from same schools used to account for possible intraschool correlation **Data verification:** Self-reported smoking status validated by assessing salivary cotinine levels for a random subsample of 654 students **Dependent variables:** Cigarette, marijuana, and alcohol use; beliefs about consequences, prevalence and expectations of use, self-efficacy **Baseline data:** • Non-white: 12.5% (largely Native American) • Female: 50% • Students in C1 less likely to be White and more likely to have used marijuana than students in G1 and G2	At 18-month followup, cigarette use in the past month: • Baseline non-users: **G1+G2:**8.6% **C1:** 11.1% *P* = < 0.01 • Baseline experimenters: **G1+G2:**28.9% **C1:** 36.6% *P* = < 0.05 • Baseline users: **G1+G2:**56.8% **C1:** 70.8% *P* = < 0.05 At 18-month followup, weekly cigarette use: • Baseline non-users: **G1+G2:**4.0% **C1:** 6.6% *P* = < 0.05 • Experimenters: **G1+G2:**18.0% **C1:** 23.5% *P* = < 0.05 • Users: **G1+G2:**45.1% **C1:** 56.0% *P* = < 0.10	**Quality rating:** Fair **Comments:** • Slight baseline differences but controlled for in analysis • Clear description of school assignment • Possible disruption of randomization process **Adequate randomization:** Yes **Attrition rate:** 9%

Evidence Table 2. Effective school-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Josendal et al 2005 **Geographic area:** Western Europe **Funding agency:** Norwegian Cancer Society **Study setting:** School-based	**Research objective:** To evaluate the BEsmokeFREE school-based, smoking-prevention program for adolescents in Norway **Population:** • Adolescents • Norwegian 7th, 8th , and 9th grade (mean age 13) **Study type:** • RCT w/ cluster randomization **Inclusion criteria:** After being sampled by technique described, the school had to agree to participate **Exclusion criteria:** NR	**Sampling plan:** • Nationally representative sample of 99 secondary schools from a list of all secondary schools in Norway • Schools sorted by ascending postal code number, every 11th school included in study; schools allocated to groups by investigators choosing a random number b/w 1 and 44 • Starting w/ that number, every 44th school selected for C and next three schools on list of comparable size (+/- 10%) allocated to three intervention groups **Sample size:** **G1:** 25 schools, 1,125 students **G2:** 25 schools, 933 students **G3:** 25 schools, 1,005 students **C1:** 25 schools, 1,092 students **Definition of smoking:** Cigarettes • Smokers: daily smokers, and weekly smokers • Nonsmokers: smoking less than once a wk, and not smoking at all

Evidence Table 2. Effective school-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Video • Parent involvment • Classroom instruction **Intervention:** **G1:** Intervention administered by teachers and other staff at school • Given to students in grades 7 and followed cohort through 7, 8, 9 grade • Number of hrs of intervention: grades 7 thru 9 were 8, 5 and 6 hrs, respectively • Classroom instruction contained non-traditional school activities such as video, games, and group work • During grade 8 adjustments to intervention were requested by students and teachers • In grade 9, students developed and carried out and evaluated their own campaign to promote a smoke free lifestyle among the 7th graders • Classroom curriculum, teacher in-service course, and parental involvement **G2:** Same as G1 Classroom curriculum and parental involvement but teacher did not receive in-service training on intervention **G3:** Same as G1 Classroom curriculum w/ teacher in-service course but no parent involvement **C1:** Education on smoking and health about half the number of hrs as intervention **Method of assessment:** Surveys administered in classroom by teachers at end of each academic yr (7th, 8th, and 9th grades), then mailed to evaluators.	**Statistical analysis:** Multilevel, multiple logistic regression analyses used to examine odds of smoking among students in intervention groups compared w/ students in C1, adjusted for gender and smoking habits at baseline Significance tested w/ Pearson's X^2, corrected for design effect; correction implies chi sq value converted to an F-value w/ number of d.f. that may deviate from integer values **Data verification:** Self-report **Dependent variables:** • Frequency of smoking • Number of cigarette hrs • Number of cigarettes smoked per wk • Use of cannabis • Frequency of cannabis use **Baseline data:** Baseline data reported but limited to smoking frequencies Mean age: 13 yrs	Proportion of smokers higher in C1 vs G1 for 3 followup yrs: • 1995: F(d.f. = 2.61; 125.49) = 5.66; $P < 0.01$ • 1996: F(2.34; 114.46) = 7.19; $P < 0.001$ • 1997: F(2.39; 112.42) = 4.05; $P < 0.05$ In G2 and G3, proportion of smokers on all followup occasions higher than G1 but lower then C1 • 1995: F(d.f. = 9.74; 886.65) = 2.84; $P < 0.01$ • 1996: F(7.87; 739.55) = 3.98 $P < .001$ • 1997: F(6.00; 485.98) = 2.46; $P < .05$ Odds of becoming a smoker during intervention period statistically lower in G1 compared to **C1:** • Daily smoking (Wald's 9.81, d.f. = 3, $P = 0.02$) • Weekly smoking (Wald's 15.65, d.f. = 3, $P = 0.0001$) • Any smoking (Wald's 16.54, d.f. = 3, $P = 0.0001$)	**Quality rating:** Good **Comments:** • Study design and randomization technique clearly described • Intervention theoretically anchored; description of scales reported in referenced article • Explored attrition by surveying drop outs **Adequate randomization:** Yes **Attrition rate:** • **G1+G2+G3:** 11.2% **C1:** 5.8% • Smokers more likely to drop out than non-smokers

Evidence Table 2. Effective school-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Perry et al., 2003 **Geographic area:** US **Funding agency:** NIDA **Study setting:** School-based	**Research objective:** To evaluate effect of middle and junior HS D.A.R.E. and D.A.R.E. Plus programs on drug use and violence **Population:** • Adolescents, 7th and 8th grade • Junior High Schools and communities in Minneapolis-St Paul region, Minnesota **Study type:** RCT w/ simple randomization **Inclusion criteria:** Minnesota school district, 7th graders in Fall 1999 **Exclusion criteria:** NR	**Sampling plan:** • Targeted Minnnesota school districts w/ schools w/ 7th grade populations of at least 200 • 24 Junior high schools matched on SES, drug use and size; schools randomly assigned to 1 of 3 conditions DARE only, DARE Plus, or C **Sample size:** **G1:** 8 schools; 2226 students **G2:** 8 schools; 2221 students **C1:** 8 schools; 1790 students **Definition of smoking:** NR

Evidence Table 2. Effective school-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Parent involvment • Extra-curricular activities • Classroom instruction • Community-activities **Intervention:** **G1:** D.A.R.E. middle and junior HS curriculum • 10 sessions taught by police officers in 1999-2001 **G2:** D.A.R.E curriculum and D.A.R.E. Plus program in 1999-2001: • Classroom sessions, peer led, parent involvement • Community leader involvement program consisting of extra curricular anti-smoking activities in and out of school, including neighborhood activities to address neighborhood issues related to drug use and violent behavior **C1:** Delayed program: Schools could receive D.A.R.E. Plus programs in 2001-2002, after final followup **Method of assessment:** Self-administered questionnaire	**Statistical analysis:** Growth curve analysis; 3-level linear, random-coefficients model **Data verification:** Self-report **Dependent variables:** • Use of cigarettes, alcohol, and marijuana; multidrug use; violent behaviors; expectations concerning drug use, perceived access/offer of drugs, parental rules and communication about drugs • Outcome expectations about tobacco **Baseline data:** Male: 51.6% White: 67.3% African American: 7.5% Asian American: 12.7% Hispani**C1:** 3.6% American Indian: 4.0% Mixed or other: 4.9%	Using growth curve analysis: D.A.R.E. Plus less likely than control to show an increase in current smoking for boys **G2:** (.28) std = 0.05 **C1:** (.31), std = 0.05 D.A.R.E. Plus less likely than D.A.R.E. curriculum alone to show an increase in tobacco use behavior and intentions. **G1:** (.95), std = 0.11 **G2:** (.68), std = 0.11 **C1:** (.96), std = 0.12 NS outcomes for females	**Quality rating:** Fair **Comments:** • Randomization and sampling technique incomplete • No baseline comparison data **Adequate randomization:** No, group-randomization method NR; exactly 8 schools per intervention **Attrition rate:** • 16% overall • Minimal differential attrition per authors

Evidence Table 2. Effective school-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Schofield et al., 2003 **Geographic area:** Australia **Funding agency:** National Health and Medical Research Council (Australia); Hunter Centre for Health Advancement **Study setting:** School-based	**Research objective:** To determine whether HPS intervention program led to lower smoking uptake and improved knowledge and attitudes among a cohort of students, and to examine factors independently predicting posttest smoking status **Population:** • Adolescents • 7th -8th grade cohort followed 2 yrs to grades 9-10 in New South Wales **Study type:** • RCT w/ cluster randomization (cohort prepost design) • Students followed over two yr period; cohort prepost design used to evaluate intervention effectiveness **Inclusion criteria:** Students in Yr 7-8 at one of participating schools who gave assent, whose parent(s) gave active consent, and whose pre and posttests could be matched for comparison **Exclusion criteria:** NR	**Sampling plan:** • Intervention randomly allocated to selected secondary schools • Randomly selected 24 of 31 secondary schools in Hunter and Taree schools districts of New South Wales • 22 of 24 schools participated, w/ 12 schools assigned to intervention, 10 to control **Sample size:** **G1:** 1,007 **C1:** 845 **Definition of smoking:** Cigarettes • Smoking status at posttest: having smoked any amount of cigarettes within past 7 days

Evidence Table 2. Effective school-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Group counseling • Social support **Intervention:** **G1:** Each school had liaison office responsible for introducing minimum set of actions and facilitating tailoring and implementation of the following actions: • Ensure curriculum covers smoking effects, distribute parent smoking pamphlet, implement school smoking policy, distribute letters to tobacco retailers, discussion group/survey w/ parents, followup action from discussion group, and training of SRC/peer leaders to deal w/ smoking issues • Schools also encouraged to take over other additional anti smoking activities of their choice **C1:** Control schools not offered any of the resources or actions to reduce smoking that intervention schools received, but if they requested assistance, project team offered support for other health-related issues and promised smoking-specific support at completion of study period **Method of assessment:** Self-reported retrospective diary (of having smoked within past 7 days), as assessed via questionnaire	**Statistical analysis:** Univariate analysis Bivariate analysis Multivariate analysis Logistic regression **Data verification:** Self-report **Dependent variables:** • Smoked in last wk • Smoking knowledge • Smoking attitudes towards schools **Baseline data:** Large variations in baseline smoking rates (11-33%) so smoking and school controlled for in regression (details NR) At pretest, smokers had: • Less positive attitudes than nonsmokers (mean for smokers: 4.3; mean for non-smokers 4.7, mean difference = 0.4, 95% CI-0.3, 0.5) • Fewer perceived negatives about smoking (smokers' mean: 3.6, non-smoker's mean = 3.9, mean difference = 0.2, 95% CI, 0.1, 0.3)	Posttest results: Smoked in last wk: NS **G1:** 17.5% **C1:** 20.5% Crude OR for G1 = 0.82 (0.65, 1.04) Maximum knowledge score: **G1:** 64% **C1:** 60% Prepost change: **G1:** 12% **C1:** 7% *P* = 0.001 Smoking attitudes: NS at pre or posttest Solely among smokers (from combined groups), positive attitudes to smoking decreased from pretest to posttest (*P* = 0.01), but not among non-smokers	**Quality rating:** Fair **Comments:** • Refusal rate: 40% • High attrition • Intervention not consistently implemented across schools, though high fidelity in implementing "key components" of intervention, authors mention potential contamination via control schools w/ personnel supportive of HPS intervention program, but no data to support/refute • Study properly addressed clustering issue through analytical methods **Adequate randomization:** Yes **Attrition rate:** **G1:** 48% **C1:** 52% (Authors mention more smokers than non-smokers lost to follow up)

Evidence Table 2. Effective school-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Share et. al., 2004 **Geographic area:** Western Europe **Funding agency:** Europe Against Cancer Programme **Study setting:** School-based	**Research objective:** To evaluate impact of a school-based intervention-SFL-which aimed to involve the community, increase tobacco knowledge, strenghthen refusal skills, and improve decision-making ability **Population:** • Adolescents, ages 13 to 15 • Leitrim, Sligo, and Donegal County, Ireland students **Study type:** RCT w/ simple randomization **Inclusion criteria:** • SLF program participants • Aged 9 to 10yrs attending 4th grade (1996-97) in North Western Health Board area (not defined) **Exclusion criteria:** NR	**Sampling plan:** SLF program participant cohort matched w/ a C located in North Western Health Board area (not defined) **Sample size:** **G1:** 450 **C1:** NR **Definition of smoking:** NR

Evidence Table 2. Effective school-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Classroom instruction **Intervention:** **G1:** Primary school phase: materials about smoking, healthy lifestyle, and growing up provided for classroom instruction; • Teachers determined order/timing of lessons; visits from health promotion staff,and yr end celebration; • Postprimary school phase: quizzes, competition, visits by health promotion staff, newsletter, website, peer education project, smoke free school buses campaign, and annual events day(no classroom materials provided) **C1:** NR **Method of assessment:** Self-report questionnaire at study's end (administered face to face in intervention group and 11 control schools; "posted" (mailed) to other control schools)	**Statistical analysis:** • SPSS • Pearsons chi sq • Spearman's Rank correlation **Data verification:** Self-report **Dependent variables:** • Smoking experimentation • Current smoking • Smoking knowledge • Attitudes about smoking • Family member smoking • Reasons for continued smoking **Baseline data:** Baseline data (i.e: at age 9 to 10) NR **Male** **G1:** 52% **C1:** 45% **Age 13:** **G1:** 12% **C1:** 14% **Age 14:** **G1:** 72% **C1:** 77% **Age 15+:** **G1:** 16% **C1:** 9%	**Tried smoking:** **G1:** 59% **C1:** 55% **Current smoking:** **G1:** 19% **C1:** 24% Females in C 2x as likely to smoke everyday and 50% more likely to currently smoke than females in intervention group, ($P < 0.05$) **Feel grown if smoke:** **G1:** 30% **C1:** 43% ($P < 0.01$) **Don't mind if friends smoke:** **G1:** 72% **C1:** 67% ($P < 0.05$) Family: correlation b/w student smoking experimentation and parent/sibiling smoking: • Mother (rs = 0.165, $P < 0.01$) • Father (rs = 0.172, $P < 0.05$) • Both parents (rs = 0.346, $P < 0.01$) • Brother (rs = 0.162, $P < 0.01$) • Sister (rs 0.277, $P < 0.01$)	**Quality rating:** Poor **Comments:** • No information on selection of subjects from primary intervention • Unable make inferences from original baseline data because followup instrument not compatible • No reliability testing of instrument • No information on randomization, or C • No baseline data and analytical methods not well described **Adequate randomization:** NR **Attrition rate:** **G1:** 22% **C1:** NR

Evidence Table 2. Effective school-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Simons-Morton et al.,2004 **Geographic area:** US **Funding agency:** NR **Study setting:** School-based	**Research objective:** To examine associations b/w initial and continuing peer affiliation and parent influences and smoking stage progression **Population:** • Adolescents, 6th, 7th, and 8th graders **Study type:** RCT w/ simple randomization **Inclusion criteria:** • 6th grader in 1996 or 1997 at one of 7 schools in un-named Maryland School District • Consent by parents **Exclusion criteria:** Special education students	**Sampling plan:** • Seven middle schools (in 1 Maryland school district) recruited and randomized: o 3 to txt condition and 4 to control • Starting w/ 1996 school yr., 2 successive cohorts of 6th-grade students recruited and followed through 9th-grade **Sample size:** Total: 3,039 at start, 1,320 final **C1:** NR **Definition of smoking:** Cigarettes • Never: no smoking in past 30 days or past 12 months + no intention of smoking in HS • 12-month smoker: smoking in past 12 months but not in past 30 days • Recent smoker: smoking 1 to 2 times in past 30 days • Frequent smoker: smoking 3+ times in past 30 days • Intent to smoke: none in past 30 days or past 12 months but intent to smoke in HS

Evidence Table 2. Effective school-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Video • Classroom instruction **Intervention:** **G1:** The Going Places Program: parent education (materials sent home), school media, social skills curriculum (to increase school engagement and prevent multiple problem behavior such as substance use, aggression, and antisocial behavior) • 18 class sessions in 6th grade, 10 in 7th grade, 6 in 8th grade **C1:** NR **Method of assessment:** • Students surveyed at beginning and end of 6th grade, toward end 7th & 8th grades, and beginning of 9th grade • Two trained proctors collected data; teachers not involved w/ survey **Baseline data:** NR	**Statistical analysis:** LGC analysis (Curran, 2000): structural equation modeling + hierarchical linear modeling **Data verification:** Self-report **Dependent variables:** • Background variable • Smoking • Friends w/ problem behaviors • Parenting practices	Final sample: • White: 66% • Black: 25% • Other: 9% • Variance of intercept factor in linear LGC model 2.23 (SE = 2.05; $P < 0.001$) indicating significant differences in tobacco use at beginning of 6th grade • Variance of slope factor 0.289 (SE = 0.038; $P < 0.01$) indicating significant differences in smoking stage progression over time • Path coefficients: intercept of adolescent smoking to slope of friends who smoke variable = 0.31($P < 0.01$) indicating adolescents at higher initial smoking stages had increased # of friends smoking over time • Path coefficient b/w parent involvement and adolescent smoking = -0.15, ($P < 0.01$) indicating parent monitoring and expectations overtime are negatively associated w/ smoking stage progression • Path coefficient directly leading from parent involvement (-.15) and indirectly to the slope of adolescent smoking stage (-.46) through the slope of friends who smoke (.66) indicating that parenting practices overtime protect against smoking progression both directly and indirectly by limiting the adoption of friends that smoke $P < 0.01$	**Quality rating:** Poor **Comments:** • Baseline data NR • C sample size NR • No txt vs comparison group data reported • 151 special education students excluded after assessment 1, suggested possibility of post randomization of exclusions **Adequate randomization:** NR **Attrition rate:** 36.3%

Evidence Table 2. Effective school-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Unger et al., 2004 **Geographic area:** US **Funding agency:** National Institutes of Health and the Calif Tobacco-Related Disease Research Program **Study setting:** School-based	**Research objective:** Determine whether a multicultural curriculum prevents initiation of smoking among middle school children at 1-yr followup **Population:** • Adolescents **Study type:** RCT w/ cluster randomization **Inclusion criteria:** Students participated if they and their parents provided active written consent **Exclusion criteria:** NR	**Sampling plan:** Sixteen middle schools in Southern Calif randomly assigned to receive multicultural curriculum or standard curriculum (8 schools in each group) **Sample size:** **G1:** 1,040 students, 8 schools **C1:** 930 students, 8 schools **Definition of smoking:** Cigarettes • Smokers: trying smoking b/w 6th and 7th grade

Evidence Table 2. Effective school-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Classroom instruction **Intervention:** **G1:** Project FLAVOR (Fun Learning about vitality, origins, and respect) provided 8 weekly classroom sessions conducted by health educators that addressed smoking-related psychosocial concepts through activities such as role-playing, trivia games and art projects, relating these issues to values of several cultures, such as Asian Yin-Yang concepts, and telenovela (soap opera) role play **C1:** 8 weekly classroom sessions conducted by health educators that addressed smoking-related psychosocial concepts through activities such as role-playing, trivia games and art projects, but without cultural references **Method of assessment:** Surveys at baseline and 1 yr followup	**Statistical analysis:** • X^2 and ANOVA analyses assessed prevention equivalence of 2 groups • Logistic regression used to examine attrition based on experimental condition, baseline smoking, and experimental condition x baseline smoking • Multi-level logistic regression w/ school as a random effect to control for intraclass correlation assessed effect of intervention on smoking initiation b/w sixth and seventh grades **Data verification:** Self-report **Dependent variables:** Smoking status **Baseline data:** • Groups similar at baseline • No significant differences in demographics or lifetime smoking prevalence b/w intervention and Cs • Hispani**C1:** 57% • Asian American: 27% • Other: 16%	Initiation among never smokers (yr 1 followup): **G1:** 8% **C1:** 11% *P* = NR Among male, Hispanic, never smokers, OR of smoking intitation by 7th grade: OR = 0.49 (95% CI, 0.27 -.88) Overall intervention effect NS: OR = 0.75 (95% CI, 0.48, 1.18)	**Quality rating:** Fair **Comments:** • Randomization scheme NR • No ITT analysis **Adequate randomization:** NR **Attrition rate:** **G1:** 16.83% **C1:** 16.77% Higher among baseline ever smokers (22%) than never smokers (16%), *P* = < 0.05

Evidence Table 3. Effective provider-based interventions

Study Characteristics	Study Design	Sample Design and Definitions
Author: Tyc et al., 2003 **Geographic area:** US **Funding agency:** NCI, ALSAC **Study setting:** Practice/provider settings	**Research objective:** To evaluate efficacy of a tobacco risk counseling intervention vs standard care for preadolescent and adolescent cancer survivors **Population:** • Adolescents who were cancer survivors age 10 to 18 (treated at St. Jude Children's Research Hopital, Memphis, TN) **Study type:** RCT w/ stratified randomization **Inclusion criteria:** • Between 10 to 18 yrs old • Survivor of pediatric cancer • Currently disease-free • At least 1 yr from completion of antineoplastic therapy at St. Jude Children's Research Hospital (TN) **Exclusion criteria:** Patients who had brain tumors (due to cognitive, functional impairments that often result from txt)	**Sampling plan:** • Stratified RCT w/ patients who were pediatric cancer survivors treated at St. Jude Children's Research Hospital, Memphis, TN, currently receiving txt there • Recruited during outpatient visits • Asked to participate and told participation did not depend on smoking status • On enrollment patients randomly assigned (stratified by age, sex, race, and self-reported smoking status) • Randomization scheme proposed by Zelen (1974) **Sample size:** **G1:** 53 **C1:** 50 **Definition of smoking:** NR

Evidence Table 3. Effective provider-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Telephone counseling • Video **Intervention:** **G1:** Administered in single session w/ periodic reinforcement of tobacco goals by telephone • Educational video discussed short- and long-term physical and social consequences of tobacco use • Late effects risk counseling focused on potential chemotherapy and radiation txt related toxicities exacerbated by tobacco use and survivors' increased vulnerability to tobacco-related health risks relative to their healthy peers • Goal setting involving tobacco abstinence or cessation depending on survivor's smoking status • A physician feedback letter that reinforced antitobacco message delivered in intervention • Tobacco literature and followup telephone counseling at 1 and 3 months after intervention • Face-to-face counseling component of intervention conducted by a master's level psychologist over a 50- to 60-minute period, and followup telephone counseling conducted by a research nurse trained by V.L.T.	**Statistical analysis:** • Descriptive • Multivariate analysis of variance, • Repeated measures • Mixed-model analysis of variance and regression **Data verification:** Self-report **Dependent variables:** • Knowledge (of adverse consequences of tobacco use generally and for cancer survivors) • Perceived Vulnerability (to tobacco related health risks) • Intentions (I) (to use tobacco) • Perceived PPE **Baseline data:** Baseline demographic and questionnaire data collected for both groups w/ no significant differences b/w groups	**Mean K score:** **G1:** 24 **C1:** 22.7 **Mean PV score:** **G1:** 35.9 **C1:** 32.5 I scores: **G1:** 7.8 **C1:** 10.0 *P* = 0.002 No significant differences in PPE at 12 mos, nor in any of dependent variables at 6 months	**Quality rating:** Fair **Comments:** • No psychometric validation of researcher-designed scales to measure knowledge and perceived positive effects of tobacco • No verification or definition of tobacco use • Limited generalizability to primarily white cancer patience • Possible ceiling and floor effects on Knowledge and intention measures makes it difficult to access meaningful changes **Adequate randomization:** Yes **Attrition rate:** At 6 months: Overall: 30% (31/103) **G1:** 32.1% (17/53) **C1:** 28% (14/50) At 12 months: Overall: 21.5% (22/103) **G1:** 20.1% (11/53) **C1:** 22% (11/50)

Evidence Table 3. Effective provider-based interventions (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Tyc et al., 2003 (continued)		

Evidence Table 3. Effective provider-based interventions (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention delivered using scripted protocol tailored to patients' individual responses to questions posed during intervention and individual goal setting. **C1:** Patients asked about their tobacco use and briefly advised about health risks associated w/ tobacco use; all tobacco users advised to stop and nonsmokers encouraged to continue to resist tobacco **Method of assessment:** Knowledge scale: • 25 true-false questions regarding adverse effects of tobacco use and w/ questions focused on increased risks of youth treated for cancer • 8-item scale measuring patients' perceptions of their vulnerability to tobacco-related health risks			

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking

Study Characteristics	Study Design	Sample Design and Definitions
Author: Bauman et al., 2000 **Geographic area:** US **Funding agency:** NIDA Grant **Study setting:** Population-based	**Study objective:** To report effectiveness of a universal family-directed program (Family Matters) for reducing/eliminating cigarette and alcohol use by adolescent users **Population:** Adolescents **Study type:** RCT w/ simple randomization **Inclusion criteria:** • In contiguous US state • Consent • Child age 12 to 14 yrs • Completion of baseline interview **Exclusion criteria:** NR	**Sampling plan:** • Eligible parent-adolescent pairs matched (by date and time of baseline interview) then randomly assigned to either Family Matters or C • Random digit dialing and basic query used to identify families w/ 12- to 14-yr old children **Sample size:** **G1:** 37 baseline tobacco users **C1:** 48 baseline tobacco users **Definition of smoking:** Cigarettes • Use on one or more days during past 30 days

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Telephone counseling **Intervention:** **G1:** Family Matters: • Successive mailing of 4 booklets and telephone discussion w/ health educator 2 wks after each mailing • Adult family members read booklets and do 15 activities w/ adolescent • Booklet topics: (1) motivation, (2) family characteristics, (3) tobacco and alcohol variables, (4) variables outside family **C1:** NR **Method of assessment:** Telephone interviews at 3 and 12 months postcompletion or dropout	**Statistical analysis:** GEE method, one-tailed test (alpha 0.05), controlled for background variables. **Data verification:** NR **Dependent variables:** Smoking 30 days before interview **Baseline data:** Groups similar on all measures except txt had younger and fewer non-Hispanic white participants Overall: 12 yrs: 30.6% 13 yrs: 35.3% 14 yrs: 34.1% Male: 49% Non-Hispanic white: 73.4% In 2-parent home: 78.8% Among smokers: • 21.6%, 40.5%, and 37.8% were 12,13, and 14 yrs old respectively in txt • 10.4%, 29.2%, and 60.4% were 12,13,and 14 yrs old respectively in control • 35.1% male (txt) vs 47.9% male (control); • 70.3% vs 95.8% non-Hispanic white in txt vs control • 75.7% vs 68.8% in 2-parent home in txt vs control	Of 85 baseline smokers, 74 completed followup at 3 months (62.2% still smoked) and 80 completed followup at 12 months (66.3% still smoked) No statistically significant difference in tobacco use b/w control and txt for baseline cigarette users (OR = 1.42, lower bound CI, 0.57, *P* = 0.2846).	**Quality rating:** Fair **Comments:** • Include only baseline users in analyses in order to focus on cessation • Only compare entire baseline groups to US or previous study population rather than each other • Used one-tailed tests • Attrition high among tobacco users • No biochemical measure of use • Small sample size **Adequate randomization:** No Groups not similar at baseline by age and race **Attrition rate:** 14% overall; 40.5% among tobacco users in txt group(Control NR)

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Etter et al., 2004 **Geographic area:** Western Europe **Funding agency:** Swiss National Science Foundation, the Swiss Cancer League, the Swiss Federal Office of Public Health, and the Health Authority of the Canton of Geneva **Study setting:** Population-based	**Study objective:** To determine whether effects of a computer-tailored smoking cessation program were maintained at 2-yr followup **Population:** Adults **Study type:** RCT w/ simple randomization **Inclusion criteria:** • 18 to 60 yrs old • Resident of French-speaking Switzerland • More than an occasional smoker • Have a postal address **Exclusion criteria:** NR	**Sampling plan:** • Baseline questionnaire sent to 20,000 18-60 yr old residents of French-speaking Switzerland, 3,124 agreed to participate in study • 2,934 randomized to txt or Cs **Sample size:** **G1:** 1,467 **C1:** 1,467 **Definition of smoking:** Cigarettes • 1 mo Abstinence: not smoking even a puff of a tobacco cigarette, cigar, or pipe in last 4 wks • 1 wk Abstinence: not smoking even a puff of a tobacco cigarette, cigar, or pipe in last 7 days

Evidence Table 4. Multi-component interventions to increase number of users who quit smoking (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Self-help **Intervention:** **G1:** After baseline questionnaire: • Received 8-pg personal counseling letters written by a computer according to answers given by participants on a 62 item questionnaire • Received 2 16-pg booklets corresponding to their current stage of change and next stage of change • Two, four, and 12 mos after entering study, participants could answer tailoring questions again to receive new letter **C1:** After completing baseline questionnaire, C participants received a letter telling them that they were in C, and not contacted again until 6- and 23-mo followup surveys **Method of assessment:** Surveys at 7- and 24-mos postbaseline	**Statistical analysis:** X^2 to compare proportions; t-tests to compare means **Data verification:** NR **Dependent variables:** • Demographic characteristics • Stage of change • Level of tobacco dependence • Perceived drawbacks of smoking • Self efficacy • Use of self help strategies • Current use • Intention to use NRT **Baseline data:** Groups similar at baseline	**At 7 mo followup:** 1 mo abstinence rates: **G1:** 5.8% **C1:** 2.2% *P* = < 0.001 1 wk abstinence rates: **G1:** 8.0% **C1:** 3.3% *P* = < 0.001 **At 24-mo followup:** 1 mo and 1 wk abstinence rates similar for both groups, differences NS Proportion of those who quit for at least 1 mo during study: **G1:** 30.9% **C1:** 24.7% *P* = < 0.001 Proportion of those who used > 1 nicotine replacement product: **G1:** 24.9% **C1:** 20.8% *P* = < 0.008	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** NR **Attrition rate:** 7-mo followup: 16% 24-mo followup: 12%

Evidence Table 4. Multi-component interventions to increase number of users who quit smoking (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Lipkus et al., 2004 **Geographic area:** US **Funding agency:** NCI grant **Study setting:** Community-based	**Study objective:** To test efficacy of self-help materials w/ or without proactive telephone counseling to increase cessation among teen smokers. **Population:** Adolescents **Study type:** RCT w/ simple randomization • 2-arm randomized intervention trial • **Inclusion criteria:** • Age 15 to 18 • Smoked a cigarette within last wk • Gave verbal consent • Obtained parental consent if < 18 yr **Exclusion criteria:** NR	**Sampling plan:** • Teen smokers recruited from 11 shopping malls and 1 amusement park in Southeastern US • Teens stratified on stage of readiness to quit, then randomized to (1)self-help materials + video (C) or (2) self-help materials + video + telephone counselors (experimental group). **Sample size:** **G1:** 193 **G2:** 209 **Definition of smoking:** Cigarettes • Smoked 1 or more within last wk

Evidence Table 4. Multi-component interventions to increase number of users who quit smoking (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Telephone counseling • Video **Intervention:** **G1:** Two self-help booklets by mail and 6 minute video and 3 telephone counseling sessions **C1:** Two self-help booklets by mail , 6 minute video, no telephone counseling **Method of assessment:** 6-item revised Fagerstrom Nicotine Tolerance Scale; self report (validated by saliva cotinine if denied smoking in last wk); Shadel and Mermelstein's 5-item scale	**Statistical analysis:** ITT; logistic regression **Data verification:** Saliva cotinine kit mailed at month 4 postbaseline if teen denied smoking in last 7 days; otherwise selfreport. Saliva kits retruned by 40% of those reporting cessation; rates of return did not differ by group **Dependent variables:** Point-prevalent abstinence at 4 and 8 mos postbaseline; sustained abstinence (proportion reporting not smoking at both followups) and predictors of cessation **Baseline data:** No arm differences on sample characteristics Age 17 or older: **G1:** 55% **C1:** 59% Male: **G1:** 47% **C1:** 51% High School: **G1:** 85% **C1:** 78% 82% white, 10% black in both groups 3 (SD 2) mean yrs smoking in both groups	No group differences observed in abstinence at either time point or for sustained abstinence **G1:** Abstinence rates: 16% and 21% for 4 and 8 mos, respectively **C1:** Abstinence rates: 11% and 19% for 4 and 8 mos, respectively Outcome Measures unchanged after adjusting for multiple variables Sustained abstinence rates (C1) 7% and (G1) 9% Participants completing more counseling calls more likely to report cessation at 4 and 8 mos postbaseline w/ ITT: (OR = 1.59, 95% CI, 1.14-2.22 for 4 mos and OR = 1.54, 95% CI, 1.15-2.07 for 8 mos) and to have sustained abstinence (OR = 2.03, 95% CI, 1.14-2.22 Intervention group less likely to watch some/all of video (44% vs 62%, $P < 0.05$) and read some/all of booklet (57% vs 78%, $P < 0.01$) Teens completing more calls more likely to report quitting at 4 and 8 mos (4 mos: OR = 1.59, 95%CI, 1.14-2.22, $P < 0.007$; 8 mos: OR = 1.54, 95% CI, 1.15-2.07, $P < 0.007$) and have sustained abstinence (OR = 2.03, 95%CI, 1.14-2.22, $P < 0.006$) The more calls teens accepted, the more negative they felt about smoking (r = 0.23, $P < 0.05$) and the more they reported wanting to stop (r = 0.23, $P < 0.05$)	**Quality rating:** Fair **Comments:** • Methods described in good detail (except randomization scheme) • Major limitation is high attrition rates **Adequate randomization:** NR **Attrition rate:** Control: 49% Intervention: 66% **Abstinence rates:** 4 mos: **G1:** 16% **C1:** 11% 8 mos: **G1:** 21% **C1:** 19%

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Lipkus et al., 2004 (continued)		

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
		Compared w/ teens who smoked more than the median number of cigarettes per day (>8), teens who smoked equal to or less than the median number of cigarettes a day more likely to have quit smoking at 4-mo (OR = 3.3, 95% CI, 1.7-5.0, $P < 0.0004$) and at 8-mo followup (OR = 2.0, 95% CI, 1.2-3.3, $P < 0.007$) and to have sustained abstinence at both followups (OR = 2.5, 95% CI, 1.2-5.0, $P < 0.01$) Teens in preparation stage more likely than precontemplators to have quit at 4-mo (OR = 2.4, 95% CI, 1.0-5.4, $P < 0.05$) and at 8-mo (OR = 2.9, 95% CI, 1.4-6.0, $P < 0.005$) followups Stage of readiness not related to sustained abstinence	

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: McBride et al; 2002 **Geographic area:** US **Funding agency:** NCI **Study setting:** Practice/provider settings	**Study objective:** To assess whether a multicomponent intervention that included feedback about genetic susceptibility to lung cancer increased risk perceptions and rates of smoking cessation compared w/ a standard cessation intervention **Population:** • Adults • African Americans • Low SES **Study type:** NR Eligible smokers randomized in a 1:2 ratio to enhanced usual care group or biomarker feedback (that included tailored feedback of genetic susceptibility to lung cancer based on presence or absence of GSTM1 and telephone counseling) group **Inclusion criteria:** • Self-identify as African American • Smoked at least one cigarette/day in prior 7 days • Would consider genetic testing for GSTM1 **Exclusion criteria:** • Not African American; being treated for substance abuse • Smoked less than 7 cigarettes/wk • Did not have a telephone • Have medical conditions that contraindicate participation, e.g., Alzheimer's disease, alcohol dependence • Non-English speaking • < 18 yrs of age	**Sampling plan:** African-American patients (seen in adult medicine, dental, urgent care and specialty clinics) current smokers, and identified by chart abstraction and provider referral Those eligible and agreed to participate called within 7 days of visits to complete participant intake assessment **Sample size:** **G1:** 185 **G2:** 372 **Definition of smoking:** Cigarettes • Smoking: At least 1 cigarette in past 7 days

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Telephone counseling • Pharmaceuticals • Genetic susceptibility feedback **Intervention:** **G1:** Enhanced Usual Care: participants received provider advice to quit smoking and referred to smoking specialist who assessed stage of readiness to quit and appropriateness of NRT • Within 2 wks after clinic visit, all smokers sent a self-help smoking cessation guide especially designed for African-American smokers, "Pathways to Freedom" • If eligible (smoked at least five cigarettes/day and in preparation stage of readiness to quit), a 14-day supply of 15 mg nicotine patches • Refill kits included a 7-day supply of patches provided as needed; • Participants allowed to request up to eight refills over study period (for a total of 10 wks of therapy)	**Statistical analysis:** • Baseline characteristics compared by intervention arm w/ X^2 statistic for discrete variables and t-tests for normally distributed continuous and ordinal variables • Wilcoxon test statistic used when variables not normally distributed • Logistic regression used for main binary outcomes of trial, abstinence from smoking in prior 7 days at 6- and 12-mo followups, and continuous abstinence (not smoking at both 6- and 12-mo followups) • All analyses done twice, first unadjusted and then adjusted by adding baseline variables that differed ($P < 0.05$) by arm and known to be associated w/ smoking cessation, including number of chronic illnesses (0 v. 1 or more), smoking within 30 min of rising (no v. yes), and desire to quit (below or equal to median v. above median) **Data verification:** • Salivary cotinine levels assessed for self-report of not smoking at 12-mo followup • Efforts to biochemically confirm self-reported cessation unsuccessful • 39% (24/61) of those who reported abstinence and agreed to provide a saliva sample returned one • Rates of return did not differ b/w two arms ($P = 0.78$)	Proportion of participants not smoking at 6-mo followup: **G1:** 10% **G2:** 19% Unadjusted $P = 0.006$ Adjusted $P = 0.03$ Proportion of participants not smoking at 12-mo followup is NS: **G1:** 10% **G2:** 15% Unadjusted $P = 0.12$ Adjusted $P = 0.34$ Continuous abstinence of participants: **G1:** 5% **G2:** 11% Unadjusted $P = 0.02$ Adjusted $P = 0.08$ Rates of prevalent and sustained abstinence for those w/ enzyme missing or present did not differ significantly at followup: • 6 mos, 17 and 23%, respectively • 12 mos, 18 and 15%; sustained, 12 and 12% Among those who declined test, rates of prevalent abstinence at 6 and 12 mos and sustained abstinence substantially lower (11, 11, and 5% for each outcome and time point, respectively	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** Yes **Attrition rate:** • 6-month followup: 26% • 12-month followup: 36% No difference in attrition b/w groups

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: McBride et al; 2002 (continued)		

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
G2: Biomarker Feedback: • Participants offered opportunity to have their blood tested for GSTM1 • Within 2 wks after clinic visit, participants priority mailed an eight-pg test result booklet written at a fifth grade reading level that included test result, information about chemical constituents of tobacco smoke and harms of exposure, regardless of genetic make-up • Those who declined test were sent an identical booklet that included same graphical displays along w/ a generic description of test and a question mark in result box • Within 1 wk after test result booklet mailed, participants called to discuss GSTM1 test and their result; counselors attempted a total of four calls w/ each participant over a 12-wk period; b/w first and second calls, participant sent "Pathways" selfhelp guide and nicotine patches, if appropriate **C1:** NR **Method of assessment:** Self-report of 7-day point prevalence smoking status Salivary cotinine levels assessed at 6 and 12-mo followup Blood analyzed for G2 group to evaluate whether or not GSTM1 present	**Data verification:** Salivary cotinine levels assessed for those who self-reported not smoking at 12-mo followup Efforts to biochemically confirm self-reported cessation unsuccessful; 39% (24 of 61) of those who reported abstinence and agreed to provide a saliva test **Dependent variables:** Primary: • smoking status Secondary: • risk perceptions • worry • depression **Baseline data:** Groups similar at baseline except: G1 arm participants had: • more chronic illnesses • less desire to quit smoking • more likely to smoke within 30 min of waking than those in G2 arm		

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Murray et al., 2002 **Geographic area:** US Canada **Funding agency:** NIH **Study setting:** Practice/provider settings	**Study objective:** To evaluate long-term persistence of effects on smoking and quitting on participants in the LHS intervention aimed at smoking cessation and to describe characteristics that distinguish those who quit smoking from those continuing to smoke **Population:** • Adults **Study type:** RCT w/ systematic randomization **Inclusion criteria:** • Smokers who had some evidence of lung function impairment (at baseline, their ratio of FEV to FVC less than 0.70 and their FEV b/w 55 and 90% of predicted normal for their age, gender, height, and race) • Willingness to participate in a smoking cessation program if randomized to smoking intervention **Exclusion criteria:** • Serious health conditions likely to affect participation in followup visits and lung function measurement • Use of prescribed medications that might alter lung function	**Sampling plan:** Original LHS recruited, in 10 clinics in U.S. and Canada, 5,887 adult volunteer smokers w/ some evidence of lung function impairment Following LHS 1, LCS enrolled 5,008 of original cohort, and followed at 6-mo intervals w/ telephone interviews to ascertain smoking status and morbidity Recruits randomized equally to three study arms **Sample size:** **G1:** 3,040 **C1:** 1,477 **Definition of smoking:** Sustained abstainers: • participants who had been sustained quitters in LHS 1 • gave no report of smoking during LCS • if not enrolled in LCS, recalled no month w/ as much as one cigarette per day in interval b/w LHS 1 and LHS 3 • ex-smokers at LHS 3 baseline, validated by expired air CO levels

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Pharmaceuticals **Intervention:** **G1:** SI(described in other articles) w/ ipratropium bromide inhaler and SIwith placebo inhaler - both groups combined for analysis because ipratropium bromide inhaler had no effect on smoking cessation **C1:** usual care (described in other articles) **Method of assessment:** • Interviews in-person and via telephone • Expired air CO levels	**Statistical analysis:** Comparisons b/w groups for quantitative variables are based on t-tests, while those for categorical variables are based on X^2 or Fisher's exact test; Logistic regression used to analyze multiple predictors of LHS 3 cross-sectional smoking status and sustained abstinence status **Data verification:** Expired air CO levels used to validate non-smoking status **Dependent variables:** Smoking status **Baseline data:** Groups similar at baseline	Biochemically validated smoking status at LHS 3 baseline - Percent quit: **G1:** 51.7 **C1:** 42.9 *P* = < 0.001 Sustained abstinence since LHS 1 baseline: **G1:** 21.9% **C1:** 6.0% *P* = < 0.001 OR of abstinence in participants assigned to G1 as opposed to C1 = 4.45	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** Yes **Attrition rate:** 16.7%

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Rabius et al., 2004 **Geographic area:** US **Funding agency:** ACS **Study setting:** Population-based	**Study objective:** To examine effects of telephone counseling on smoking cessation among smokers 18 to 25 yrs old and smokers over 25 yrs old **Population:** • Young adults • Adults **Study type:** RCT w/ simple randomization **Inclusion criteria:** Of those who called a toll-free ACS number to inquire about cessation, adult current daily smokers willing to make a quit attempt in next two wks **Exclusion criteria:** NR	**Sampling plan:** • Cessation assistance offered to smokers from anywhere in US that called ACS' general toll-free number for information about cessation • Adult current daily smokers willing to make a quit attempt in next 2 wks and gave consent , interviewed and randomized to 2 txt or control • All participants received three ACS booklets that provide standard advice; half of participants randomized to receive an offer of telephone counseling **Sample size:** Total: 3,522 **G1:** Half of participants; exact N NR **C1:** Half of participants; exact N NR **Definition of smoking:** Cigarettes • Current smoking: any smoking within last 48 hrs

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Telephone counseling **Intervention:** **G1:** Three ACS booklets w/ standard advice plus up to five sessions of proactive telephone counseling **C1:** Three ACS booklets w/ standard advice **Method of assessment:** Interview at 15 wks after enrollment (approximately 3 mos postquit date); if participants reported abstinence at 3 mo interview, then interviewed again at 6 mos postquit date	**Statistical analysis:** • Logistic regression for studies of factors predicting study retention and quitting success, t-tests for comparing means • X^2 for comparing proportions **Data verification:** NR **Dependent variables:** Study retention by intervention; abstinence; use of NRT or Zyban **Baseline data:** Proportion of participants in younger age group (18-25 yrs old): 12% (n = 420), similar to larger population Women outnumbered men overall Proportion of men: 18-25 yrs: 39% Over 25 yrs: 33% *P* = < 0.01 Proportion of married men: 18-25 yrs: 19% over 25 yrs: 49% *P* = < 0.001 Frequency of cigarette use: 18-25 yrs: 18 cigarettes Over 25 yrs: 24 cigarettes *P* = < 0.001	Prevalence of reported 48 hr abstinence at 3 mo followup among 18-25 yr olds: **G1:** 19.6% **C1:** 9.3% *P* = < 0.005 Prevalence of reported 48 hr abstinence at 3 mo followup for over-25 yr olds: **G1:** 15.1% **C1:** 9.6% *P* = < 0.001 Proportion of 18-25 yr olds reporting 48 hr abstinence at both 3 and 6-mo followups: **G1:** 9.8% **C1:** 3.2% *P* = < 0.01 Proportion of over-25 yr olds reporting 48 hr abstinence at both 3 and 6-mo followups: **G1:** 8.8% **C1:** 5.3% *P* = < 0.005 Estimate of prolonged abstinence at 6 mo followup (reported 48 hr abstinence plus 5 or fewer • Logistic regression analysis examining relationships b/w demographic variables, smoking behavior and history, and txt condition found the following: among 18-25 yr olds, txt condition only significant predictor of 48 hr abstinence at 3-mo followup (*P* = < 0.01) • Among over-25 yr olds, 48 hr abstinence at 3-mo followup significantly higher in txt group (*P* = < 0.001), those w/ more education (*P* = < 0.01), and those w/ lower baseline smoking rates *(P* = < 0.001)	**Quality rating:** Fair **Comments:** **Adequate randomization:** NR **Attrition rate:** Overall: 36% Attrition at 3-mo followup: 18-25 yr olds: 48% Over-25 yr olds: 34% *P* = < 0.001 Attrition among those abstinent and eligible for followup at 6 mos: 18-25 yr olds: 36% Over-25 yr olds: 15% *P* = < 0.001 Logistic regression found that successfully followed participants more likely to be female (*P* = < 0.01) and better educated (*P* = < 0.01) than those not retained in study

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Smith et al.; 2004 **Geographic area:** Canada **Funding agency:** Ontario Ministry of Health; Heart and Stroke Foundation of Ontario **Study setting:** Population-based	**Study objective:** To examine options for use, efficiency, and effectiveness of telephone counseling for structuring a population-based telephone smoking cessation service **Population:** • Adults **Study type:** RCT w/ stratified randomization **Inclusion criteria:** • Current smokers • At least 18 yrs of age • Daily smokers • Non pregnant • Intend to quit within 7-20 days • Live in specified geographic recruitment areas • Consent to participate in study **Exclusion criteria:** NR	**Sampling plan:** Counselors answered incoming toll-free calls and determined study eligibility of callers; ineligible callers sent cessation materials designed to respond to their needs (e.g., pregnancy); eligible callers randomized (stratified within communities) to one of five conditions **Sample size:** Total: 632 **Definition of smoking:** Cigarettes • Point abstinence: 7-day abstinence at time of followup call • Continuous abstinence: 7-day abstinence at all followup calls

Evidence Table 4. Multi-component interventions to increase the number of users who quit smoking (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Telephone counseling • Pharmaceuticals **Intervention:** **G1:** Initial 50 minute telephone counseling, 2 five to 10 minute followup calls, booklet **G2:** Initial 50 minute telephone counseling, 2 five to 10 minute followup calls, pamphlet **G3:** Initial 50 minute telephone counseling, 6 five to 10 minute followup calls, booklet **C1:** Print materials only **Method of assessment:** Research staff, blind to txt conditions, called participants in all 5 conditions at 3,6, and 12 mos to assess smoking status; 7 attempts made at each followup call before recording it as missed	**Statistical analysis:** NR **Data verification:** No biochemical validation of self-reported smoking status performed **Dependent variables:** • Smoking status • Participant rating of print materials • Participant rating of telephone counseling **Baseline data:** No significant differences across the 5 groups at baseline	Point abstinence at 3 mos: **G1:** (1, 2, 3, 4 collapsed) = 15% **C1:** 13% *P* = < 0.05 Point abstinence at 6 mos: **G1:** (1, 2, 3, 4 collapsed) = 15% **C1:** 14% *P* = < 0.05 Point abstinence at 12 mos: **G1:** (1, 2, 3, 4 collapsed) = 17% **C1:** 20% *P* = < 0.05 Continuous abstinence: **G1:** (1, 2, 3, 4 collapsed) = 5% **C1:** 1% *P* = < 0.05	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** Yes **Attrition rate:** Attrition: 30.6% • Died: 0.003% • Withdrew: 7.1% • Lost to followup: 23.2%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations

Study Characteristics	Study Design	Sample Design and Definitions
Author: Aveyard et al., 2003 **Geographic area:** United Kingdom **Funding agency:** West Midlands health authorities **Study setting:** Practice/provider settings	**Research objective:** To examine the population impact and effectiveness of the Pro-Change smoking cessation course based on the Transtheoretical Model (TTM) compared to standard self-help smoking cessation literature **Population:** Patients of general pracitioners employed at 65 West Midlands general practices **Study type:** RCT **Inclusion criteria:** Current smokers **Exclusion criteria:** All selected patients were eligible unless terminally ill, violent or other unusual circumstances pertained	**Sampling plan:** • 3 wave recruitment process – wanted to estimate the proportion of smokers that could be recruited from British general practice • 1st wave: used random sampling. West Midlands GP practices were selected with probability proportional to size and then a fixed number of patients (300) were selected for invitation • From wave 1, became clear that insufficient patients would be recruited so invited originally recruited practices to repeat the process (2nd wave) • When 2nd wave failed to reach target number, non-randomly selected new practices approached to participate. • In all waves, potential participants were sent invitation packs containing a cover letter from GP to patients expressing concern about smoking, assuring patients never to late to quit, and offering to help stop smoking at the surgery, if not by trial entry. • Participants signaled consent by returning baseline questionnaire • On receipt of baseline questionnaire, participants then randomly assigned either to control group (standard self-help literature), manual intervention group (received Pro-Change system), the telephone group (received Pro-Change system plus 3 telephone calls) or the nurse group (received Pro-Change system, 3 telephone calls and 3 visits to practice nurse **Sample size:** **G1:** 683 **G2:** 685 **G3:** 413 **C1:** 690 **Definition of smoking:** Cigarettes • Current Smoker - NR

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help quit guides and tip cards • Workbook and questionnaires • Telephone counseling • Nurse visits **Intervention:** **G1:** Pro-Change self-help system with workbook and 3 questionnaires to generate tailored feedback **G2:** G1 plus three telephone calls **G3:** G1 plus three nurse visits **C1:** 2 standard self-help quit guides and 2 tip cards **Method of assessment:** Asked the question "are you currently a smoker?" at 12 months post baseline - verified by salivary cotinine, obtained by visit to participant's house or by mail **Baseline data:** No significant differences b/w any of the groups	**Statistical analysis:** • Recruitment of new practices in wave 3 where participants only allocated to 3 arms (no one allocated to G3) complicated analysis, b/c no guarantee overall that participants' characteristics balanced b/w arms – therefore, analyzed the data as 2 separate trials – calculated the percentage quitters in each arm and performed an overall chi-square test to calculate differences between arms • Odds ratios for the risk of quitting relative to control arm and the percentage and OR for quitting in 3 intervention groups (G1, G2, G3) combined vs. control arm were calculated • To examine if difference b/w 4-arm and 3-arm trials in effectiveness of intervention arms relative to control arm, added a multiplicative term for trial x trial arm to a logistic regression model • The study reported results using intent-to-treat analysis, as well as results that used only those that followed-up **Data verification:** Self-report, salivary cotinine (values >14.2 ng/ml taken as indicative of active smoking) **Dependent variables:** • Point prevalence of being quit at 12 months • Point prevalence of sustained abstinence of at least 6 months	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-months sustained abstinence and 12-months point prevalence	**Quality rating:** Fair **Comments:** • Authors conclude Pro-Change system unlikely to provide important alternative to current network of smoking cessation clinics and prescription of NRT **Adequate randomization:** Yes **Attrition rate:** 29%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Bier et al., 2002 **Geographic area:** NR **Funding agency:** Arizona Disease Control Research Commission **Study setting:** NR	**Research objective:** To examine the effect of acupuncture alone and in combination with education on smoking cessation and cigarette consumption **Population:** Age 18 years or older **Study type:** Prospective, quasi factorial design **Inclusion criteria:** • Aged 18 years or older • Attempted to stop smoking at least once without success **Exclusion criteria:** • Actively psychotic • Suffering from any neurological or physical illness or other impairment that would prevent understanding of research consent form • Not able to read and write sufficiently to understand and complete the forms • Not willing to participate in a treatment protocol involving acupuncture • Currently taking phenothiazine, tricyclic antidepressants, lithium carbonate or beta blocking medication • Chronically using sympathomimetic drugs such as ephedra, ephedrine, amphetamines, or sedative medication	**Sampling plan:** Blind random assignment to groups **Sample size:** **G1:** 38 **G2:** 45 **C1:** 58 **Definition of smoking:** NR

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Individual counseling by health professional **Intervention:** **G1:** Acupuncture, 20 sessions over 4 weeks (5 per week) **G2:** Same as GI, but also received 5 weeks educational smoking cessation program (multisession, multicomponent behavioral training, education, social support, relapse prevention, 1.5 hours twice per week for first week, then once per week for next 4 weeks) **C1:** Sham accupuncture, 20 sessions over 4 weeks (5 per week) plus 5 weeks educational smoking cessation program (multisession, multicomponent behavioral training, education, social support, relapse prevention, 1.5 hours twice per week for first week, then once per week for next 4 weeks) **Method of assessment:** Cigarette pack self monitoring chart, recording number and times cigarettes smoke in past 7 days, pre and post intervention; asked about smoking at clinic visit **Baseline data:** No significant differences	**Statistical analysis:** • Power analyses for sample size (.05 for power of .80) • Mixed model with repeated measures • Covariance between any 2 periods considered autoregressive **Data verification:** Self report **Dependent variables:** • Beck Depression Inventory score • Zung Self-Rating Anxiety Scale • # of cigarettes smoked per day • Age of initiation • # of years smoking • Smoking or not smoking at visit • % decrease in smoking • Decrease in # of cigarettes smokes • VAS Score • Pack year history	**Not Smoking (%) at 18 months** **G1:** 20% **G2:** 40% **C1:** 53% NS Greater the estimated pack year history before treatment, the greater the decrease in total number of cigarettes smoked per day following treatment	**Quality rating:** Poor **Comments:** • Very high attrition rate • Group has a higher pack year history than in other studies **Adequate randomization:** Yes **Attrition rate:** At 18 months Total: 66% **G1:** 68% **G2:** 65% **C1:** 66%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Bohadana et al; 2000 **Geographic area:** Western Europe **Funding agency:** Pharmacia and Upjohn Consumer Healthcare **Study setting:** Practice/provider settings	**Study objective:** To investigate whether short-term (6-wk) addition of a NPto nicotine inhaler txt improves early smoking cessation rates, and whether this txt combination improves likelihood of abstinence at 6 and 12 months **Population:** • Adults **Study type:** • RCT w/ systematic randomization • Double-blind, randomized, placebo-controlled trial **Inclusion criteria:** • Aged 18 to 70 yrs • Smoked 10 or more cigarettes per day for 3 or more yrs • Expired CO level of 10 ppm or more • Made 1 or more previous attempts to quit • Personally motivated to stop smoking • Fluent in French **Exclusion criteria:** • History of myocardial infarction within past 3 mos • Unstable angina • Severe cardiac arrhythmia • Serious renal, pulmonary, endocrine, or neurological disorders • Pregnancy or breastfeeding • Use of any form of ST or nicotine substitution • Participation in any smoking cessation program during past 6 mons • Alcoholic or illegal drug user • Use psychoactive drugs • Have generalized dermatological diseases	**Sampling plan:** • Subjects from Nancy, France, and surrounding towns recruited by means of local newspaper • First subject enrolled in March 1996, and followup completed in February 1998 • Approximately 1,000 people who contacted the Centre Hospitalier Universitaire de Nancy-Brabois, 462 underwent a prospective telephone screen to enroll 400 subjects who met inclusion criteria **Sample size:** Total: 400 **Definition of smoking:** Cigarettes • 3-mo cessation rate, rate of continuous abstinence at all time points: self-reported nonsmoking b/w wk 2 and mo 12 and an expired CO level less than 10 ppm at each followup visit

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Individual counseling by health professional • Pharmaceuticals **Intervention:** **G1:** Nicotine inhaler (plastic tube containing a perforated plastic plug impregnated w/ 10 mg of nicotine, approximately 4 mg of which is available for inhalation, and menthol to reduce irritant effect of nicotine) plus 30-cm2 NPcontaining 0.83 mg of nicotine per square centimeter, delivering 15 mg per 16 hrs **C1:** Nicotine inhaler (plastic tube containing a perforated plastic plug impregnated w/ 10 mg of nicotine, approximately 4 mg of which is available for inhalation, and menthol to reduce irritant effect of nicotine) plus placebo patch that contained no nicotine **Method of assessment:** Baseline assessments included patient characteristics, vital signs, patient weight, smoking history, expired CO, blood cotinine, psychological status, SES, pulmonary measures (symptoms and function) and medical history; during txt and followup, weight measured, smoking history and expired CO assessed, blood cotinine measured, craving and withdrawal symptoms and all adverse events; pulmonary measures (symptoms and function) collected at 12 mos	**Statistical analysis:** • Data analyzed on an ITT basis (ie, all subjects who entered study and received medication, irrespective of medication use or outcome); Intergroup differences in ITT abstinence rates at all time points calculated by X^2 (or Fisher exact test if necessary) • Proportions of participants remaining abstinent over time calculated by comparing relapse w/ smoking curves of 2 groups by means of log rank test • Continuous variables compared b/w groups by parametric t-tests whenever possible, and Mann-Whitney rank sum test used for data non-normally distributed **Data verification:** Self-reported smoking status validated by blood cotinine levels and expired air CO levels **Dependent variables:** 3-mo cessation rate, rate of continuous abstinence at all time points, nicotine inhaler use, nicotine substitution, incidence of withdrawal symptoms, adverse events, and changes in body weight **Baseline data:** No significant differences b/w 2 groups except for a greater number of cigarettes per day in G1	Percentage of participants completely abstinent at 6-wk followup: **G1:** 60.5 **C1:** 47.5 *P* = 0.009 3-mo followup: **G1:** 42.0 **C1:** 31.0 *P* = 0.02 No significant difference in complete abstinence b/w **G1** and **C1** at 6- and 12-mo followups Pulmonary findings confirm beneficial respiratory effects of smoking cessation and that slowing down of decline in FEV volume in 1 second appears to be relatively rapid in those who quit smoking Mean body weight gain significantly higher in **C1** than **G1** by wk 2 (0.49 kg v. 0.99 kg) (*P* = 01) No significant difference in mean body weight gain at 1 yr (4.22 kg and 5.06 kg *P* = 0.14) Subjects in C1 reported significantly more intense withdrawal symptoms at wk 1 (*P* < 0.001) and craving symptoms at wk 6 (*P* = 0.04) than those in G1 Adverse events rare and tolerable	**Quality rating:** Fair **Comments:** Attrition rate NR **Adequate randomization:** Yes **Attrition rate:** 1 person withdrew from study due to a serious adverse event, but overall attrition rate NR

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Canga et al., 2000 **Geographic area:** Western Europe **Funding agency:** NR **Study setting:** Hospital Practice/provider settings	**Study objective:** Evaluate effectiveness of a nurse-managed smoking cessation intervention aimed at helping diabetic smokers quit smoking **Population:** • Young adults • Adults **Study type:** RCT w/ systematic randomization **Inclusion criteria:** • Type 1 and 2 diabetic patients registered in centers under study who were either current smokers or who had quit < 1 yr ago **Exclusion criteria:** • Had quit smoking for over 1 yr or was misclassified in medical record as a diabetic smoker	**Sampling plan:** • Type 1 and 2 diabetics at 2 hospitals and 15 primary care clinics randomized to receive either usual care or a nurse-led, face-to-face cessation counseling intervention • All clinical records of Type 1 & 2 diabetics registered at 15 primary care clinics and 2 hospitals b/w Dec 1997 and Dec 1998 reviewed to confirm smoking status • Smokers contacted through a letter and telephone call to participate in a general lifestyle study of diabetic patients • Smokers randomly assigned to intervention or C using computer-generated allocation; randomized assignment blinded **Sample size:** **G1:** 147 **C1:** 133 **Definition of smoking:** Cigarettes Current smoking: having smoked > 100 cigarettes during a subject's lifetime and having smoked at least 1 cigarette in last wk

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Pharmaceuticals **Intervention:** **G1:** Initial 40 min face-to-face interview w/ a research nurse that included personalized advice about benefits of quitting and strategies that may be useful, based on patient's clinical condition, smoking history, and personal interests; self-help materials w/ quitting cues; 3 months of transdermal NRT offered to those w/ no contraindications who smoked > 19 cigarettes per day and those who had not succeeded after trying to quit at least once; followup program of 5 contacts scheduled according to negotiated cessation date: 1) telephone call the day before quit date, 2) a followup visit 2 wks post quit date, 3) a letter 3 wks post quit date, 4) a followup visit 2 months post quit date, and 5) a final evaluation carried out 6 months post quit date **C1:** Usual care for diabetic smokers that is routinely provided by hospital or primary care clinic and is established in the Navarre diabetes care program, including advice to quit smoking **Method of assessment:** Followup interview conducted by a nurse at 6 months after initial interview; urinary cotinine levels obtained from those who self-reported quitting	**Statistical analysis:** • Two-tailed Fisher's exact tests used to compare proportion of quitters b/w both groups • Two-tailed t-tests used to compare change in average number of cigarettes smoked daily • Incidence ratio, incidence difference, and number needed to treat w/ their respective 95% CIs used to estimate effect of intervention **Data verification:** Urinary cotinine levels obtained from self-reported quitters and analyzed using method developed by Jarvis, et al **Dependent variables:** • Urinary cotinine validated cessation • Mean number of cigarettes smoked daily • Stage of change according to Prochaska's model **Baseline data:** Intervention and Cs similar at baseline in demographic characteristics, diabetes history, and history of tobacco use	Proportion of smokers who quit at 6-month followup (validated): **G1:** 17.0% **C1:** 2.3% Difference: 14.7 (CI, 8.2, 21.3) *P* = < 0.001 6-mo followup, change in mean cigarettes per day: **G1:** -4.6 (CI, -3.2, -6.0) **C1:** -1.6 (CI, -0.4, -2.8) Difference: -3.0 (CI, -1.1, -4.9) *P* = < 0.001 6-mo followup, patients in precontemplation stage: **G1:** 39.5% **C1:** 56.4% Difference: -16.9% (CI, -5.3, -28.9) *P* = < 0.001 6-month followup, patients in contemplation stage: **G1:** 9.5% **C1:** 29.3% Difference: -19.8% (CI, -10.7, -34.1) *P* = < 0.001 6-mo followup, patients in action and maintence stages: **G1:** 17.0% **C1:** 2.3% Difference: 14.8% (CI, 8.2, 21.3) *P* = < 0.001 6-mo followup, patients in relapse stage: **G1:** 33.3% **C1:** 10.5% Difference = 22.8% (CI, 13.6, 32.0) *P* = < 0.001	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** Yes **Attrition rate:** Overall = 0.71% **G1:** 0.68% **C1:** 0.75%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Carpenter et al., 2004 **Geographic area:** USA **Funding agency:** National Institute on Drug Abuse **Study setting:** Population-based	**Research objective:** To assess whether a behavioral treatment to reduce smoking combined with NRT followed by brief advice to quit versus motivational advice plus brief advice to quit produces a greater incidence of quit attempts **Population:** NR **Study type:** RCT **Inclusion criteria:** • Not Interested in quitting **Exclusion criteria:** • No current smoker in household (96%) • Smokes less than 10 cigarettes a day • Less than 18 years of age • Secondary Exclusion • Nursing, pregnant, planning to become pregnant in next 9 months • Cardiovascular disease or high blood pressure not controlled by medication • Currently taking prescription medications for depression or asthma (79%) • Not accessible by telephone throughout duration of the study	**Sampling plan:** Randomized **Sample size:** **G1:** 212 **G2:** 197 **C1:** 207 **Definition of smoking:** Abstinence: greater than or equal to 3 cigarettes per day

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Telephone counseling **Intervention:** **G1:** Telephone based reduction counseling and NRT and brief advice to quit **G2:** Motivatiiona advide (5Rs) and brief advice **C1:** No treatment **Method of assessment:** Mailed questionnaire at 0,3,6,12 and 24 weeks **Baseline data:** • Smoking habits • Urine cotinine levels • Fagerstrom Test for Nicotine dependence • Stage of change • Demographics • Parity • Proportion having a partner • Proportion whose partner smoked • Educational achievement • Household net income	**Statistical analysis:** • Logistic regression **Data verification:** Self report **Dependent variables:** • # of cigarettes per day over previous 7 days • Intention to quit in next 1 to 6 months • Stage of change • Self-efficacy • Quit attempts within past 24 hours • Point prevalence abstinence (no smoking at all in past 7 days)	**Percentage with "24-hour Quit Attempts" over 6 months** **G1:** 43% **G2:** 51% **C1:** 16% G1 vs **G2:** NS G1 + G2 vs **C1:** $P < 0.01$ **Percentage with "24-hour Quit Attempts" at 6 weeks (when intervention was completed)** **G1:** 36% **G2:** 18% **C1:** NR **Percentage with "24-hour Quit Attempts" after 6 weeks (when intervention was completed)** **G1:** 64% **G2:** 82% **C1:** NR% **Abstinence Rates** **G1:** 18% **G2:** 23% **C1:** 4% **Seven-day Point Prevalence at 6 months:** $P<0.01$ Smoking reduction using NRT does not undermine cessation but rather increases likelihood of quitting to a degree similar to motivational advice	**Quality rating:** Fair **Comments:** • Source of database used to recruit people for study is unclear • No biochemical verification **Adequate randomization:** NR **Attrition rate:** NR

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Chalmers et al., 2001 **Geographic area:** Canada **Funding agency:** Health Canada, Tobacco Programs Unit, Health Promotion Directorate and the Canadian Lung Association **Study setting:** Practice/provider settings	**Study objective:** Smoking reduction and cessation program implemented w/ registered nurses **Population:** • Adults • Women (only) **Study type:** Self-selected intervention **Inclusion criteria:** • RN **Exclusion criteria:** • No other type of nurses	**Sampling plan:** Advertised study in a variety of medium and participants allowed to select intervention type **Sample size:** **G1:** 75 **G2:** 44 **Definition of smoking:** Cigarettes NR

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Group counseling **Intervention:** **G1:** Group participation **G2:** Self-study **G3:** NR **C1:** NR **Method of assessment:** Questionnaires administered prior to and at end of 8-wk interventions and at 6 and 12 months postintervention	**Statistical analysis:** • SAS and Excel used • Descriptive statistics obtained and t-tests used in pre and posttest analyses • Variance difference considered across 4 time periods • Duncan's Multiple Range test implemented for all post hoc comparisons • Time-study analysis techniques used to organize data and observe and test for trends **Data verification:** None **Dependent variables:** Stage of quiting **Baseline data:** No comparisons made	Statistically significant changes at 8 wks in nurses' smoking practices found on number of nurses continuing to smoke, mean number of cigarettes smoked, and movement in stage of behavioral change	**Quality rating:** Poor **Comments:** No ITT, self-selection of intervention, no comparisons b/w groups. **Adequate randomization:** No Not randomised! **Attrition rate:** Pretest: 0 (0%) 8 wks: 27 (23%) 6 months: 47 (40%) 12 months: 62(53%)

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Clark et al; 2004 **Geographic area:** US **Funding agency:** NCI **Study setting:** Hospital Practice/provider settings	**Study objective:** To examine effectiveness of standard written self-help materials for nicotine dependence compared to written materials consisting of internet-based resources on smoking abstinence rates in a lung cancer screening population **Population:** • Adults **Study type:** RCT w/ simple randomization **Inclusion criteria:** • Asymptomatic • Men and women 50 yrs of age or older • Current cigarette smokers w/ at least a 20 pack-yr history of smoking • Access to a computer w/ Internet service • Written informed consent to participate **Exclusion criteria:** • History of any cancer within five yrs, other than non-melanomatous skin cancer, cervical cancer in situ, or localized prostate cancer • Mentally incompetent • Not healthy enough to potentially undergo pulmonary resection (i.e., have congestive heart failure or disabling dyspnea at time of enrollment) • Serious illness that decreased life expectancy to less than 5 yrs	**Sampling plan:** Community informed about low-dose fast spiral chest CT screening study by local and regional television and newspaper coverage carrying information on general outline of study and eligibility requirements, as well as funding by NCI **Sample size:** Total: 171 **Definition of smoking:** Cigarettes • Abstinence: no cigarettes in last 7 days

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Computer-based program **Intervention:** **G1:** Received handout w/ a list of 10 Internet sites related to stopping smoking and a brief description of each site; Web sites included: the American Heart Association, ACS, NCI, Cancer Information Service, CDC Tips, Tobacco Information/Prevention Source, Mayo Clinic Nicotine Dependence Center, Quit Now! (the National Tobacco Campaign), the No Smoke Caf, Massachusetts Quitline, Nicotine Anonymous, and the American Lung Association; these sites include information on health risks related to tobacco use, benefits of stopping smoking, specific behavioral strategies, support for stopping, review of stop smoking medications, and references to local resource **C1:** Received a copy of Clearing the Air: How to Quit Smoking and Quit for Keeps (24-pg self-help manual describing multiple behavioral strategies for stopping smoking), a publication of the National Cancer Institute; participants also given the American Lung Association booklet, Quit Smoking Action Plan, which provides up to date information on available pharmacotherapies for nicotine dependence	**Statistical analysis:** Responses from 1-mo followup survey, and tobacco use variables collected at 1-yr followup, compared b/w txt groups using X^2 For 1-yr smoking abstinence outcome, subjects that missed the visit or failed to provide tobacco use information, classified as smoking All other analyses performed using available data w/ no imputation of missing values For biochemically confirmed 7-day smoking abstinence, exact binary confidence intervals calculated for each txt group and a logistic regression analysis performed using smoking abstinence as dependent variable and txt group as independent variable Logistic regression used to assess whether screening recommendations associated w/ 1-yr tobacco use outcomes In all cases, two-sided tests performed w/ *P*-values; < 0.05 used to indicate statistical significance **Data verification:** Self-reported smoking status confirmed w/ expired air CO levels at 1 yr followup	No statistically significant differences in smoking status found at 1-mo (13 vs 7%, *P* = 0.248) or 1-yr followup (5 vs 10%, *P* = 0.166, OR = 0.4, 95% CI, 0.1-1.4) At yr 1 followup more subjects receiving internet-based resources, compared to C1, reported that they had made an attempt to stop smoking in last yr (68 vs 48%, *P* = 0.011) Recommendation of additional followup from chest CT screening exam not found to be associated w/ abstinence (OR = 0.5, *P* = 0.267), making a quit attempt (OR = 0.8, *P* = 0.412) or advancement in state of change from baseline to 1-yr (OR = 0.6, *P* = 0.222)	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** Yes **Attrition rate:** No attrition at 1-yr followup (study followup coincided w/ 1-yr followup for lung cancer screening)

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Clark et al; 2004 (continued)		

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Method of assessment: Questionnaire at 1-mo followup: • Smoking status self-reported In-person visit at 1 yr followup: • Smoking status and expired air CO levels assessed	**Dependent variables:** Biochemically-confirmed smoking status **Baseline data:** Both groups similar at baseline		

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Covey et al., 2002 **Geographic area:** US **Funding agency:** Pfizer, Inc **Study setting:** Population-based	**Research objective:** To evaluate sertraline as an effective aid to smoking cessation for smokers with a history of major depression **Population:** Adults **Study type:** RCT, double blind, placebo control study **Inclusion criteria:** • Subjects required to meet DSM-III-R criteria for at least one episode of major depression, which must have remitted more than 6 months befor the start of the study • Age 18 to 70 • Daily use of 20 or more cigarettes for at least a year • One prior attempt to quit **Exclusion criteria:** • Serious medical illnesses • Use of a psychotropic medication • Major depression, alcohol or drug dependence, panic disorders, post-tramatic stress disorder, anorexia nervosa, or bulimia nervosa within the past 6 months • Life time diagnosis of bipolar disorder, antisocial or schizotypal personality disorder, severe borderline personality disorder, obsessive-compulsive disorder, or psychosis including schizophrenia • Pregnancy or lactation	**Sampling plan:** • Respondents were first screened by telephone, those who met initial criteria were seen at the first clinical visit • Eligible participants obtained a 1 week single-blind washout phase of one placebo tablet per day • Once medically confirmed to meet criteria, participants were randomly assigned in a double blind fashion to receive sertraline (50mg tablet) or placebo **Sample size:** **G1:** 68 **C1:** 66 **Definition of smoking:** • Smoking measured by cotinine level, non-smokers < 25 ng/ml

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Pharmacotherapy **Intervention:** **G1:** Received sertraline for 11.3 weeks: 1 week placebo washout, 3 weeks for medication buildup before quit day, 6 weeks at full dose (200mg), and a 9 day taper period. **C1:** Same as G1 but used placebo **Method of assessment:** 7-Day point prevelance self-report (biochemically verified by cotinine levels less than 25 ng/ml) **Baseline data:** Lower nicotine dependence scores for participants in G1; no other baseline differences	**Statistical analysis:** Chi square and t-tests of significants **Data verification:** Self-report and cotinine tested **Dependent variables:** • Abstience • Nicotine dependence level • Depression • Withdrawal symptoms • Compliance with NRT treatment	At the end of treatment, abstience rates were 28.8% for C1 and 33.8% for G1, this was not significant At 6 months, the abstience rates were G1=11.8 and C1=16.7%, NS No modifying effects of depressed mood at baseline, nicotine dependence level, or gender were observed	**Quality rating:** Poor **Comments:** Similar to a run-in periods this study participants if not motivated to quit after week 1 (9%) **Adequate randomization:** Yes **Attrition rate:** 25.4%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Croghan et al; 2003 **Geographic area:** US **Funding agency:** NCI, Public Health Service and NCI, DHHS Medications provided by NcNeil Consumer Products **Study setting:** Community-based Practice/provider settings	**Study objective:** To determine whether combined use of NP and a NNS would improve smoking abstinence rates compared to either therapy alone without behavioral counseling; to determine frequency and severity of adverse events experience **Population:** Adults **Study type:** RCT w/ stratified randomization • Multi-center, randomized, open-label clinical trial • Txt assignment carried out using a dynamic allocation procedure that balanced marginal distributions of stratification factors among three txt groups • Stratification factors used gender, number of cigarettes smoked per day reported at time of study entry (15–39 vs 40 or more cigarettes per day), and total yrs of smoking (fewer than 5 yrs vs 5–9 yrs vs 10 or more yrs) • Open-label, randomized, 3-intervention, multi-center trial. **Inclusion criteria:** • 18 yrs of age or older • Smoking at least 15 cigarettes per day for past yr • Good health verified by medical history • Female subjects of childbearing potential had to be using contraception, • Ability to participate in all aspects of study	**Sampling plan:** After dissemination of a local news release (radio and print), interested smokers contacted their regional NCCTG cancer control site and underwent telephone screening Brief discussion of study provided, informed consent obtained, demographic information collected, and an interview based on inclusion and exclusion criteria conducted over phone Study subjects who fulfilled basic study entry criteria were invited to attend an information meeting, at which time details of study were explained and an informed consent signed **Sample size:** Total: 1,384 **Definition of smoking:** Cigarettes • At least 15 per day over past yr NR

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Pharmaceuticals **Intervention:** **G1:** 15 mg transdermal NPfor 16 hr a day; new patch each morning; initiated within 7 days of randomization and continued for 6 wks **G2:** NNS that delivered 0.5 mg of nicotine per spray; recommended dose one puff per nostril as needed to a maximum of five doses per hr or 40 doses per day; initiated within 7 days of randomization and continued for 6 wks **G3:** 15 mg transdermal NPfor 16 hr a day, putting on a new patch each morning, plus nicotine nasal spray that delivered 0.5 mg of nicotine per spray, recommended dose of one puff per nostril as needed to a maximum of five doses per hr or 40 doses per day; initiated within 7 days of randomization and continued for 6 wks **C1:** NR **Method of assessment:** Subjects returned to clinic at 3 wks, 6 wks, and 6 mos postintervention; self-reported smoking rates, expired air CO levels, and reports of adverse events collected Questionnaire about smoking history, Fagerstrom, Health Status Questionnaire	**Statistical analysis:** Tests of balance in baseline characteristics across txt arms carried out via X^2 procedures for categorical variables, Kruskal-Wallis tests for ordinal-level data, and ANOVA for interval- and continuous-level variables; effect of sociodemographic variables on abstinence rate comparison investigated via logistic regression modeling Standard equality of binomial proportions, logistic regression modeling **Data verification:** CO levels of expired air collected to verify self-reported smoking status Expired CO < 8 ppm confirmed smoking abstinence **Dependent variables:** Smoking status: wk 6 biochemically confirmed 7-day point prevalence smoking abstinence rate. **Baseline data:** No reported differences among txt groups, but no data given Overall, mean age = 42.0 (+/-10.8); 58% female; mean 26.2 (+/-9.8) cigarettes per day; mean 23.2 (+/-10.7) yrs of smoking	CO confirmed 7-day point-prevalence smoking abstinence rates at 6-wks after initial quit date: **G1:** 20.7% **G2:** 13.6% **G3:** 27.1% *P* = < 0.001 Differences in CO confirmed 7-day point-prevalence smoking abstinence rates at 6 mos were NS **Abstinence rates (6 wks):** **G1:** 20.7% **G2:** 13.6% **G3:** 27.1% *P* < 0.001 NNS associated w/ more adverse events than NP (*P* < 0.001): burning in nose or throat (63% vs 12%), watery eyes (48% vs 14%), sneezing (49% vs 21%)	**Quality rating:** Poor **Comments:** Attrition quite high at 6 mos (70%); overall, 45% of participants non-compliant w/ study protocols - a larger proportion than were compliant (34%); study may not have had enough power Baseline data not given by txt group **Adequate randomization:** Yes **Attrition rate:** 6 wks: 47% 6 mos: 70%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Croghan et al; 2003 (continued)	**Exclusion criteria:** Exclusion criteria included • Recent (< 3 mos) history of myocardial infarctionangina pectoris, serious cardiac arrhythmia, or other medical conditions that the health care provider deemed incompatible w/ study participation • Presence of current (within 30 days) psychiatric disorders (major depression, bipolar disorder, schizophrenia); current use of major psychiatric drugs(antipsychotics, lithium) • Chronic nasal disorders such as nasal polyps, chronic nasal congestion, allergies, or sinusitis that would preclude use of a nasal spray • Pregnancy or current breast feeding • Current use of tobacco products other than cigarettes • Current use of nicotine replacement therapy • Use of an investigational drug within 30 days of start of study • Concomitant use of clonidine, buspirone, doxepin, bupropion, or fluoxetine • History of skin allergies or evidence of chronic dermatosis • Participation within last 12 mos in a formal smoking cessation program	

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Dalsgareth et al., 2004 **Geographic area:** Denmark **Funding agency:** GlaxoSmithKline, Denmark **Study setting:** Hospital	**Research objective:** To evaluate treatment with buproprion hydrochloride sustained release (Zyban) compared with placebo as an aid to smoking cessation in healthcare workers **Population:** Hospital employees from 5 hospitals in eastern part Denmark **Study type:** RCT – double-blinded **Inclusion criteria:** • Age ≥18 yrs old • Average use of ≥10 cigarettes per day throughout the last year • Motivation to quit smoking **Exclusion criteria:** • Use of other pharmacological support for smoking cessation • History of or current major depression reported by participant • Sever neurological, cardiopulmonary, liver or kidney disease • Epilepsy, predisposition to or former epidsodes of seizures • Use of medicine known to lower seizure threshold • Pregnancy and lack of sufficient contraception were additional exclusion criteria for fertile women.	**Sampling plan:** • Employees were informed of study via E-mail, notification accompanying paychecks, posters and personal contact • Eligible participants screened • Participants underwent detailed baseline interview to obtain health-disease profile and info on smoking behavior in general and at work • Subjects were given info on physiological and harmful effects of smoking as well as on the assumed mechanism of action and likely side-effects of buproprion • All subjects received behavioral counseling aimed at establishing rational smoking cessation process • Each participant agreed on a target quit date of 8-13 days after baseline • Participants then randomly assigned either to receive buproprion 150 mg or placebo **Sample size:** **G1:** 222 **C1:** 114 **Definition of smoking:** Cigarettes • User: smoked ≥10 cigarettes daily • Continuous smoking abstinence: not even a puff

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Telephone counseling • Clinic visits • Buprprion 150 mg over 7-week period **Intervention:** **G1:** 2 motivating phone calls, 5 clinic visits, and sustained-release bupropion hydrochloride **C1:** 2 motivating phone calls, 5 clinic visits, and placebo **Method of assessment:** Clinic visits at weeks 3,7,12,23 and 26 (post-baseline) **Baseline data:** No significant differences b/w G1 and C1	**Statistical analysis:** • Intent -to-treat analysis, in which all randomized patients who took ≥1 dose of study medication were counted • Mantel-Haenszel chi-square test at two-sided 5% level of significance used analysis of smoking abstinence endpoints • Analysis of covariance was used for analysis of change in weight from baseline and nicotine dependence; treatment, center and baseline values were covariates • Participants with missing cigarette counts after 7-week treatment phase assumed to be treatment failures **Data verification:** • Self-report – completion of daily diary cards • Expired-air carbon monoxide measurements (<10 ppm CO was the cutoff) **Dependent variables:** • Smoking status • Tobacco craving • Weight gain	Twelve months after pretest (posttest 2), in-school intervention successful in preventing vocational school students from continuing to smoke, compared w/ students in control condition OR = 0.49; 95% CI 0.29–0.84 Eighteen months after pretest (posttest 3), tailored out-of-school intervention successful in preventing smoking initiation, compared w/ students in control (OR = 0.42; 95% CI, 0.18–0.96) Effect of combined approach not larger than sum of effects of in-school and out-of-school effects.	**Quality rating:** Fair **Comments:** • Refusal rate NR • Randomization description unclear regarding number of schools in txt groups • Out-of-school intervention poorly implemented (65% of personalized letters read by participants) **Adequate randomization:** Yes **Attrition rate:** School level • Posttest 1: 5.6% (2 schools) • Posttest 2: 8.3% (3 schools) • Posttest 3: 18.5% (NR) Student level: • Posttest 1: 17.3% • Posttest 2: 5.4% • Posttest 3: 24.6%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Davies et al., 2005 **Geographic area:** Southeastern US **Funding agency:** National Cancer Institute **Study setting:** Hospital	**Research objective:** To evaluate the impact of a stage-matched smoking cessation intervention in a sample of hospitalized, low-income, African American smokers admitted to an indigent care hospital **Population:** • Low income hospitalized adult African Americans **Study type:** Experimental, pretest-posttest design **Inclusion criteria:** • Adult • African American • Admitted to medical and surgery units of the study hospital • Smoker **Exclusion criteria:** • Life expectancy less than one year • Mental conditions (not defined)	**Sampling plan:** 90 % of patients approached agreed to participate **Sample size:** 248 **Definition of smoking:** NR

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • individual counseling **Intervention:** **G1:** Physician-delivered stage-specific advice to quit smoking; individualized counseling based on the smokers stage of readiness and individual smoking pattern; self-help materials tailored to the African American smokers and their support networks; and a follow-up booster session in the form of a phone call following the patient's discharge from the hospital (at @6 months) **C1:** usual care (not defined) **Method of assessment:** In person and telephone survey at about 6 months **Baseline data:** Between group differences are not reported	**Statistical analysis:** • Mann-Whitney U used to examine intervention effects by baseline stage • Z Test used to compare overall differences between treatment groups (forward movement, success in quitting smoking) • T tests used for 5 measures (Pros, Cons, Confidence, 2 Nicotine Dependent measures) • Intention to treat analysis used only for cessation rates **Data verification:** Self report **Dependent variables:** • Sociodemographic characteristics • Smoking history • Present smoking habit • Stage of change • Decisional balance • Self-efficacy to remain abstinent • Perceived nicotine dependence • Perceived health status • Presence of chronic disease	Intervention patients more likely to advance in stage than control patients Dependence score increased as stage of readiness increased Intervention had a higher proportion of subjects in the preparation and action stages at follow-up, significantly ($P < 0.05$) for those at contemplation stage at baseline Greater percentage of intervention than controls progressed at least one stage (40% vs 21.7%, $P < 0.01$) ITT analysis for cessation non-significant (**G1:**7.9% vs **C1:** 5.8%)	**Quality rating:** Poor **Comments:** • 60% failed to complete 6 month follow-up • ITT analysis used for cessation rates does not state that all of those with no follow-up data were categorized as smokers **Adequate randomization:** Not defined, plus there was a second adjustment made by assigning shared rooms to either the intervention or control groups **Attrition rate:** • 152 of 248 were loss to follow-up • Reasons: - no telephone, - telephones disconnected, - changed residence, - became homeless, - went to prison - died • Several follow-up interviews took place well after 6 months

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Garvey et al., 2000 **Geographic area:** United States **Funding agency:** National Institute on Drug Abuse and the Department of Veteran Affairs **Study setting:** Community-based	**Research objective:** To investigate the long-term efficacy of 4-mg and 2-mg gum for smokers classified at baseline as low or high in dependence on nicotine **Population:** • Smokers from greater Boston area • ≥20 years old **Study type:** RCT **Inclusion criteria:** • Aged ≥20 years, smoke ≥5 cigarettes per day • Adequate health **Exclusion criteria:** • Cardiologist deemed subjects in "inadequate" health based on medical tests, including hematology analyses, liver-function profiles, urinalyses and if over 50 years old, electrocardiograms	**Sampling plan:** • Recruited smokers from greater Boston area via newspaper ads and press releases • Subjects needed to obtain a letter from their doctor stating they had no obvious medical conditions that would prevent them from entering the study; those who didn't have primary care physician required to undergo testing at medical lab in Boston • Subjects chose a quit-day and reported for their baseline visits a median of 3 days before their quit days – at baseline, they completed the Heaviness of Smoking Index and a 2-question subset of the Fagerstrom Test for Nicotine Dependence. Results were used to classify subjects as either low-dependence or high-dependence • Subjects within each dependence group were assigned to placebo, 2-mg, or 4-mg gum treatment using a randomized, double-blind procedure • Subjects were instructed on proper use of gum, recommended to use 9-15 pieces of gum a day for 2 months, after which they would wean themselves from the gum – would be weaned off by 5 months post-cessation **Sample size:** **G1:** 87 **G2:** 88 **G3:** 115 **G4:** 115 **C1:** 88 **C2:** 115 **Definition of smoking:** Cigarettes • Current Smoker – Smoking ≥5 cigaretters per day • Relapser – if returned to a regular pattern of smoking at any time during the 1-year period of follow up • Regular pattern of smoking – 7 or more consecutive days or episodes of smoking • Day of relapse – the day post-cessation that began the regular pattern of smoking

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self help booklet (all groups) • Brief behavioral counseling (all groups) • Nicotine gum – 2mg or 4mg **Intervention:** **G1:** Low dependence 2 mg gum **G2:** Low dependence 4 mg gum **G3:** High dependence 2 mg gum **G4:** High dependence 4 mg gum **C1:** Low dependence placebo **C2:** High dependence placebo **Method of assessment:** Follow up visits at 1, 7, 14, 30 days and 2, 3, 6, 9, and 12 months post-cessation **Baseline data:** Placebo, 2-mg and 4-mg gum users were comparable on most baseline variables – those in 4-mg group had higher mean CO values (*P*= 0.01) and heart rates (*P* = 0.02) High-dependence smokers were more likely to be older and less-educated, slightly more likely to be males, and they had significantly larger values on other indices of depencence	**Statistical analysis:** • Wilcoxon rank sum tests were used to compare percentage baseline cotinine replaced by each dose of nicotine gum • Logistic regression analysis and pairwise dose comparisons were used to assess differences in abstinence rates among groups at each post-cessation visit. Two dummy variables (each coded 1 or 0) were used to represent the 3 nicotine-gum doses in these analyses • Chi-square tests for binomial trends were used to examine the significance of dosage effects • Effects of nicotine gum dose on withdrawal symptoms and urges to smoke were assessed for the 1st 30 days post-cessation using repeated-measures analysis of variance • For withdrawal indices, changes from baseline on various indices of withdrawal were dependent variables in repeated-measures analysis; while values obtained at 1,7,14,and 30 were used to supplement repeated-measures analysis • Because of occasional missing data, number of subjects available for some statistical analyses were reduced) **Data verification:** Self-report, saliva cotinine and CO levels **Dependent variables:** Quit rates	At 1 year follow-up quit rates for low dependence were Placebo 11.2% 2 mg gum 19.5% 4 mg gum 18.4% (NS) High dependence smokers quit rates at 1 year 2 mg gum compared to placebo (15.7% vs. 6.1%, *P* = 0.02) 4 mg gum compared to placebo (20.7% vs. 6.1% *P* = 0.002) No statistical differences between 2 and 4 mg gum doses. Both 2 and 4 mg gum users significantly (*P* < 0.008) more likely to abstain than placebo at all post-cessation assessments, except for day 1 Other variables related to abstinence at 1 year post-cessation were a longer period of abstinence on a prior quit attempt, being married, higher education level, and having a non-smoking spouse or significant other	**Quality rating:** Fair **Comments:** • 3 subjects withdrew from study due to adverse effects – dizziness, nausea and vomiting **Adequate randomization:** Yes **Attrition rate:** Overall attrition not reported but 3 left due to adverse events

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Hahn et al; 2004 **Geographic area:** US **Funding agency:** American Legacy Foundation **Study setting:** Community-based	**Study objective:** To evaluate impact of a quit and win contest on smoking cessation among low-income tobacco users **Population:** • Adults • Low SES **Study type:** Two-group, quasi-experimental study **Inclusion criteria:** Intervention group: • at least 18 yrs old • volunteered to participate in a quit-and-win contest • registered for contest by September 10, 2001 • earned <$25,000 per yr **C1:** • regular tobacco user who had smoked cigarettes or used another form of tobacco in last 30 days • had not been exposed to promotional media campaign • earned <$25,000 per yr **Exclusion criteria:** NR	**Sampling plan:** Intervention group: sample of volunteer registrants in a quit-and-win contest **C1:** participants randomly selected from outside media campaign geographic area using random digit dialing and meeting inclusion criteria **Sample size:** Total: 538 **Definition of smoking:** Cigarettes • Quitter: not used any form of tobacco in last 7 days Smokless tobacco • Quitter: not used any form of tobacco in last 7 days

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Group counseling • Telephone counseling • Computer-based Program • Social support • Media campaign **Intervention:** **G1:** A community quit date requiring participants to quit using tobacco for 30 days to be eligible for a large cash prize lottery; provider advice on gender-specific cessation information to participants through weekly mailed postcards during 30-day contest period; online computer registration and quit assistance; one-on-one telephone quit assistance through a toll-free number provided by Cancer Information Service's smoking cessation call center; a media campaign that included paid radio and television advertisements, intensive billboard promotions, magazine or newspaper registration, newspaper features, registration brochures, and promotional flyers; and support from community organizations, work sites, physicians, health professionals, and community leaders	**Statistical analysis:** Group comparisons performed using X^2 of equal proportions for nominal variables Kruskal– Wallis tests for ordinal variables, or two-sample t-tests for continuous variables Repeated measures analysis for logistic regression based on GEE approach used to determine predictors of quit status over three postcontest time periods Each model included control variables of baseline age, gender, race (Caucasian v. other), education (<HS v. >HS), marital status (married v. unmarried), and stage of change status to adjust for differences in personal characteristics among participants **Data verification:** All participants who reported quitting were asked to provide a urine sample to test for cotinine; cotinine level determined by Accutest NicoMeter **Dependent variables:** Tobacco use status	Percentage of participants w/ self-reported 7-day point prevalence abstinence at 3-month followup: **G1:** 23.3, **C1:** 3.1 *P* = < 0.001 Percentage of participants w/ confirmed 7-day point prevalence abstinence at 3-month followup: **G1:** 11.3 **C1:** 0.7 *P* = < 0.001 Percentage of participants w/ self-reported 7-day point prevalence abstinence at 6-month followup: **G1:** 21.2 **C1:** 5.9 *P* = < 0.001 Percentage of participants w/ confirmed 7-day point prevalence abstinence at 6-month followup: **G1:** 9.3 **C1:** 0.7 *P* = < 0.001 Percentage of participants w/ self-reported 7-day point prevalence abstinence at 12-month followup: **G1:** 23.3 **C1:** 8.7 *P* = < 0.001 Percentage of participants w/ confirmed 7-day point prevalence abstinence at 12-month followup: **G1:** 8.1 **C1:** 0.7 *P* = < 0.001	**Quality rating:** Poor **Comments:** • High attrition • Intervention group volunteer sample • C care NR • Exposure to intervention low • Not generalizable **Adequate randomization:** NR **Attrition rate:** Loss to followup by 12-month followup: **G1:** 41% **C1:** 44%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Hahn et al; 2004 (continued)		

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Community organization support included promoting the contest at work sites and in community newsletters, recruiting participants via flyers at physician offices and health fairs, and coordinating group cessation classes to coincide w/ the contest. **C1:** NR **Method of assessment:** Telephone interviews conducted at baseline, then 3, 6, and 12 months after baseline interview	**Baseline data:** Participants more likely to be married in the intervention group than in the control More than half of intervention group had at least some college education, while only 1/4 of C had any postsecondary education; intervention group significantly younger than control (Median age: **G1:** 35.9, **C1:** 42.3, t = 5.3, 535 df, *P* = < 0.0001); those lost to followup at 1 yr were significantly younger than those who remained in study (loss to followup: mean age = 37.5, remained in study: mean age = 41.2, t = 3.0, *P* = 0.003)		

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Hall et al., 2004 **Geographic area:** United States **Funding agency:** NIDA **Study setting:** Population-based	**Research objective:** To determine the effects of brief versus extended treatment with nortriptyline and group counseling **Population:** General public **Study type:** RCT **Inclusion criteria:** Smoked >=10 cigarettes per day **Exclusion criteria:** • Cardiovascular disease • History of seizure • Severe allergies • Life-threatening disease • Bipolar disorder • Current major depressive disorder • Use of l-dopa • Migraine headaches • Current use of any psychiatric medication including bupropion • Suicidal or psychotic symptoms • Current use of NRT • Previous treatment for cigarettes smoking with nortriptyline • Treatment for drugs or alcohol within 6 months • Psychiatric hospitalization within 1 year • Pregnancy or lactation	**Sampling plan:** • Subjects were recruited through advertising, PSAs, and flyers • Interested persons completed a telephone screening and orientation meeting • After informed consent was obtained, potential subjects were invited to a baseline physical assessment • For those who did not have any exclusion criteria, 160 subjects smoking ≥ 10 cigarettes per day were stratified by: - baseline number of cigarettes - history of nicotine replacement therapy - history of major depressive disorder • Subjects were then randomized to four treatment cells **Sample size:** 160 subjects **Definition of smoking:** Subject must meet all three criteria to be considered abstinent: • self-report of not having had a cigarette in past seven days, not even a puff • carbon monoxide levels ≤ 10 ppm • cotinine levels of ≤ 50 ng/ml

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Transdermal nicotine patch • Group counseling • Bupropion **Intervention:** **G1:** Brief Nortriptyline: Nortriptyline for 12 weeks; 5 counseling sessions and NRT patch at week 5 **C1:** Brief placebo: Placebo for 12 weeks; 5 counseling sessions and NRT at week 5 **G2:** Extended Nortriptyline: G1 + extended pharmacotherapy and counseling (1/month) for 52 weeks **C2:** Extended placebo: G2 but used placebo instead of Nortriptyline **Method of assessment:** • In-person self-report • Carbon monoxide • Urinary cotinine **Baseline data:** No significant differences among the intervention conditions	**Statistical analysis:** • Powered at 80% with alpha = .05 • Logistic regression was used to test the effect of drug/placebo dose and treatment duration on repeat 7-day abstinence • Generalized estimating equation was used to test hypotheses about point prevalence abstinence at weeks 24,36,52 • Compared baseline variables among the four groups using ANOVA for continuous and chi-square for categorical to examine if randomization had been compromised • To identify potential covariates, used point-biserial correlations • Differences in weeks of medication / placebo dispensed were determined by a two-way ANOVA with individual comparisons with the Tukey test • Differences in withdrawal symptoms were determined using repeated measures ANOVA • Chi-square tests or Fisher's exact tests were used to determine differences in side effects • All tests for all analyses were two-tailed **Data verification:** • Expired carbon monoxide and urinary cotinine were used at 24, 36, and 52 week follow-ups • Expired carbon monoxide only was used at 12 week follow-up **Dependent variables:** • Abstinence • Nortriptyline adherence • Withdrawal symptoms • Side effects	A duration by dose by time of assessment effect was significant (X^2 = 11.90, df=3, *P* = 0.008) Brief Nortriptyline vs brief placebo (OR = 0.69, 96%CI; 0.49-0.92, *P* = 0.02) Brief Nortriptyline vs extended placebo (OR = 0.47, 95%CI; 0.30-0.75, *P* = 0.001) Extended Nortriptyline did not differ significantly from extended placebo	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** Unknown – did not state how they randomized participants **Attrition rate:** • 13% for brief nortriptyline • 7% for brief placebo • 10% for extended nortriptyline • 27% for extended placebo

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Hand et al., 2002 **Geographic area:** UK **Funding agency:** Author's endowment fund **Study setting:** Hospital-based	**Research objective:** To investigate the effectiveness of combined NRT (Patch and inhaler) for smoking cessation in patients hospitalized for smoking related disease. **Population:** Adults **Study type:** RCT **Inclusion criteria:** • Hospitalized inpatients or outpatients with smoking related disease referred to counselor by hospital doctor • Age 18 or older **Exclusion criteria:** • Patients with alcoholism, drug dependeny, active psychiatric illness, preterminal or terminal patients, pregnant women, and patients who suffered a myocardial infarction during previous month	**Sampling plan:** • Recruitment began on October 1, 1998 and all patients recruited during this month and in any even month over the next 13 months were given NRT • Those patients recruited in the following month and in any odd month over the next 12 months were given advice and support • One extra month of patients were randomized to the NRT group resulting in unequal groups **Sample size:** **G1:** 136 (NRT and advise and support) **C1:** 109 (advice and support) **Definition of smoking:** Abstinence • Carbon monoxide levels less than 10ppm

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Pharmacotherapy **Intervention:** **G1:** Received NRT (combination of nicotine patch and inhalator) for 3 weeks; dosage determined by number of cigarettes smoked; plus G2 **C1:** Four weekly sessions and patient encouraged to set quit date (45 to 60 minutes); followed by 3 weekly 15-30 minute sessions **Method of assessment:** Carbon monoxide validated Self-report at 1 week, 3, 6 and 12 months **Baseline data:** No baseline differences	**Statistical analysis:** Chi square test of significants **Data verification:** Carbon monoxide verified **Dependent variables:** • Smoking status • Compliance with NRT treatment	At week 1, abstinence rates were higher for G1 compared with C1 (54% vs 33%, $P < 0.001$) At 6 months this significant difference disappeared between the two groups. At year 1, 14% of the total sample were verified as abstinent (G1=15%, C1=14%, NS) 30% of G1 used the full supply of NRT and 43.9% of these patients successfully quit at year 1	**Quality rating:** Fair **Comments:** NA **Adequate randomization:** No **Attrition rate:** 0%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Helgason et al., 2004 **Geographic area:** Sweden **Funding agency:** NR **Study setting:** Population-based	**Research objective:** To assess variables related to 12-months abstience using proactive compared to reactive telephone quitline smoking interventions **Population:** Adults **Study type:** Cohort study **Inclusion criteria:** Contacted toll-free Swedish quitline from April to October 1999 **Exclusion criteria:** NR	**Sampling plan:** Immediately after the first call all patients expressing an interest in beign registered as clients received a registration from by mail confirming their idenity **Sample size:** **G1:** 694 (reactive quitline) **G2:** 900 (proactive quitline) **Definition of smoking:** Abstience • Not a single puff of smoke during the last week

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Telephone quitline **Intervention:** **G1:** Tailored materials to the patients motivation to quit (stage of change) is offered free of charge; treatment protocal is described as a combination of motivational interviewing, cognitive behavioral therapy, and pharmacological counseling **G2:** same as G1 with 4 to 5 proactive counseling calls **Method of assessment:** Self-report at 12 to 13 months after first contact **Baseline data:** NR	**Statistical analysis:** Logistic regression was used to calculate Odds Ratios **Data verification:** Self-report **Dependent variables:** • Smoking status • Stage of change • NRT use • Exposure to second hand smoke • Treatment compliance • Periods of depressive moods • Use of additional support	Additional support (i.e., being referred to the quitline by a health professional) was associated with abstience and persisted with the exclusion of patients with severe smoking related symptoms Overall abstience was not significantly higher in the proactive compared with the reactive group (33% vs 28%, NS) When men and women are assessed separately, women were signifcantly more likely to be abstinent in the procative compared with the reactive group (34% vs 27%, *P*.03)	**Quality rating:** Poor **Comments:** NA **Adequate randomization:** NA **Attrition rate:** 30%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Hennrikus et al., 2005 **Geographic area:** US **Funding agency:** NIH **Study setting:** Hospital	**Study objective:** Evaluation of effectiveness of three smoking cessation interventions for a hospital-based population **Population:** Adults **Study type:** RCT w/ systematic randomization **Inclusion criteria:** • Patient smoked a cigarette in wk before admission and considered themselves a regular smoker for at least 1 mo during yr before admission • Between 18 and 75 yrs old • Length of hospital stay of 24 hrs or greater • Ability to understand consent process • Availability for telephone contact **Exclusion criteria:** • Pregnancy • Chemical dependency or psychiatric disturbance as primary reason for admission • Severe physical or mental distress	**Sampling plan:** Research assistant obtained list of all general admissions from previous day at four hospitals and screened patients meeting age and admission dz requirements for smoking status and other eligibility requirements Research assistants approached patients for informed consent and asked consenting patients to complete a baseline interview; participants then randomized by research assistant by looking up next available group assignment on a list on which 3 conditions were randomly ordered within blocks of 30 assignments **Sample size:** **G1:** 703 **G2:** 696 **C1:** 696 **Definition of smoking:** Cigarettes • Regular smoker: smoked more than 100 cigarettes in lifetime • Current smoker: uses cigarettes now

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Telephone counseling • Referral to community resources, clinician reminder **Intervention:** **G1:** Participants given 2 smoking cessation manuals designed for hospital in-patients, a directory of smoking cessation community resources, a label in medical record to cue doctors and nurses to provide brief (60 second) smoking cessation advice and document that advice, and a letter after discharge reiterating that their health care providers would like for them to quit and to encourage them to read manuals provided **G2:** Participants given 2 smoking cessation manuals designed for hospital in-patients, a directory of smoking cessation community resources, a label in medical record to cue doctors and nurses to provide brief (60 second) smoking cessation advice and document that advice, a letter after discharge reiterating that their health care providers would like for them to quit and to encourage them to read manuals provided, a more extended bedside counseling session in the hospital, and three to six telephone calls from a research nurse during 6 mos after discharge **C1:** Participants received 2 smoking cessation manuals tailored for hospital in-patients and a directory of smoking cessation community resources **Method of assessment:** Followup interviews 7-18 days and 12 mos post discharge; for those who reported abstinence at 12 mo followup, salivary cotinine levels assessed	**Statistical analysis:** Using SAS statistical package, multivariate logistic regression conducted to examine the outcome variable "abstinence from tobacco use; " Mantel-Haenszel test for homogeneity of effects performed for each outcome to determine whether results from 4 hospitals could be pooled; X^2 analyses of relationships b/w txt condition and outcomes also performed **Data verification:** Salivary cotinine levels assessed for those who reported abstinence at 12-mo followup **Dependent variables:** Abstinence; use of NRT **Baseline data:** Groups similar at baseline	Percentage of those self-reporting abstinence at 7-day followup: **C1:** 26.0% **G1:** 24.0% **G2:** 25.2% *P* = > 0.05 Percentage of those self-reporting abstinence at 12-mo followup: **C1:** 15.0% **G1:** 15.2% **G2:** 19.8% *P* = < 0.05 Percentage of those abstinent verified by salivary cotinine at 12-mo followup: **C1:** 8.8% **G1:** 10.0% **G2:** 9.9% *P* > 0.05	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** Yes **Attrition rate:** • 7-day followup: 13.5% • 12-mo followup: 24.1%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Hitsman et al., 1999 **Geographic area:** US **Funding agency:** VA Merit Review award by NIDA, and Eli Lilly and Company **Study setting:** Population-based	**Study objective:** To identify individual differences that predict cessation when fluoxetine is combined w/ CBT **Population:** • Adults **Study type:** RCT w/ simple randomization **Inclusion criteria:** Participants are: • 18 to 65 yrs of age • have smoked daily for at least one yr • exhibit a baseline expired CO level of greater than 8 ppm • agree to declare a quit date within 2 wks after second study visit (Source: Borrelli, et al. 1997) **Exclusion criteria:** • Clinically significant depression HDRS score greater than 14 • Pregnancy • Hypertension • Use of psychotropic medication or current psychiatric illness • Alcohol or drug abuse in past yr • Current use of nicotine replacement • Unstable medical condition or major health event in past 6 months • Use of ST, pipes or cigars • Recent experience of a major life event (e.g., divorce or major job change) • Suicidal ideation • History of bipolar disorder (Source: Borrelli, et al. 1997)	**Sampling plan:** Specific randomization scheme NR. **Sample size:** Total: 253 **Definition of smoking:** Cigarettes • Reported smoking • Expired CO greater than 8 ppm • Saliva continine value greater than 10 ng/ml

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Individual counseling by health professional • Pharmaceuticals **Intervention:** **G1:** Nine, 1-hr individual CBT sessions + fluoxetine 30 mg for a total of 10 wks • Participants required to set a quit date within 2 wks after drug txt began • Participants quit smoking at 3rd CBT session • Medication stopped at 9th CBT session, at which time 6-month followup period began • CBT not explained • Patients w/ fluoxetine level less than or equal to 150 ng/ml considered compliant **G2:** Same as **G1:**, except fluoxetine dose of 60 mg and fluoxetine blood level less than or equal to 300ng/ml considered compliant **C1:** Same as G1, except given placebo **Method of assessment:** Self report of smoking, expired CO, and saliva continine Also used depresion scale, nicotine dependence, weight restraint scale, and self-efficacy questionnaire	**Statistical analysis:** Constructed predictive models using logistic regression w/ hierarchical approach to variable selection. Models evaluated w/ parallel analyses using stepwise selection procedure **Data verification:** Expired CO and saliva continine **Dependent variables:** Depression, nicotine dependence, weight concerns, self-efficacy about quitting smoking **Baseline data:** No significant difference b/w txt groups in baseline characteristics: age, gender, education, smoking history, baseline level of nicotine dependence, depression, weight concern, and self-efficacy	At 1 wk postcessation: higher levels of depression predicted failure to achieve abstinence (ITT analysis); higher levels of nicotine dependence and depression associated w/ decreasing likelihood of abstinence (analysis of txt-compliant patients) and likelihood of abstinence for participants on fluoxetine tended to be higher than for those on placebo (P = 0.06); At 1 month postcessation: higher levels of weight concern predicted lower abstinence (X^2 4.8, P = 0.78); patients on fluoxetine had positive association b/w degree of depression and likelihood of abstinence (highest quartile HRSD = 3, OR = 2, 95% CI, 0.85-4.70); At 3 months postcessation: patients treated w/ fluoxetine had positive association b/w HRSD scores and abstinence likelihood (highest quartile HRSD = 3, OR = 1.44, 95% CI, 0.53-3.91) Smoking characteristics predicting txt compliance were nicotine intake at baseline, saliva cotinine (X^2 = 11.4, P < 0.001), and expired CO (X^2 = 5.3, P < 0.05)	**Quality rating:** Fair **Comments:** • Authors didn't report numbers of participants per arm of study, baseline demographic characteristics of those groups, nor 6 month followup results • Inclusion/ exclusion criteria are described in companion article, Borrelli, et al. 1997 **Adequate randomization:** NR **Attrition rate:** NR

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Holt et al., 2005 **Geographic area:** New Zealand **Funding agency:** GlaxoSmithKline **Study setting:** Community-based Population-based	**Study objective:** To determine whether bupropion is effective in txt of smoking cessation in indigenous Maori population of New Zealand **Population:** • Adolescents • Young Adults • Adults **Study type:** • RCT w/ systematic randomization • Placebo controlled, double blind, parallel group study **Inclusion criteria:** • Self-indentified Maori • Age 16 to 70 • Smoked at least 10 cigarettes per day over last yr • Desire to quit • Nonpregnant women w/ reliable contraception **Exclusion criteria:** History of: • epilepsy • febrile convulsion • CNS tumor • head injury • cerebrovascular dz • anorexia • bulima • CD • other severe illnesses • pregnant or lactating • drug/alcohol abuse • unwilling to quit marijuana	**Sampling plan:** • Self-recruitment from mall advertisements • Recruited from Maori health networks • Randomized (by computer generated code) **Sample size:** **G1:** 88 **C1:** 46 **Definition of smoking:** Cigarettes • Smoke ≥ 10 per day on average over last yr

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Individual counseling by health professional • Individual counseling by non health professional • Telephone counseling • Pharmaceuticals **Intervention:** **G1:** Bupropion 150 mg once daily for 3 days, then 150 mg twice daily for 7 wks; smoking cessation counseling Clinic visits (to assess smoking status, exhaled CO, and adverse events) at 3 wk, 7 wk, 3 mo, 6 mo, 9 mo, and 12 mo after target quit date **C1:** Same as G1 except given identical placebo pills **Method of assessment:** • Self-report • Fagerstrom score • exhaled CO **Baseline data:** Mean age (SD): 41.79 (9.2) txt vs 38.0 (11.1) placebo Mean Fagerstrom index (SD): 5.8 (2.2) txt vs 5.3 (2.0) placebo Mean initial weight (SD): 85.4kg (18.9) txt vs 80.2 (16.8) placebo; 69.3% female in txt vs 76.1% in placebo	**Statistical analysis:** Primary: normal approximation to binomial distribution Secondary: GEE Exploratory: general additive model **Data verification:** Exhaled CO **Dependent variables:** Continued abstinence from smoking at 3 and 12 months (or other time points, secondarily)	Rates of continued abstinence in bupropion and placebo groups, respectively = 44.3% vs17.4% at 3 months (RR = 2.54; 95% CI 1.30-5.00); = 21.6% vs10.9% at 12 months (RR = 1.99; 95% CI 0.79-5.00). Bupropion group more likely to have insomnia (26% vs9% w/ RR = 3.0 and 95% CI 1.1-8.2)	**Quality rating:** Fair **Comments:** • No ITT analysis • No attrition reported • Fell just short of sample size needed according to power analysis • No analysis for confounders. **Adequate randomization:** Yes **Attrition rate:** NR

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Jones et al., 2001 **Geographic area:** United Kingdom **Funding agency:** NR **Study setting:** Hospital	**Study objective:** Determine whether ICU patients' smoking cessation after critical illness is aided by provision of a rehabilitation program **Population:** • Adults **Study type:** RCT w/ simple randomization **Inclusion criteria:** • Minimum 48 hr ICU admission • Had been ventilated **Exclusion criteria:** NR	**Sampling plan:** Recovering ICU patients recruited to study 2 wks after ICU discharge, randomized to receive either usual care followup of unit visits and ICU clinic appointments or routine followup plus an ICU rehabilitation manual **Sample size:** **G1:** 31 (20 smokers) **C1:** 30 (16 smokers) **Definition of smoking:** Cigarettes NR

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Social support **Intervention:** **G1:** Verbal encouragement to remain non-smoking at ICU discharge, at 8-wk clinic vist, and six month clinic visit; patients' immediate family instructed not to smoke in same room as patient; 2 wks postdischarge introduction to 6-wk self help ICU rehabilitation manual read by patient and relative that emphasized importance of remaining non-smoking and provided practical tips **C1:** Verbal encouragement to remain non-smoking at ICU discharge, at 8-wk clinic vist, and six-mo clinic visit; patients' immediate family instructed not to smoke in same room as patient **Method of assessment:** Followup in clinic at 8 wks and 6 mos postdischarge **Baseline data:** No significant differences in baseline data among C1 and G1	**Statistical analysis:** NR **Data verification:** Smoking status verified by information from a close family member **Dependent variables:** • Smoking status • Levels of anxiety • Depression • PTSD-related symptoms	Of smokers preICU admission, those returning to smoking at 8-wk followup: **G1:** 2 **C1:** 5 RR = 0.24 (CI 0.03-1.84) Of smokers preICU admission, those returning to smoking at 6-mo followup: **G1:** 3 **C1:** 10 RR = 0.11 (CI 0.02-.64) No differences in anxiety, depression or PTSD-related symptoms at 6 mos b/w patients who continued to smoke and those who had quit (Mann Whitney U, HAD anxiety *P* = 0.51, HAD Depression *P* = 0.74, Impact of Events Scale *P* = 0.50)	**Quality rating:** Fair **Comments:** Very small study; due to type of article, details about randomization and sampling NR **Adequate randomization:** NR **Attrition rate:** O% attrition

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Jorenby et al; 1999 **Geographic area:** US **Funding agency:** Glaxo Wellcome **Study setting:** Community-based	**Study objective:** To determine whether buproprion plus NPis more effective for smoking cessation than either cessation aid alone or a placebo **Population:** • Adults **Study type:** • RCT w/ systematic randomization • Double-blind, placebo-controlled, randomized control trial **Inclusion criteria:** • At least 18 yrs of age • To smoke at least 15 cigarettes per day • To weigh at least 45.4 kg (100 lb) • To be motivated to quit smoking • To speak English • Only one smoker per household allowed to enroll in study **Exclusion criteria:** Subjects excluded for following reasons: • Serious or unstable cardiac, renal, hypertensive, pulmonary, endocrine, or neurologic disorders, as assessed by study-site physician • Ulcers • Seizure or dermatologic disorders • A current dz of major depressive episode or a history of panic disorder, psychosis, bipolar disorder, or eating disorders • Use of a nrt within six mos before study enrollment • Pregnancy or lactation • Abuse of alcohol or a non–nicotine-containing drug within preceding yr • Use of a psychoactive drug within wk before enrollment • Use of an investigational drug within mo before enrollment • Prior use of bupropion • Current use of other smoking-cessation treatments • Regular use of any noncigarette tobacco product	**Sampling plan:** • Subjects recruited at four study sites by advertisements in the media • First subject enrolled in August 1995, and followup completed in March 1997; subjects randomly assigned to one of four treatments w/ use of an unequal-cell design • Randomization not balanced within sites **Sample size:** **G1:** 245 **G2:** 244 **G3:** 244 **C1:** 160 **Definition of smoking:** Cigarettes • Abstinent: no smoking since last clinic visit and expired air CO 10 ppm or less • Continuously abstinent: no smoking since quit date at expired air CO 10 ppm or less at every clinic visit over 12 mos

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Pharmaceuticals **Intervention:** **G1:** sustained-release bupropion (subjects received 150 mg of bupropion in morning and a placebo tablet in evening on days 1, 2, and 3 of txt; and one bupropion tablet in morning and one in evening on days 4 to 63) plus NP(one patch per day; patches from wks 2 to 7 each contained 21 mg of nicotine, those used during wk 8 each contained 14 mg, and those used during wk 9 each contained 7 mg) **G2:** sustained-release bupropion (subjects received 150 mg of bupropion in morning and a placebo tablet in evening on days 1, 2, and 3 of txt; and one bupropion tablet in morning and one in evening on days 4 to 63) plus placebo patch **G3:** NP(one patch per day; patches from wks 2 to 7 each contained 21 mg of nicotine, those used during wk 8 each contained 14 mg, and those used during wk 9 each contained 7 mg) plus placebo pills 2x per day **C1:** placebo pills 2x per day plus placebo patch one time per day **Method of assessment:** Followup at 10 wks, 3 mos, 6 mos, and 12 mos after start of study; assessment consisted of self-reported smoking status, vital signs, measurement of expired air CO, and the Beck Depression Inventory	**Statistical analysis:** X^2 and ANOVA used to test for baseline differences in demographic and smoking-history variables All statistical tests two-sided and had an alpha level of 0.05 Logistic-regression analysis used to determine pairwise differences among groups in abstinence rates Kaplan–Meier method used to analyze differences in rates of continuous abstinence; homogeneity among treatments and pairwise differences tested w/ log-rank test **Data verification:** Expired air CO levels assessed to validate self-reported smoking status **Dependent variables:** • Primary: smoking status • Secondary: withdrawl symptoms, body weight, and Beck Depression Inventory scores **Baseline data:** No significant differences b/w groups	Proportion of participants abstinent at 6 mo followup: **G1:** 38.8% OR = 2.7 (95% CI, 1.7-4.4) *P* = < 0.001 **G2:** 34.8% OR = 2.3 (95% CI, 1.4-3.7) *P* = < 0.001 **G3:** 21.3% OR = 1.2 (95% CI, 0.7-1.9) *P* = 0.53 **C1:** 18.8% Proportion of participants abstinent at 12 mo followup: **G1:** 35.5% OR = 3.0 (95% CI, 1.8-4.9) *P* = < 0.001 **G2:** 30.3% OR = 2.3 (95% CI, 1.4-3.9) *P* = < 0.001 **G3:** 16.4% OR = 1.1 (95% CI, 0.6-1.8) *P* = 0.84, **C1:** 15.6% All four groups had significant increases in withdrawal symptoms during first wk of txt (*P* < 0.001) but changes smaller in three active-txt groups than in placebo group during first six days after quitting date and during following wks No txt effect on Beck Depression Inventory scores Subjects in combined-therapy group had gained significantly less weight than those in placebo group (*P* < 0.05) or bupriopion group (*P* < 0.05) at wk 7 but no significant differences b/w groups in mean weight changes after wk 7	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** Yes **Attrition rate:** 6 month followup: 30.8% 12 month followup: 34.6% Adverse events: 8.8%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Killen et al., 2000 **Geographic area:** US, San Jose, CA **Funding agency:** University of California Tobacco-Related Disease Research Program; SmithKline Beecham **Study setting:** Population-based	**Research objective:** To examine efficacy of smoking cessation treatment that combined nicotine replacement therapy via transdermal system with antidepressant paraxetine **Population:** Adults **Study type:** RCT, double-blind **Inclusion criteria:** • Adults over age 18 **Exclusion criteria:** • Pregnant, or lactating • History of severe liver or kidney disease, epilepsy, bipolar disorder, schizophrenia, • Receiving active treatment for or reported current depression or substance abuse • Taking antidepressants, psychotropics, or other drugs that could interact with paraxetine resulting in potentially adverse consequences • Unable to obtain permission from personal physician to participate in the study – for patients with history of heart disease, diabetes, thyroid disease, recent chest pain, very high blood pressure, skin conditions or peptic ulcer	**Sampling plan:** • Recruitment from local newspapers, then telephone interview screen, then initial office visit screen • Double blind allocation **Sample size:** Total: 224 About 75 in each group **Definition of smoking:** • Greater than or equal to 10 cigarettes per day • Abstinence: nonsmoking not even a puff for 7 consecutive days and saliva cotinine level below 20ng/ml an a CO level below 9ppm • Smokers – reported abstinence but failed to provide a saliva sample

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling **Intervention:** **G1:** NRT transdermal system patch for 8 weeks plus 20 mg paroxetine for 9 weeks **G2:** NRT transdermal system patch for 8 weeks plus 40 mg paroxetine for 9 weeks **C1:** NRT transdermal system patch for 8 weeks plus placebo for 9 weeks **Method of assessment:** • In person interview and biomarkers at initial clinic visit • Telephone interview at 1, 4, 10 and 26 weeks • Via an interactive voice response system at 24 hours, weeks 2 and 6 **Baseline data:** • Demographics • Medical status questions • Smoking history • Screen for current major depression • Modified Fagerstrom Tolerance Questionnaire • Self-reported depression symptoms • Clinical diagnosis of depression • BMI • Blood pressure and heart rate	**Statistical analysis:** • Intention to Treat analysis • Logistic regression • 75% poser to detect at least a 20% increase in abstinence **Data verification:** • Self report • Saliva cotinine concentrations • Blood level to determine paroxetine compliance level **Dependent variables:** • Craving • Adverse events • Smoking status • Compliance • BMI • Heart rate • Blood Pressure • Expired air CO level • Depressive symptoms	**Abstinence Rates (NS)** At 4 weeks **G1:** 48% **G2:** 57% **C1:** 45% **At 10 weeks** **G1:** 33% **G2:** 39% **C1:** 36% **At 26 weeks** **G1:** 21% **G2:** 27% **C1:** 25% **Chemical Confirmation** At 4 weeks: 95% At 10 weeks 98% At 26 weeks 86% **Subanalysis of Compliant Persons** At 4 weeks **G1:** 64% **G2:** 74% **C1:** 46% $P < 0.001$ **At 10 weeks** **G1:** 43% **G2:** 51% **C1:** 35% **At 26 weeks** **G1:** 33% **G2:** 38% **C1:** 24% Those who reported greater use of nicotine patches and those with higher blood levels of paroxetine in Week 4 were more likely to be abstinent	**Quality rating:** Good **Comments:** NR **Adequate randomization:** Yes **Attrition rate:** Not clear

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Lancaster et al., 1999 **Geographic area:** United Kingdom **Funding agency:** NR **Study setting:** Practice/provider settings	**Study objective:** To determine whether receiving brief advice from a GP plus extended counseling and followup from a trained nurse resulted in patients' cessation more than brief advice from a GP alone **Population:** • Adults **Study type:** RCT w/ systematic randomization **Inclusion criteria:** • Adults ages 18 and over who smoked at least one cigarette per day **Exclusion criteria:** • NR	**Sampling plan:** • Opportunistic recruitment of patients attending the practice w/ unrelated complaints • Letters to patients identified as smokers by practice records • 497 patients from 6 practices systematically randomized to receive brief advice from a GP or brief advice from a GP plus extended counseling and followup from a trained practical nurse **Sample size:** **G1:** 249 **C1:** 248 **Definition of smoking:** Cigarettes • Smoker: At least one cigarette smoked per day and/or salivary cotinine levels < 113.5 nmol/l

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Pharmaceuticals **Intervention:** **G1:** Brief verbal or written advice to quit from the patients' general practitioners, plus: extended counseling and followup from a trained practing nurse; Health Education Authority leaflet on cessation; fact sheet on NRT; invitation to contact research nurse for more intensive, tailored counseling that included CO breath test and a personalized message about benefits of quitting - minimum one 15 min visit plus 1 followup, max five, 10-min followup visits; NRT if necessary **C1:** Brief advice to quit from patients' general practitioners **Method of assessment:** Surveys administered at 3 and 12 months post quit date; salivary cotinine assessed for self-reported quitters; those who did not provide followup information were assumed to be smokers	**Statistical analysis:** • Chi sq used to test for differences b/w proportions and 95% CI calculated • ITT analysis **Data verification:** Salivary cotinine levels obtained to validate self-reported quitters **Dependent variables:** • Sustained abstinence at 3 and 12 mos • Biochemically validated • Forward movement on stage of change **Baseline data:** G1 and C1 similar at baseline in terms of demographics and smoking status	Abstinence at 3 month followup: **G1:** 9.2% **C1:** 8.1%, NS Abstinence at 12 month followup: **G1:** 6.8% **C1:** 11.3%, NS Sustained abstinence (abstinent at both 3- & 12-month followup): **G1:** 3.6 **C1:** 4.4 Difference: -0.8% (CI, -4.3%, 2.6%) Validated (-3.3 vs4.0) Any forward change in stage of change: **G1:** 20.9% **C1:** 26.6% Difference: -5.7% (CI, -13.2%, 1.7%)	**Quality rating:** Fair **Comments:** **Adequate randomization:** Yes **Attrition rate:** 3 mo followup: 19% 12 mo followup:25%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Lawrence et al., 2005 **Geographic area:** West Midlands, UK **Funding agency:** Department of Health and the West Midland Health Authorities **Study setting:** Practice/provider settings	**Research objective:** To evaluate the effect on quitting smoking at 18 months post partum of smoking cessation intervention based on TTM delivered in pregnancy compared to current standard of care **Population:** Women patients at of antenatal clinics in general practices **Study type:** Cluster randomized trial **Inclusion criteria:** • At least 16 years of age • Still smoking at 12 weeks gestation **Exclusion criteria:** NR	**Sampling plan:** • Recruited 16 of the 19 midwifery services for West Midlands • 100 general practices randomized into trial arms • Allocated by computerized minimization algorithm **Sample size:** **G1:** 305 **G2:** 324 **C1:** 289 393 (42%) eligible smokers were followed up on **Definition of smoking:** • Urine cotinine of 1.5 ug/ml • Abstinence: declared nonsmoking and no cigarette consumption in last 24 hours

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Self-help **Intervention:** **G1:** TTM-based self help manuals **G2:** TTM-based self help manuals plus sessions with interactive computer program giving individualized smoking cessation advice **C1:** Standard care **Method of assessment:** Medical chart abstraction and follow-up telephone interview **Baseline data:** • Smoking habits • Urine cotinine levels • Fagerstrom Test for Nicotine dependence • Stage of change • Demographics • Parity • Proportion having a partner • Proportion whose partner smoked • Educational achievement • Household net income	**Statistical analysis:** • Cluster randomization • Random effects liners regression **Data verification:** Self report **Dependent variables:** • Cotinine saliva • Continuous and point prevalence abstinence since pregnancy	Continuous abstinence since 10 days PP: G1+G2 vs **C1:** 1.20 (95% CI: 0.29-4.88) Point Prevalence for Abstinence: G1+G2 vs **C1:** 1.15 (95% CI: 0.66-2.03) Seven of the 54 (13%) who quit at end of pregnancy were still quit 18 months later No evidence that TTM-based interventions were superior in preventing relapse 18 of the 54 (33%) of those who had quite 10 days PP were still quite at 18 months, though 11 of these were not continuously	**Quality rating:** Poor **Comments:** NR **Adequate randomization:** NR **Attrition rate:** NR

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Lerman, et al., 2004 **Geographic area:** United States **Funding agency:** National Cancer Institute; National Institute on Drug Abuse, and Public Health Services Research grant **Study setting:** Population-based	**Research objective:** To evaluate the comparative efficacy of transdermal nicotine and nicotine nasal spray and identify predictors of treatment outcome **Population:** Adults ≥18 years old enrolled at Georgetown University and the University of Pennsylvania **Study type:** RCT **Inclusion criteria:** • 18 years of age or older • Had smoked 10 or more cigarettes per day for the previous 12 months **Exclusion criteria:** • Pregnancy or lactation • Uncontrolled hypertension • Unstable angina • Heart attack or stroke within the previous 6 months • Current treatment or recent diagnosis of cancer, drug or alcohol dependence • Current diagnosis or history of a psychotic disorder • Current use of bupropion or nicotine-containing products other than cigarettes	**Sampling plan:** • Participants were recruited through: - local media ads for free smoking cessation treatment - physician referral • Eligible participants randomly assigned to receive transdermal nicotine or nicotine nasal spray **Sample size:** 299 adults **Definition of smoking:** • Prolonged abstinence defined as not having smoked for 7 consecutive days at any time during the follow-up period • Point prevalence defined as 7 days of continuous abstinence immediately before the follow-up point

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Nicotine nasal spray • Transdermal nicotine therapy • Standardized behavioral group counseling **Intervention:** **G1:** 8 weeks of nicotine nasal spray and 7 sessions of behavioral group counseling **G2:** 8 weeks of transdermal nicotine therapy (i.e., patch) and 7 sessions of behavioral group counseling **Method of assessment:** 8 weeks and six month telephone interviews plus biochemical verification for point prevalence **Baseline data:** Participants at the University of Pennsylvania site were significantly more likely to be non-white, obese, and have lower levels of education	**Statistical analysis:** • Calculated sample size of 140 per group to detect a between-group difference in quit rates of 8% or greater with 80% power (alpha = 0.05) • Chi square and Wilcoxon rank-sum tests were used to examine differences in pre-treatment variables • Chi square and Wilcoxon rank-sum tests were used to compare treatment groups on abstinence outcomes • Logistic regression analysis was used to examine the independent effects of treatment group assignment, pretreatment variables, and their interactions on prolonged abstinence and verified point prevalence abstinence • Wilcoxon rank-sum tests were used to examine differences between treatment group in use and percentage of cotinine replacement **Data verification:** • Self-report for prolonged abstinence • Self-report for point prevalence plus carbon monoxide reading < 10 ppm **Dependent variables:** • Smoking status	No statistically significant difference found between treatment groups at 6 months (**G1:** 12.2%, **G2:** 15%, NS) Abstinence rates similar to those achieved in other studies Smokers who were highly dependent, obese, or members of minority groups achieved higher rates of abstinence with nasal spray	**Quality rating:** Fair **Comments:** Authors stated that stratification was done by study site but no mention of what was stratified, or how or why **Adequate randomization:** Yes **Attrition rate:** 18% lost-to-follow-up

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: MacLeod et al., 2003 **Geographic area:** Australia **Funding agency:** GlaxoSmithKline **Study setting:** Population-based	**Research objective:** To investigate the effectiveness of telephone counseling as an adjunct to nicotine replacement therapy (NRT) by transdermal patch in smoking cessation **Population:** • Smokers from New South Wales • ≥18 years old **Study type:** RCT **Inclusion criteria:** • Aged ≥18 years • English-speaking • Smoking ≥10 cigarettes per day for the previous year • Ready to begin a quit attempt within 1 week **Exclusion criteria:** • History of cardiovascular disease, diabetes or skin sensitivity • Currently breastfeeding, pregnant or intending to become pregnant • Using contraindicated medications	**Sampling plan:** • Recruited smokers from New South Wales via newspaper ads • Consent forms, questionnaires on health, smoking history and attitudes to quitting were mailed to people who responded to the ads. • Responses were screened by a pharmacist in accordance with the approved product information for transdermal nicotine patches and eligibility criteria for the study • Those deemed eligible were randomly allocated to either NRT alone or NRT plus telephone counseling • Participants were contacted by telephone data collectors to verify their understanding of the study (baseline) **Sample size:** **G1:** 412 **C1:** 442 **Definition of smoking:** Cigarettes • Current Smoker – Smoking ≥10 cigaretters per day for the previous year • 28-day continuous abstinence (used at 3 and 6 month follow up calls) – complete abstinence, “not even a puff” for at least the previous 28 days • 90-day continuous abstinence – the reported date of the last cigarette smoked was at least 90 days before 6 month follow-up call

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • NRT - patch • Telephone counseling **Intervention:** **G1:** Nicotine Patch and 5 telephone counseling calls, scheduled at 1,2,3,6 and 10 weeks after baseline **C1:** Nicotine Patch only **Method of assessment:** Brief (5 minute) follow-up telephone questionnaires were administered at 1, 2, 3, and 6 months post-baseline **Baseline data:** No significant differences b/w the 2 groups	**Statistical analysis:** • Intent-to-treat approach used, where missing values on smoking status imputed as smokers with 0 days abstinence in that period, unless continuous abstinence between calls was subsequently reported • Statistical significance between groups was tested by X2 tests and logistical regression (categorical variables) or t tests (continuous variables) • Logistic regression analysis was conducted with both treatment group and duration of patch use included as predictors of 90-day abstinence **Data verification:** • Self-report, bogus pipeline technique used, with possibility of carbon monoxide breath testing mentioned in the consent form and at the 3- and 6-month monitoring calls **Dependent variables:** • 28-day continuous abstinence at 3 and 6 months • 90-day continuous abstinence at 6 months	Telephone counseling improves cessation rates when used in conjunction with the patch 28-day continuous abstinence rates at 6-months: G1 30.6%, C1 22.4%, *P* =.01 90-day continuous abstinence rates G1 26.7%, C1 18.6%, *P* = 0.004 Logistic regression analysis revealed the duration of patch use and telephone counseling made independent contributions to prediction of 90-day abstinence Odds of successful quitting increased with each extra week of patch use when treatment group held constant (OR=1.24, *P* < 0.05) When controlling for weeks of patch use, the odds of success were higher for those in the counseling group (OR=1.46, *P* < 0.05)	**Quality rating:** Good **Comments:** No biochemical verification of abstinence – relied solely on self-report **Adequate randomization:** Yes **Attrition rate:** 16%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: McBride et al., 2004 **Geographic area:** United States **Funding agency:** National Cancer Institute **Study setting:** Military Medical Center	**Research objective:** • To evaluate whether relative to usual care and a previously evaluated woman-only intevention, if training in optimal support behaviors and giving support to partners increased abstinence rates among pregnany women during and after pregnancy • 2nd aims – decrease postpartum relapse and increase rates of smoking cessation among partners **Population:** • Pregnant woman who received prenatal care at the Womack Army Medical Centers • Their live-in partners **Study type:** RCT **Inclusion criteria:** • Eligible women were ≤20 weeks pregnant • Aged ≥18 years • Current smokers or recent quitters • Living with an intimate partner • Willing to have the partner contacted for participation in the study **Exclusion criteria:** • >20 weeks pregnant • Partner not available, or refused partner contact	**Sampling plan:** • Introductory letters describing the study were sent on behalf of WAMC to all women identified from automated appointment logs with a scheduled 1st prenatal visit. • Women who did not call study's toll-free number w/in 10 days to decline contact were called to complete screening survey • Eligible women who agreed to participate were stratified by smoking status (smoker or recent quitter), their partner's smoking status (smoker or nonsmoker) and partner's level of willingness (not at all vs somewhat or very) • Once stratified, participants were then randomly assigned to one of 3 conditions: usual care (UC), woman only (WO) or partner assisted (PA) • Women and partners completed telephone surveys at baseline (about 11 weeks of pregnancy) **Sample size:** **G1:** (WO): 192 **G2:** (PA): 193 **C1:** (UC): 198 **Definition of smoking:** Cigarettes • Current Smoker – NR • Recent quitter – smokers in the 30 days prior to pregnancy but not smoking at intake • Prevalent abstinence – no smoking in prior 7 days • Sustained abstinence – no smoking across all 4 follow-up times

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Provider advice • Self-help quit guides • Telephone counseling • Pregnancy relapse kit • Telephone counseling and support guide geared towards partners **Intervention:** **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: provider advice to quit and self-help guide **Method of assessment:** • Telephone surveys of the women and partners at 28 weeks pregnant, postpartum and 2, 6, and 12 months • Self reported smoking status assessed at each follow up with the question "have you smoked any cigarettes in the past 7 days?" • Saliva samples collected by mail at 28 weeks pregnancy and 12 months postpartum from women and partners who reported not smoking in the previous 7 days **Baseline data:** No significant differences b/w any of the groups	**Statistical analysis:** • Logistic regression was used to compare the 2 experimental conditions to the control condition on each outcome measure, controlling for baseline smoking-specific support variables and predictors known to be associated with smoking cessation trials • Intent-to-treat approach used, where missing values on smoking status imputed as "smoker" • Comparison on the experimental conditions to the control condition on dichotomous secondary outcomes, such as postpartum relapse and partners' prevalent abstinence, were made with logistic regression • Proportional hazards model was used to compare conditions on time to relapse, where time to relapse defined as the number of days b/w woman's delivery date and the date she resumed smoking • Differences by condition for changes in women's and partner's smoking-specific support and general support across time were tested with mixed linear-model repeated measures analysis **Data verification:** Self-report, salivary cotinine **Dependent variables:** • Abstinence at 28 weeks, 2, 6 and 12 months postpartum • Sustained abstinence	No statistically significant difference between groups at any follow up point No statistically significant difference between groups in the proportion relapsed at any postpartum follow-up In late pregnancy (28 weeks), more partners abstinent in G2 group (15%) than C1 group (5%) $P = 0.02$ Women in all groups consistently reported a decline in positive partner support from baseline to 12-month postpartum (F=81.43, df=1322, $P < 0.001$)	**Quality rating:** Fair **Comments:** By only including women who agreed to involve their partners, couples who were inclined to support each other and attentuated treatment effects may have been over-represented **Adequate randomization:** Yes **Attrition rate:** 19%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Mermelstein et al., 2003 **Geographic area:** US **Funding agency:** National Heart, Lung and Blood Institute and National Cancer Institute **Study setting:** NR	**Research objective:** To compare the relative efficacy of two types of proactive telephone calls following a group cessation program. **Population:** Participants completing a group smoking cessation program **Study type:** RCT **Inclusion criteria:** NR **Exclusion criteria:** NR	**Sampling plan:** • Participants recruited primarily through paid advertisements, media coverage of the program, flyers and referrals • 905 smokers attended the first group meeting • 771 smokers completed the group program • 756 smokers were assessed at least once over the follow-up period **Sample size:** **G1:** (basic): 375 **G2:** (enhanced): 381 **Definition of smoking:** Tobacco dependence as measured by the Fagerstrom Tolerance Questionnaire

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Group meetings • Telephone counseling **Intervention:** **G1:** Enhanced: Basic program (see C1 below) plus telephone counseling call content varied by participants' smoking status (i.e., still smoking, abstinent, slipped or relapsed); if still smoking or relapsed also received a videotape; plus abstinent counseling on keeping motivation and self-efficacy high using a variety of techniques **C1:** Basi**C1:** 7 week group treatment program of telephone counseling giving only words of encouragement without specific guidance **Method of assessment:** 3-,6-,9-,12- and 15-month follow-ups via telephone **Baseline data:** No significant differences between conditions on any variables or on percentage with a history of depression	**Statistical analysis:** NR **Data verification:** Expired air carbon monoxide and saliva cotinine used to verify abstinence at each major assessment point for participants reporting abstinence **Dependent variables:** • Abstinence: no smoking at all in the past 7 days • Relapse: smoking one one or more days of the past 7 after achieving an initial 7-day period of abstinence at the end of the group program	Point Prevalence of Abstinence: no significant differences by condition at any assessment point Post-hoc analysis by condition by gender at all assessment points showed that men receiving the enhanced condition were more likely to abstain while women were more likely to abstain when participating in the basic condition.	**Quality rating:** Poor **Comments:** • No true control group (i.e., those in group program with no telephone follow-up). So no true comparison of whether calls had an effect. • Random assignment method NR • Population not described • No inclusion/exclusion criteria specified **Adequate randomization:** NR **Attrition rate:** 6-month: 1% 15-month: 4%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Murray et al., 2001 **Geographic area:** US **Funding agency:** Division of Lung Disease of the National Heart, Lung, and Blood Institute **Study setting:** Practice/provider settings	**Study objective:** To evaluate hypothesis that Black smokers will respond differently than Whites to a smoking cessation intervention program where no adjustments are made in recognition of cultural differences **Population:** • Adults • African Americans **Study type:** RCT w/ simple randomization **Inclusion criteria:** • Age 35-60 yrs • Mild COPD • Current smoker **Exclusion criteria:** • Serious health conditions likely to to affect lung function or ability to stay in trial for 5 yrs • Use of regular medications that might alter lung function	**Sampling plan:** NR **Sample size:** **G1:** 3,923 **C1:** 1,964 **Definition of smoking:** Cigarettes Defined as smoking at any clinic visit

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Group counseling • Pharmaceuticals **Intervention:** **G1:** SI (12-wk group program using a quit day in second wk, followed by 4 consecutive days of group meetings) w/ bronchodilator therapy **G2:** SI w/ placebo inhalers **C1:** Usual care- annual physician visits **Method of assessment:** • Interviews at baseline and annually for 5 yrs • Annual saliva collection	**Statistical analysis:** Covariate data used to explore differences using regression t-tests etc. **Data verification:** • Salivary cotinine annually • Expired CO throughout intervention program and subsequently at 4-mo intervals **Dependent variables:** Smoking cessation **Baseline data:** Baseline data comparisons b/w 2 groups showed significant differences Black population had more women (46% vs37%) *P* = 0.01, less education, less income, less likely to be married (48% vs70%), smoked less (23.5 vs32.9 per day)	Quitting at 1 yr G1 vs **C1:** Blacks: AOR: 1.48 Whites: AOR: 5.99 *P* = 0.002 Quitting at 5 yrs: G1 vs C1 Blacks: AOR: 1.87 Whites: AOR: 3.34 *P* = 0.06 Significant txt effect for Blacks over 5 yrs of study (OR = 1.95, *P* = 0.04)	**Quality rating:** Poor **Comments:** Large differences in baseline comparisons b/w white and black negate any differences that occur in outcomes, small sample size **Adequate randomization:** No Study not designed for this comparison **Attrition rate:** NR

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Peterson, 2004 **Geographic area:** US **Funding agency:** National Heart, Lung, and Blood Institute **Study setting:** Hospital	**Study objective:** To evaluate whether a nurse-managed smoking cessation and relapse prevention program reduced smoking rates at 12 mos in women admitted to hospital w/ CD **Population:** • Adults, • Women (only) **Study type:** RCT w/ systematic randomization **Inclusion criteria:** • Female • At least 18 yrs of age • Admitted to hospital w/ CVD or peripheral vascular disease • Had smoked cigarettes in month before admission • Willing to make a serious attempt to quit smoking after discharge **Exclusion criteria:** • Medical instability • Alcohol or substance abuse • Dementia • Schizophrenia	**Sampling plan:** NR **Sample size:** **G1:** 142 **C1:** 135 **Definition of smoking:** Cigarettes • Abstinent: no smoking in past 7 days

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Telephone counseling **Intervention:** **G1:** Brief physician counseling and usual care plus nurse managed, cognitive behavioural, relapse prevention intervention given before discharge, <5 structured telephone contacts 2–90 days after discharge, and relapse management counseling as needed **C1:** Brief physician counseling, a self help pamphlet, and a list of community resources **Method of assessment:** NR	**Statistical analysis:** NR **Data verification:** Self-reported smoking status (abstinence in past 7 days) verified by cotinine levels and family/friends **Dependent variables:** Smoking status **Baseline data:** NR	At 12-month followup, 7-day point prevalence for non-smoking: **G1:** 48% **C1:** 42% RBI: 14% (95% CI, -14 to 51), *P* = NS	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** NR **Attrition rate:** 11%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Quist-Paulsen and Gallefoss, 2003 **Geographic area:** Norway **Funding agency:** Vest-Agder Council for Public Health and the charity Sykehuset i vaare hender **Study setting:** Cardiac ward of a general hospital	**Research objective:** To determine whether a nurse led smoking cessation intervention affects smoking cessation rates in patients admitted for coronary heart disease **Population:** Adults under 76 yrs of age **Study type:** RCT **Inclusion criteria:** • Patients under the age of 76 admitted for myocardial infarction, unstable angina, or cardiac bypass surgery who had been daily smokers until the start of their present coronary symptoms. Patients had to be sufficiently recovered to reliably receive the intervention and had to live in Vest-Agder or Aust-Agder county. **Exclusion criteria:** • Patients with serious illness associated with short life expectancies, serious psychiatric problems, alcoholism, and dementia	**Sampling plan:** • Invited to participate in study all patients admitted to Vest-Agder Hospital for myocardial infarction, unstable angina, or care after coronary bypass surgery performed at other hospitals • 1016 patients assessed for eligibility • Nurses recruited patients 2-4 days after admission • Participants answered baseline questionnaire and were randomly allocated to usual care (control group) or intervention • Nurses given serially numbered sealed envelopes from secretary otherwise uninvolved in study • Randomization was in blocks of varying sizes • 250 patients randomized; 10 were later withdrawn **Sample size:** **G1:** 118 **C1:** 122 **Definition of smoking:** • Daily smoker until start of present coronary symptoms

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Group sessions with cardiac nurses, including seeing a video and getting info booklet • Telephone counseling • Self-help **Intervention:** **G1:** Cardiac nurse consulted patients 1-2 times during hospital stay. Intervention based on booklet focusing on fear arousal and prevention of relapse. Booklet emphasized health benefits of quitting smoking after coronary event, including illustrations showing mortality differences for those who continued smoking after coronary condition vs. those who quit, information on how to prevent relapse, how to stop smoking, how to use nicotine replacement.; also explained how to identify & cope with high risk situations for relapse. Nurses contacted participants by telephone 2 days, 1 week, 3 weeks, 3 months & 5 months after discharge. At 6 weeks aoo participants in G1 had consultation at outpatient clinic with nurse. **C1:** Patients were offered group sessions twice/week with nurses where importance of smoking cessation was mentioned; a video was shown and booklet distributed giving general information on coronary heart disease and advice on quitting smoking. No further specific instructions on how to quit were given **Method of assessment:** Self report and biochemical verification of smoking cessation rates at 12 months **Baseline data:** • Fewer employed in C1 than in G1 • More with post primary education in C2 than in G1	**Statistical analysis:** • Chi-square test used to assess effect of intervention • NNT calculated with confidence intervals • Simple and multiple logistic regression models used to test relation between baseline characteristics and outcome measures • SPSS used for all analyses **Data verification:** Self-report and urine analysis **Dependent variables:** • Number of days spent in ICU • Myocardial infarction as reason for admission • No previous coronary heart disease • Employment	Quit rate at 12 months: **G1:** 57% **C1:** 37% (absolute risk reduction 20%, 95% CI 6.4 – 33.0; P = 0.004) NNT to get one additional person who would quit was 5 Assuming dropouts relapsed at 12 months, smoking cessation rates were: • **G1:** 50% • **C1:** 37% (absolute risk reduction 13%, 95% CI 0% - 26%) Smokers who stated they were still smoking were classified as smokers Those who claimed they had quit and had a nicotine metabolite concentration in urine < 2.0 mmol/mol creatinine were classified as non-smokers **G1:** average of 1.6 (SD 0.7) consultations as inpatients and 1.6 (SD 1.5) as outpatients; also received a mean of 8.5 (SD 3.2) telephone calls Mean total time devoted to each patient was 147 minutes (SD 50) Use of nicotine replacements: **G1:** 36% **C1:** 28% (without a statistically significant difference) 9% of patients who smoked while in hospital or at 6 wks were abstinent at 12 months	**Quality rating:** Good **Comments:** • Well-reported—interventions and methods fully described • Objective outcome measure (urine test) • Loss-to-follow up treated as relapsed smokers yielding valid ITT analysis **Adequate randomization:** Yes **Attrition rate:** • 10 post-randomization exclusions • LTF at 12 months(not including post-randomization exclusions): 9% (**G1:** 15.3%, **C1:** 3.1%)

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Ratner et al., 2004 **Geographic area:** Western Canada **Funding agency:** National Cancer Institute of Canada **Study setting:** Teaching hospital	**Research objective:** Test an intervention to help smokers abstain (fast) from smoking before surgery, maintain abstinence postoperatively, and achieve long-term cessation **Population:** Patients admitted for presurgical assessment from Nov. 1999 to Oct 2001 **Study type:** Randomized pretest-posttest control group experiment **Inclusion criteria:** • Self-identified smokers within previous 7 days • Remain in hospital for at least 24 hours following surgery • Speak and write English • Able to be contacted by phone • Willing and able to participate **Exclusion criteria:** NR	**Sampling plan:** Elective-surgical patients in • Cardiovascular • Opthalmology • Orthopedics • Plastics • Urology **Sample size:** 237 **Definition of smoking:** • Smoked in 7 days before surgery

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Counseling • Nicotine replacement therapy **Intervention:** • 2 face to face counseling sessions • 9 telephone counseling sessions **Method of assessment:** • CO measure • Cotinine assay • Self-report **Baseline data:** Similar in both groups	**Statistical analysis:** • Univariate descriptive statistics • Hypothesis testing using contingency tables and chi-square • Treatment effect- multi-step logistic regression **Data verification:** • Cotinine assay • CO measure **Dependent variables:** • # days until follow-up • Age • Education • Self-efficacy • POMS • Fagerstrom test • Other household smokers • Smoking stage of change	Treatment group participants (73.0%) were more likely to fast than were controls (53.0%): $\chi^2(1, N = 228) = 8.89$, $P = .003$, and more likely to be abstinent 6 months after surgery (31.2% vs. 20.2%). There was no significant difference in the abstinence rates at 12 months after surgery, $\chi^2(1, N = 169) < 0.001$, $P = 1.00$.	**Quality rating:** Fair **Adequate randomization:** Yes **Attrition rate:** 28.7%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Reid et al., 2003 **Geographic area:** Ottawa, Canada **Funding agency:** NR **Study setting:** Tertiary care cardiac facility	**Research objective:** To determine whether stepped-care treatment helped smokers hospitalized with CAD to quit smoking over 3-month and 1-year follow-up periods. **Population:** • Patients hospitalized with CAD • Age of 18 years or more • Motivated to quit smoking **Study type:** RCT **Inclusion criteria:** • At least 18 years or age • Hospitalized with coronary artery disease **Exclusion criteria:** • Unresolved unstable angina • Life-threatening arrhythmias • Vasospastic diseases (buerger's disease, prinzmental's variant angina) • Pregnant or lactating women • Those who lived more than 1 hour of travel time away	**Sampling plan:** • 8330 patients admitted for coronary angiography, PTCA, MI, or CABG were screened • 1379 (16.6%) were identified as cigarette smokers • 419 individuals who met all eligibility criteria • 254 (60.6%) agreed to participate **Sample size:** **G1:** 126 **C1:** 128 **Definition of smoking:** • 5 or more cigarettes a day • Did not include users of pipes, cigars or smokeless tobacco exclusively

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Stepped-care treatment **Intervention:** **G1:** called by a nurse-counselor 4 weeks after discharge and questioned. If not smoking, provided positive reinforcement and reminded about relapse prevention information in the booklet. If smoking, nurse counseling was begun, 3 - 20 minute face to face sessions over 8 weeks and nicotine patch therapy was made available **C1:** no additional counseling after hospital discharge; free to seek assistance from community or primary care physician **Method of assessment:** Surveyed by mail 3 months and 1 year after hospital discharge. If the questionnaire was not returned promptly, the participants were called, and the questionnaire was completed by telephone **Baseline data:** • Groups balanced for age, gender, education level, reason for admission, cigarettes per day, Fagerstrom score, years of smoking, quit attempts, motivational readiness to quit smoking, self-efficacy, and preference for cessation assistance	**Statistical analysis:** • Baseline subject characteristics - ***t*** tests for continuous variables and chi-square tests for categorical variables. • Primary analysis- a Fisher's exact test was used to compare 3-month and 1-year rates A secondary analysis univariate and multivariate logistic regression procedures **Data verification:** Self-reported with a random sample of 25 tested for CO levels **Dependent variables:** • Demographic factors • reason for admission • smoking history • nicotine dependence • self-efficacy • motivational readiness variables	At 3 months stepped-care treatment increased smoking cessation rates from 42% to 53% during a 3-month follow-up period ($P = 0.05$) 1-year follow-up minimal intervention group of 36% versus 39% for the stepped-care group ($P = 0.36$)	**Quality rating:** Good **Comments:** • Well-thought out design • Well reported **Adequate randomization:** Yes **Attrition rate:** **C1:** 19.5% **G1:** 9.5%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Rowe et al., 1999 **Geographic area:** United Kingdom **Funding agency:** NR **Study setting:** Worksite	**Study objective:** To evaluate effectiveness of offering an individualized approach to smoking cessation to qualified nurses and student nurses in Northern Ireland **Population:** • Adults **Study type:** Cohort study **Inclusion criteria:** • Qualified nurse ("nurse") or student nurse • Smoked at least one cigarette daily • Expressed desire to quit smoking • Agreed to participate in study as an intervention or control participant **Exclusion criteria:** Did not meet all inclusion criteria	**Sampling plan:** • Nurses and student nurses from a college of nursing and a large hospital trust who self-identified as smokers and wanting to quit were invited to participate in study • Participants could choose to be in intervention group or control **Sample size:** **G1:** 22 (nurses) **G2:** 32 (Student nurses) **C1:** 23 (nurses); 33 (student nurses) **Definition of smoking:** Cigarettes • Unclear, but to enroll, had to report smoking at least one cigarette daily (also see Dependent Variables section)

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by Health professional • Social support **Intervention:** **G1:** (Qualified nurses): received individual counseling to: (1) assess health beliefs and motivation to quit smoking; (2) plan and implement strategy for quitting (set quit date, discuss coping strategies, identify social support, keep smoking success and failure diary) and make subjects aware follow up would occur at 6 wks, 6 months, 1 yr postintervention. **G2:** (Student nurses): Same intervention as G1 **C1:** (Qualified nurses) and C2 (Student nurses) received no smoking cessation counseling or assistance, but were followed up at 6 months and 1 yr postenrollment **Method of assessment:** Self-report on questionnaires and biochemical verification of non-smoking status Followup conducted at 6 wks postintervention for intervention groups, at 6 months and 1 yr for both intervention and Cs **Definition of smoking:** Cigarettes • Unclear, but to enroll, had to report smoking at least one cigarette daily (also see Dependent Variables section)	**Statistical analysis:** Frequencies Fisher's Exact Test Qualitative data **Data verification:** Self report of smoking status For those reporting no smoking, verified through CO in expressed alveolar air (2-10 ppm = non-smoker; 11-60 ppm = smoker) and through salivary cotinine concentrations (20 ng/ml = non-smoker) **Dependent variables:** • Verified quit rate • Perceptions of smoking and health • Perceptions of their health promotion role **Baseline data:** Nurses: G1 and C1 similar (age 23-56 yrs; 45% of G1 and 49% of C1 had spouses, partners, or parents who smoked; 95.5% female) G1 and C1 similar in smoking history (89% began smoking before nursing, 64% smoked 20 cigarettes daily; 82% had been smoking more than 10 yrs) 68% G1 vs100% C1 tried to quit smoking previously (no test)	Verified quit rate: **G1:** 22.7% vs 8.6% (C1) $P < 0.05$ **G2:** 25% vs 6% in C2 $P < 0.05$	**Quality rating:** Poor **Comments:** Participants self-selected to intervention and comparison group status; at 1 yr followup, participants self-selected whether to answer a questionnaire for smokers or for non-smokers; motivation and determination to quit smoking higher among intervention groups vscomparison groups, factors not controlled for in analyses; not given all data regarding intervention vscomparison groups (sometimes %s given, but not per group status) **Adequate randomization:** Not a RCT, but problematic group membership because participants self-selected into intervention or comparison group per their desire to receive smoking cessation assistance (intervention groups) or to try to stop smoking on their own (comparison group) **Attrition rate:** At 1 yr, 5% overall (no further attrition detail provided and unable to determine from tables presented)

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Rowe et al., 1999 (continued)		

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
	Student nurses: 62% b/w 17-21, range 17-36; 60% had family members who smoked; 91% female; 91% single (no further detail by group) 97% of G2 and 94% C2 began smoking before entering nursing; range of smoking = 1-10 yrs, 68% smoked b/w 1- 6 yrs 88% G2 and 73% C2 smoked 10-20 cigarettes daily About 75% of each group had tried to stop smoking at least once before 100% of G2 and C2 accepted smoking did or might influence their or their family's/friends' health 78% of G2 and 45% C2 experiencing some ill health effect of smoking # Perception of role as health promoter: **G1:** 100% **C1:** 96% **G2:** 94% **C2:** 82% (no test) All Groups: Motivation to quit smoking ("want to very much" or "would like to"): **G1:** 100% vs **C1:** 65%, $P < 0.01$ **G2:** 61% vs C2: 61% ($P < 0.01$)		

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Saules, et al., 2004 **Geographic area:** US **Funding agency:** National Institute on Drug Abuse and State of Michigan **Study setting:** Population-based	**Research objective:** To test effect of fluoxetine on smoking cessation in the context of a program that includes group cognitive-behavioral therapy (6 weeks) and transdermal nicotine patch (10 weeks) **Population:** Adults **Study type:** Randomized, double-blind, placebo-controlled trial **Inclusion criteria:** • Adults 21-65 • Smoking > 15 cigarettes/day • Producing CO. 15ppm **Exclusion criteria:** • Candidates in acute psychiatric crisis • Met criteria for apsychieatric disorder within the past six months • Were currently taking psychiatric medications • Clinically significant medical conditions • Pregnant • Inability to comprehend and respond to measures	**Sampling plan:** • Participants recruited by flyers and notics distributed throughout the university and through paid advertisements in local newspapers and radio stations. • Telephone screening of all respondents. • Candidated attended a screening visit at which expired CO reading were required to be greater ahn or equal to 15 ppm. **Sample size:** **G1:** 51 **G2:** 51 **C1:** Placebo Note: planned sample size was 168 with 56 participants per arm **Definition of smoking:** Self-reported smoking of any cigarettes at all (or even part of one cigarette), CO greater than or equal to 10 ppm

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Pharmaceuticals: fluoxetine and transdermal NRT • Cognitive-behavioral counseling (CBT) **Intervention:** **G1:** Fluoxetine (20mg) 4 weeks before quit date, changed to 40 mg fluoxetine after one week, CBT starting 2 weeks before quit date and 15 mg NRT patch on morning after quit date visit **G2:** Fluoxetine (20mg) 4 weeks before quit date and for 15 weeks total, CBT starting 2 weeks before quit date and 15 mg NRT patch on morning after quit date visit **C1:** Placebo and CBT starting 2 weeks before quit date and 15 mg NRT patch on morning after quit date visit **Method of assessment:** NR **Baseline data:** No significant differences across groups except for significant differences in baseline depression with elevated levels among those randomized to placebo.	**Statistical analysis:** Chi-square analysis **Data verification:** Expired CO of less than 10 ppm obtained for self-reported quitters **Dependent variables:** Documented nonsmoking: self-reported abstinence combined with CO less than 10 ppm	No significant differences observed in smoking status at end of trial (assuming that end of trial was at 12-months post quit date although time frame is not stated in the article text or table for these assessments): **C1:** 35.4% **G1:** 43.1% **G2:** 43.1% Change in weight was significant for treatment group (P = 0.010), smoking cessation (P = 0.037) and their interaction (P = 0.012). Withdrawal symptom scores were significantly lower in both fluoxetine groups as compared to the placebo group (P = 0.038)	**Quality rating:** Fair **Comments:** Random assignment method NR **Adequate randomization:** NR **Attrition rate:** 40% Drop-out was related to smoking status, as 90% of the people who did not complete the study had documented smoking at their last assessment whereas only 32% of those who completed the study had documented smoking at the last assessment ($X^2(1)=9.94$, P = 0.002)

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Simon et al., 2004 **Geographic area:** United States **Funding agency:** California Tobacco-Related Disease Research Program **Study setting:** Hospital	**Research objective:** Whether the addition of bupropion to transdermal NRT and cognitive-behavioral counseling would increase quit rates compared with standard therapy using NRT and cognitive-behavioral counseling only **Population:** Adults **Study type:** RCT **Inclusion criteria:** • Smoked 20 or more cigarettes during the week prior to enrollment • Have a telephone and no plans to leave the catchment area during the study period • In the contemplation or preparation stages of quitting according to the Prochaska and DiClemente Stages of Change model • ≥ 20 years of age **Exclusion criteria:** • Contraindications to bupropion or NRT • Serious psychiatric illness including major depression • History of alcohol abuse within the past three months or consuming more than 3 alcoholic beverages per day	**Sampling plan:** Participants were recruited from the three following sources: • Lists of known smokers from previous smoking cessation clinical trials at the San Francisco VA Medical Center • Hospital-based advertising at major teaching hospitals • Local Bay Area advertising and PSAs Eligible smokers were assessed for their readiness to quit smoking Subjects in the contemplation or preparation stages of quitting were randomized to either treatment or control arm **Sample size:** 244 adults **Definition of smoking:** Non-smoker • Self-report of no smoking for the past seven days during each follow-up counseling call • Follow-up self report of no-smoking in the past six months and twelve months • Among those who reported no smoking at 12 months, follow-up saliva cotinine level had to be less than 15 ng/ml Continous non-smoker • Self-reported quitting at each follow-up assessment, and biochemical or proxy verification of no smoking at 12 months Smoker • Self-reported no smoking but using NRT and salivary cotinine levels >= 15 ng/ml • Stopped smoking cigarettes but using other tobacco products

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Bupropion • Transdermal nicotine replacement therapy • Cognitive-behavioral counseling **Intervention:** **G1:** 7 week course of Bupropion, 2 months transdermal nicotine replacement therapy, 1 visit with counselor (30-60 minute session), and 5 telephone follow-up calls **C1:** Same as G1 except participants received placebo instead of Bupropion **Method of assessment:** Follow-up at 7 weeks (end-of treatment), 3 months, 6 months, and 12 months by telephone **Baseline data:** No statistically significant differences in any of the baseline demographic of medical characteristics between the samples in the 2 study arms Males: 86%	**Statistical analysis:** • 2-sample t tests and Wilcoxon rank sum tests for continuous variables • Chi square tests for categorical variables • Calculated relative risk and 95% CIs • For multi-variate analysis, used backward stepwise procedure to examine relationship between demographic and historical variables and smoking cessation • Variables were retained in the model if they remained associated with quitting at $P \leq 0.20$ • All regression models were adjusted for treatment assignment • Hosmer-Lemeshow goodness-of-fit test was used to assess adequacy of the models • 2-tailed P values < 0.05 were considered significant **Data verification:** Self-report plus cotinine saliva for those who self-reported quitting at the 12 month followup **Dependent variables:** Quit rates	No statistically significant differences in smoking cessation rates at end of medication 3, 6, and 12 months The addition of 7-week treatment with Bupropion did not significantly increase quit rates over NRT and counseling	**Quality rating:** Fair **Comments:** No power analysis **Adequate randomization:** Yes **Attrition rate:** • 1% lost to followup • 2% died

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Swan[a], et al., 2003 and Swan[b] et al., 2003 **Geographic area:** US, Seattle **Funding agency:** National Cancer Institute Bupropion SR provided by Group Health Cooperative Pharmacy **Study setting:** Non-profit consumer-governed health care system serving 600,000 residents of western Washington (GHC)	**Research objective:** Swan:[a] To identify individual characteristics predictive of more clinically relevant smoking end-points beyond end of treatment in smokers prescribed bupropion SR and counseling. Swan:[b] To determine the differential effectiveness of 2 doses of bupropion in combination with behavioral interventions of minimal to moderate intensity. **Population:** • 18 years of age or older **Study type:** • Data from a large, randomized effectiveness trial • Two dosage levels of bupropion SR (Zyban, 150 and 300 mg) were crossed with two behavioral treatment programs of lower or higher intensity to create a four-cell design. **Inclusion criteria:** • Individuals at least 18 years of age • Smoking an average of 10 or more cigarettes per day in the 12 months prior to enrollment • Motivated to stop smoking • Otherwise in good general health and had proper GHC coverage **Exclusion criteria:** • Predisposition to seizure • Current use of medications contraindicated for use with bupropoion SR or know to lower seizure threshold • History of or current diagnosis of anorexia nervosa or bulimia or presence of any severe chronic medical condition • Use of any investigational drug within 1 month of treatment with buropion SR • Participation in GHC's Free and Clear smoking cessation program in the previous 12 months • Current depression • Recent high frequency or binge drinking • Abuse of other substances including recreational/street drugs • Current pregnancy or plans to become pregnant • Current nursing of a child	**Sampling plan:** • Participants who called the study center were screened over the telephone. • Eligible volunteers were sent a pretreatment questionnaire and consent form. • Participants were randomly assigned to 4 treatment arms by a computer-generated number. • The computer code calculated probabilities of group assignment that were dynamically modified based on the number of members in each group so that final group sizes were equal. • No restrictions such as stratification or blocking were used in the process. **Sample size:** **G1:** 382 **G2:** 381 **G3:** 383 **G4:** 378 **Definition of smoking:** • Any smoking within the past 7 days (7 day point prevalence)

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Pharmacologic treatment • Tailored mail program (ZAP) • Proactive telephone counseling program (Free and Clear Program) **Intervention:** **G1:** 150 mg bupropion SR and proactive telephone counseling (Free and Clear Program) **G2:** 150 mg bupropion SR and tailored mail (Zyban Advantage Plan - ZAP) **G3:** 300 mg bupropion SR and proactive telephone counseling (Free and Clear Program) **G4:** 300 mg bupropion SR and (ZAP) **Method of assessment:** 3- and 12-month follow-up **Baseline data:** • Reported by gender not treatment condition. • Men had significantly more years of formal schooling, smoked more cigarettes per day, had higher number of previous attempts to quit. • Women significantly more likely to report perceived stress, social support depression, ever having depression in lifetime or percentage of family ever depressed.	**Statistical analysis:** • Intent-to-treat analysis • Logistic regression for assessing pretreatment characteristics for their relationship to point-prevalent smoking at 12 months **Data verification:** Self-report **Dependent variables:** • Smoking: any smoking within the 7 days prior to follow-up	**Swan 2003a** At 12-month follow-up, type of behavioral treatment had a strong association with point-prevalent smoking (e.g., participation in the less-intensive TM program being associated with a greater likelihood of smoking) whereas dose and the dose x treatment interaction had little or no association with outcome OR=1.21 (95% CI, 1.08 - 1.35). **Swan 2003b** • At 3 months: 300mg **G3:** 35% vs 150 mg **G1:** 24.4% (*P*=0.001); 300mg **G3:** 35% vs 150mg **G2:** 24.2% (*P* =0.001); 300mg **G3:** 35% vs 300mg G4= 26.7% (*P* =0.01) ▪ At 12 months: 300mg **G3:** 33.2% vs 150mg **G2:** 23.6% (*P* =0.004) 300mg **G3:** 33.2% vs 300mg **G4:** 25.7% (*P* =0.02) 150 mg **G1:** 31.4% vs 150mg **G2:** 23.6% vs (*P* =0.02)	**Quality rating:** Fair **Comments:** • Lack of blinding • No biochemical confirmation of self-reported smoking status • No objective measurement of adherence to the therapeutic regime **Adequate randomization:** NR **Attrition rate:** • 3-month follow-up: 20.8% • 12-month follow-up: 14.9%

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Wakefield et al., 2004 **Geographic area:** South Australia Funding agency: National Health and Medical Research Council **Study setting:** Hospital-based	**Research objective:** To determine whether a motivational interviewing intervention increased successful smoking cessation attempts of patients with cancer attending a South Australian public hospital, as compared with usual care **Population:** • Cancer patients at South Australian public hospital **Study type:** RCT **Inclusion criteria:** • Participant must have a cancer diagnosis • Smoke tobacco more than weekly • Speak English • Be cognitively able to consent • Have a prognosis exceeding 6 months • Live close enough to maximize biochemical confirmation at follow-up assessment* (changed to include patients living remotely to increase participation numbers) **Exclusion criteria:** See above	**Sampling plan:** • Patients were screened by doctors after scheduled appointments in the radiation therapy, medical oncology, and hematology departments at Royal Adelaide Hospital over 20 month period • After several months, accrual of participants too slow, so patients living remotely were approached to increase numbers • Once patients consented to participate, they completed a baseline questionnaire • 6-month follow up interviews were done and those who said had stopped smoking were asked to provide either a urine sample for cotinine analysis or a CO reading using a breath monitor **Sample size:** **G1**: 74 **C1:** 63 **Definition of smoking:** Tobacco • Current Smoker – Smoke tobacco at least weekly

Evidence Table 5. Strategies to improve success rates for quit attempts for general and special populations (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Visit with smoking cessation counselor • Booklets • NRT • Family advice to quit • In-person or telephone follow-up conversation **Intervention:** **G1:** Specific advice and booklets about benefits of quitting for patients with cancer, telephone and in-person counseling using the framework of motivational counseling, supplemented with NRT if patient smoked ≥15 cigarettes per day **C1:** brief advice to quit, widely-available quit-smoking brochures, and info about well-promoted state-based telephone quit-line service Method of assessment: In-person follow up visit or telephone assessment at 6 months post-baseline **Baseline data:** Patients in intervention group were more likely than control patients to have ever tried to quit (P = 0.04) and to have made more quit attempts in the past year (P = 0.02) Control patients were more likely to live remotely (P = 0.04)	**Statistical analysis:** • Data were analyzed using SPSS • Fisher's exact tests and chi-square tests were used to establish whether groups differed significantly across categorical variables, and t-tests were used for continuous variables • An intention to treat analysis was used, as well as an analysis excluding those lost to follow-up evaluation • Phi coefficients were calculated to determine the degree of association between the intervention and control groups across variables • Binary logistic regression was used to examine predictors of smoking cessation **Data verification:** Self-report, urine cotinine and CO levels **Dependent variables:** • Quit rates – 3 month period prevalence, 7-day period prevalence	**Outcome Measures:** • At 6-month follow up, no difference in biochemically confirmed 3-month prevalence quit rates between the intervention (5%) and control (6%) groups • Sensitivity analysis using more lenient criteria indicated quit rates of 29% for intervention group and 18% for control group (P = 0.32) • Predictors of smoking cessation at 6 months for all patients included a smoking-related cancer site, more cessation attempts in the year before the enrollment study, and no radiation therapy	**Quality rating:** Poor **Comments:** Study lacked power, had a high attrition rate and there were significant differences in groups at baseline **Adequate randomization:** No **Attrition rate:** 36%

Evidence Table 6. Community strategies to increase the implementation of proven population-level tobacco use cessation strategies

Study Characteristics	Study Design	Sample Design and Definitions
Author: Borland et al., 2003 **Geographic area:** Australia **Funding agency:** NHMRC grant, supplemented by The Cancer Council Victoria; callbacks funded by Quit Victoria **Study setting:** Population-based	**Study objective:** To assess effectiveness computer-generated tailored advice for callers to telephone helpline; to assess if it enhanced series of callback telephone counseling sessions in aiding smoking cessation. **Population:** • Adolescents • Young adults • Adults **Study type:** RCT w/ simple randomization Randomization done by shuffling questionnaires **Inclusion criteria:** • English-speaking • No obvious psychiatric or neurological problems • Called quitline b/w October 1996 and August 1997 **Exclusion criteria:** • Small # of callers who sought callback service proactively after self-help materials offered	**Sampling plan:** Recruited eligible callers of Victorian Quitline telephone counseling and advice service **Sample size:** **G1:** 523 **G2:** 528 **C1:** 527 **Definition of smoking:** NR

Evidence Table 6. Community strategies to increase the implementation of proven population-level tobacco use cessation strategies (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Telephone counseling • Computer-based program **Intervention:** **G1:** Offered a 'Quit Pack' and a series of 3 computer-generated tailored letters **G2:** Offered a 'Quit Pack'and a series of 3 computer-generated tailored letters and callback counseling service **G3:** NR **C1:** Offered a 'Quit Pack', printed self-help materials consisting of: a 30 pg booklet based on stage of disease, leaflets promoting smoking cessation courses and card w/ strategies to reduce cravings **Method of assessment:** Baseline interview; mailed survey at 3, 6, and 12 months post baseline	**Statistical analysis:** Data analyzed using SPSS ITT analysis **Data verification:** NR **Dependent variables:** • Self-reported smoking status at 3-, 6-,and 12-month followups, both point prevalence and 9 months' sustained absitinece • Duration of cessation • Use of nicotine replacement • Extent of participation in callback **Baseline data:** Smoked average of 22.8 cigarettes/day: Prepartion stage: 45% Contemplation stage: 54% Groups similar at baseline by gender, age, education, level of addiction, stage of readiness, quit attempts in past yr	Quit attempts w/ 95% CI **G1:** 56% (51.3-60.7) **G2:** 62.8% (58.2-67.4) **C1:** 57.4% (52.5-61.5) Smoking point prevalence at 12-mo followup: **G1:** 22.6% (18.5-26.7) **G2:** 25.6% (21.3-29.9) **C1:** 22.1% (18.1-26.1) Chi sq 1.5, *P* 0.46	**Quality rating:** Good **Comments:** Groups similar at baseline in spite of suboptimal randomziation scheme **Adequate randomization:** Yes **Attrition rate:** Overall: 23.4% **G1:** 23.1% **G2:** 25.9% **C1:** 21.1%

Evidence Table 6. Community strategies to increase the implementation of proven population-level tobacco use cessation strategies

Study Characteristics	Study Design	Sample Design and Definitions
Author: Maguire et al., 2001 **Geographic area:** United Kingdom **Funding agency:** Medical Research Council and the Northern Ireland DHSS **Study setting:** Community-based	**Study objective:** To evaluate whether a structured community pharmacy-based smoking cessation program would result in a higher smoking cessation rate compared to ad hoc advice from pharmacists **Population:** • Adults **Study type:** • RCT w/ systematic randomization • Comparing a structured intervention w/ usual care **Inclusion criteria:** • More than 18 yrs of age • Not pregnant • Expressing a wish to stop smoking **Exclusion criteria:** • NR	**Sampling plan:** • 100 pharmacists working in community pharmacies in N. Ireland and 24 in London participated in study • Each asked to enroll 12 smokers Pharmacists promoted study to: • People who used pharmacy for non-medical reasons, using window displays, posters in-pharmacy and leaflets at cash registers • People reporting and asking for advice on minor ailments, e.g. chest cold, asking them about smoking and telling them about program • People being dispensed medicines, asking them about smoking and telling them about program **Sample size:** **G1:** 265 smokers **C1:** 219 smokers **Definition of smoking:** NR

Evidence Table 6. Community strategies to increase the implementation of proven population-level tobacco use cessation strategies (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Media campaign • Pharmaceuticals **Intervention:** **G1:** Initial interview lasting b/w 10 and 30 minutes; smoking cessation contract; indication for NRT assessed and offered if appropriate; leaflet; weekly followup for 4 wks, then monthly followup for 3 months **C1:** Normal pharmaceutical service (including provision of NRT as appropriate) provided by pharmacist **Method of assessment:** • Telephone interviews at 3, 6, and 12 mos • Urinary cotinine assessed to validate self-reported non-smoking at 12 mos • Qualitative assessments also conducted using semi-structured telephone interviews and focus groups	**Statistical analysis:** NR **Data verification:** Urinary cotinine assessed to validate self-reported non-smoking at 12 months **Dependent variables:** Smoking status **Baseline data:** Numbers given but no tests for significance	Self-reported non-smoking status at 3-month followup: **G1:** 27.5% **C1:** 11% Self-reported non-smoking status at 6-month followup: **G1:** 18.5% **C1:** 8.2% Self-reported non-smoking status validated by urinary cotinine (50 ng/ml) at 12-month followup: **G1:** 14.3% **C1:** 2.7% $X^2 = 16.2$ $P = <.001$	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** Yes **Attrition rate:** **G1:** 10.2% **C1:** 14.2%

Evidence Table 6. Community strategies to increase the implementation of proven population-level tobacco use cessation strategies

Study Characteristics	Study Design	Sample Design and Definitions
Author: Ronda et al., 2004 **Geographic area:** Western Europe **Funding agency:** Netherlands Heart Foundation **Study setting:** Community-based	**Study objective:** To assess whether Hartslag community smoking cessation intervention resulted in increased smoking cessation in Maastricht region as compared to control region **Population:** • Adults **Study type:** • Cohort Study • A pretest–posttest C design w/ two posttests **Inclusion criteria:** • Over 18 yrs old • Living in intervention or control regions **Exclusion criteria:** • NR	**Sampling plan:** A cohort research population of 1,200 smokers (age 18 and over) recruited in each region by taking a stratified random sample of 6,500 inhabitants in each region from computerized telephone registers, based on number of inhabitants i n each municipality included in region **Sample size:** **G1:** 4,242 (35.4% of whom were smokers) **C1:** 4,697 (34% of whom were smokers) **Definition of smoking:** Cigarettes • Smoker: smoked at all in last 7 days

Evidence Table 6. Community strategies to increase the implementation of proven population-level tobacco use cessation strategies (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Telephone counseling • Media campaign **Intervention:** **G1:** Regional mass media-led smoking cessation campaign Proficiat (Congratulations) implemented in January and February 2000 and 2001, consisting of radio commercials, advertisements and messages in papers, billboards along roads, and posters and postcards in waiting rooms and public buildings; local activities organised by working groups consisting of representatives of local organizations, such as a non-smoking campaign for parents of children in playgroups **C1:** National mass media-led smoking cessation campaign Dat kan ik ook (I can do that too) implemented around the turn of the century, consisting of various television programmes, an info line, non-smoking courses, mailings to variousorganizations, billboards in bus shelters, brochures, posters **Method of assessment:** Short structured telephone interviews	**Statistical analysis:** • Multiple logistic regression analysis conducted to identify potential dropout bias (w/ attendance v. dropout as the dependent variable and baseline values for gender, age, education, and condition as independent variables) • Multiple logistic regression analysis used to identify potential baseline differences b/w G1 region and control region • Independent variables in this analysis were baseline values for gender, age and education • Only respondents who completed all surveys included • Analyses performed using SPSS 10.0 **Data verification:** NR **Dependent variables:** Primary: smoking status Secondary: intention to quit, cessation self-efficacy, perceived social support for cessation **Baseline data:** Respondents from G1 region significantly older, more often female, and more highly educated than respondents from control region	**Outcome measures:** No significant differences found b/w G1 and control regions regarding smoking status and determinants of smoking behavior	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** NR **Attrition rate:** 37.9%, net attrition after excluding unreachable respondents from T0 to T2 18.7%

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Cornuz et al., 2002 **Geographic area:** Western Europe **Funding agency:** Swiss Federal Office for Public Health, Swiss Medical Association, Swiss Foundation for Health Promotion **Study setting:** Practice/provider settings	**Study objective:** To assess efficacy of an educational program based on behavioral theory, active learning methods and practice w/ standardized patients for internal medicine residents in helping patients abstain from smoking and changing counseling practices **Population:** • Young adults • Adults **Study type:** RCT w/ cluster randomization **Inclusion criteria:** • 16 to 75 yrs old • Understood French • Consulted an outpatient clinic for a followup or an emergency visit • Had smoked 1 or more cigarettes daily during previous wk **Exclusion criteria:** • NR	**Sampling plan:** • 35 residents at 2 general medicine clinics randomly assigned by computer and stratified by clinic to either intervention group trained in smoking cessation or C trained in dyslipidemia • Patients screened for eligibility by research assistants • Eligibile patients asked for written informed consent to participate in a study about preventive care **Sample size:** **G1:** 17 residents, 115 patients **C1:** 18 residents, 136 patients **Definition of smoking:** Cigarettes • 1-wk point prevalence of abstinence: no smoking in last wk

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional **Intervention:** **G1:** Intervention training program for residents based on active learning of counseling skills and interventions that matched patients' readiness to quit; after training, residents supposed to reach the following objectives: Systematically identify all smoking patients, clearly advise smokers to quit, assess each smoker's readiness to quit, use applied counseling strategies and offer a brochure that matched patient's stage of readiness, propose an individual smoking cessation program, follow smokers in short and long term, and facilitate implementation of smoking cessation in routine practice; received control training 4 months later, after 3 month patient recruitment period had ended **C1:** Traditional diadactic training program on management of dyslipidemia; received intervention training 4 months later, after 3 month patient recruitment period had ended **Method of assessment:** Baseline information collected by research assistant immediately after a patient's medical visit; 1-yr followup survey administered by mail; self-reported abstinence validated at one clinic by measurement of exhaled CO by a research assistant blinded to group allocation	**Statistical analysis:** To compare baseline data, X^2 and Fisher exact tests used for categorical data and t-test and Wilcoxon rank-sum test used for continuous data; to measure outcomes, logistic regression performed w/ a generalized estimating equation to stratify by clinic and adjust for clustering by resident; all statistical analysis performed using STATA **Data verification:** Self-reported abstinence validated at one clinic by measurement of exhaled CO by a research assistant blinded to group allocation **Dependent variables:** Primary: Smoking status Secondary: Counseling score, willingness to quit, daily cigarette consumption **Baseline data:** • Both groups of residents similar at baseline • Both groups of patients similar at baseline	At one-yr followup, 1-wk point prevalence of abstinence: **G1:** 13% (95% CI, 7% to 21%) **C1:** 5% (95% CI, 1% to 9%) *P* = 0.005 OR = 2.8 (95% CI, 1.4 to 5.5) Residents who recieved study training provided better counseling (mean score 4 vs2.7, *P* = 0.002) Smokers willingness to quit higher in IG (94% vs80%, *P* = 0.007) No significant trend toward lower daily cigarette consumption in G1.	**Quality rating:** Fair **Comments:** No comments **Adequate randomization:** Yes **Attrition rate:** Loss to followup at 1 yr: **G1:** 33% **C1:** 26.5%

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation

Study Characteristics	Study Design	Sample Design and Definitions
Author: Goldstein et al., 2003 **Geographic area:** US **Funding agency:** NCI **Study setting:** Community-based Practice/provider settings	**Study objective:** To determine effect of a community-based academic detailing intervention on quit rates of a population-based sample of smokers **Population:** • Adults **Study type:** • Cross-sectional • Community-based, quasi-experimental study **Inclusion criteria:** • Physicians eligible if they practiced a primary care specialty (i.e., family medicine, internal medicine, obstetrics /gynecology), provided primary care for at least 25% of their patients, completed postgraduate training, and planned to practice in the state for the 3 study yrs • Patients recruited through random digit dialing • Patients must be 18 to 75 yrs old • Live in a household w/ a phone • Current smokers **Exclusion criteria:** • Full-time hospital-based physicians excluded • Only one smoking patient per household included	**Sampling plan:** • A list of all licensed physicians obtained from Rhode Island Department of Health, Folio's Medical Directory of Rhode Island, 1990, and local health care institutions • Physicians received mailed invitations followed by postcards, and then phone calls from physician recruiters • Principal Investigator contacted nonresponders to complete recruitment process • All physicians providing direct care to adults in Newport, Washington, and Kent counties targeted for participation in intervention and delayed intervention (control) arms of PCS trial **Sample size:** **G1:** 376 patients **G2:** 385 patients **G3:** 332 patients **C1:** 1253 patients **Definition of smoking:** Cigarettes • Smoker: currently smokes cigarettes

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Multi-component office-based intervention • Academic detailing **Intervention:** **G1:** Physicians provided 4 A's to patients **G2:** Smokers provided w/ computer-generated, stage-tailored information about quitting smoking at home **G3:** Physician delivered 4 A's to patients, and patients received computer-generated, stage-tailored smoking cessation information at home **C1:** No intervention **Method of assessment:** Telephone survey at 6, 12, 18, and 24 mos	**Statistical analysis:** • Descriptive statistics (mean, median, proportions) used to characterize study sample at baseline and to examine demographic differences b/w study groups which might confound study outcomes at 24 months • Multivariate logistic regressions done to examine differences in smoking status at 24 mos **Data verification:** NR **Dependent variables:** Self-reported smoking status **Baseline data:** • Those residing in physician intervention areas (G1 & G3) less likely to be less than HS educated and more likely to be college educated than C • C more likely to be in preparation state of change for cessation than intervention groups • Those visiting physicians more likely to be older female, higher education, report poorer health	Percentage of patients who quit smoking at 6-month followup: **G1:** 8.4 **G2:** 7.6 **G3:** 8.9 **C1:** 7.1 *P* = NR Percentage of patients who quit smoking at 12-month followup: **G1:** 17.0 **G2:** 16.5 **G3:** 16.9 **C1:** 16.1 *P* = NR Percentage of patients who quit smoking at 18-month followup: **G1:** 25.2 **G2:** 24.8 **G3:** 19.2 **C1:** 20.0 *P* = NR Percentage of patients who quit smoking at 24-month followup: **G1:** 33.3 **G2:** 26.3 **G3:** 25.7 **C1:** 22.6 *P* = 0.006	**Quality rating:** Fair **Comments:** **Adequate randomization:** NR **Attrition rate:** At 24 mos, of 2346 participants, 35% attrition in controlled/delayed G1, 35% attrition in physician only IG, 35% attrition in physician and home G1

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Joseph, Arikian, et al., 2004 **Geographic area:** US **Funding agency:** Veterans Administration Health Services Research and Development Service (CPG 97-039) **Study setting:** Provider-based	**Research objective:** To test the effect of modest intensity, practical systems change that might increase delivery of smoking cessation treatment within Veterans Affairs. **Population:** • Adults (N = 5,678) • 20 Veteran Affairs Medical Centers (results from this analysis were not used because sample size too small) **Study type:** • Cross-sectional design (individual analysis) • RCT w/ simple randomization (organizational analysis) **Inclusion criteria:** • Existence of referral-based smoking cessation program that treated a minimum of 50 patients/year, information resource management capacity for data collection, institutional review board, and evidence of commitment to participation in the project **Exclusion criteria:** • Facilities serving predominatly psychiatric patients, or displayed communication problems.	**Sampling plan:** • Telephone surveys were conducted among 3 cohorts of patients • A cross-sectional survey was conducted at baseline among a sample randomly selected from patients who had seen their primary care provider within 6 months (preintervention) • A second cross-sectional survey sample was obtained 1 year after the intervention using the same sampling technique (post intervention) • Preintervention smokers at baseline were surveyed 1 year after intervention • Medical records reviewed 6 months before intervention and 6 months following intervention for all subjects who provided consent and smoked and a random sample of equal size of subjects that did not smoke. **Sample size:** Total: 5,678 Adults Preintervention **G1:** 2,112 **C1:** 2,142 Post intervention **G1:** 641 **C1:**783 **Definition of smoking:** Cigarettes • Current smokers

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Multicomponent intervention **Intervention:** **G1:** Received documentation of tobacco use status in medical records; delivery of intervention to all smokers; liberal use of smoking cessation medication; organizational support; site visits; 2 day training meeting; an interventionist at coordinating site. **C1:** NR **Method of assessment:** Medical record review and telephone survey **Baseline data:** No differences at baseline between intervention and control group sites.	**Statistical analysis:** • A McNemar odds on change was calculated to assess difference in change between the intervention groups • The significance of the resulting odds was computed by the Pearson chi square • For continuous variables measured at facility level a Wilcoxon rank sum test was used. **Data verification:** Self-report (no biochemical verification) and medical record review **Dependent variables:** • Smoking status • General health • Nicotine dependence • Services provided at last visit to primary care provider • Mood • Alcohol use • Demographics	**G1:** 11.4% quit smoking **C1** 13.2% quit smoking, NS No effects of the intervention on change scores between groups for reporting that their provider asked about smoking, or being counseled to quit at 1 year post intervention Intervention had no effect on smokers' report of being counseled to quit Smokers only group, 30% of smokers in G1 were counseled before the intervention and 44% counseled after the intervention; C1 smokers counseled 39.1% before intervention and 42.2% post intervention. Amomg smokers who had a change in counseling before and after the intervention, the subjects in the intervention group had 2 times the odds of being counseled relative to controls (OR=2.24, 95% CI, 1.17 to 4.28, *P*=.014). Medical records: Post intervention had a significant effect on smoking status documentation where intervention records were more likely to document smokers (67% vs 60%, *P*=.0007) Smokers were more likely to be documented as smokers than non smokers were to be documented as nonsmokers	**Quality rating:** Fair **Comments:** • Organizational level analysis was not used (N = 20) **Adequate randomization:** Yes for VA hospitals only not individual subjects **Attrition rate:** • Pre-intervention = 21% • Smokers followup = 13% • Post- intervention = 16%

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation

Study Characteristics	Study Design	Sample Design and Definitions
Author: Katz et al., 2004 **Geographic area:** US **Funding agency:** National Cancer Institute and University of Wisconsin Comprehensive Cancer Center. **Study setting:** Community-based Practice/provider settings	**Study objective:** To compare MAs' and LPNs' performance of recommended smoking cessation activities w/ that of RNs **Population:** • Adults **Study type:** • Secondary analysis of data from a RCT of guideline implementation • Intake clinicians (RNs, LPNs, MAs) paired w/ primary care physician (PCP) • Clinic randomized to receive help implementing AHRQ cessation guidelines vs control • Patients interviewed after clinic visit **Inclusion criteria:** • NR **Exclusion criteria:** • NR	**Sampling plan:** NR **Sample size:** **G1:** 724 patients By intake clinician: RN: 100 LPN: 154 MA: 470 **C1:** 497 patients By intake clinician: RN: 153 LPN: 256 MA: 88 **Definition of smoking:** Cigarettes • At least one per day on average

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Individual counseling by non health professional • Telephone counseling **Intervention:** **G1:** In original RCT: study personnel worked w/ intake clinicians to implement guideline intervention (tutorial w/ feedback, real-time reminder, self-help material, onsite pharmacotherapy, and proactive telephone counseling) • Survey administered to intake clinicians immediately preceeding intervention • After clinic visit, study personnel interviewed consecutive adults who had routine, non-emergency appointment and who smoked ≥ 1 cigarette per day • Patients asked whether they received cessation counseling from intake clinician **C1:** Intake clinicians completed survey just prior to tutorial session at end of intervention period, but had no help w/ guideline implementation **Method of assessment:** Exit interview of patients	**Statistical analysis:** Two-level hierarchical logistic regression **Data verification:** NR **Dependent variables:** Proportion of patients receiving guideline-recommended counseling at time of scheduled clinic visit **Baseline data:** Patients seen by MA vsRN at control site = 57% vs43% male (P = 0.01), and 49% vs71% w/ regular clinician (P = 0.02) Patients seen by MA vsRN at test site = 57% vs75% w/ regular clinician (P = 0.001)	Ask about smoking: Control RN/LPN/MA: 67%/35%/41% vstest site RN/LPN/MA: 92%/86%/78%. Assess willingness to quit: control RN/LPN/MA = 15%/8%/7% vstest site RN/LPN/MA = 85%/75%/60%. Advise to quit: control RN/LPN/MA = 16%/7%/9% vstest site RN/LPN/MA = 41%/46%/28%. Assist in quitting: control RN/LPN/MA = 17%/8%/9% vstest site RN/LPN/MA = 73%/69%/51%. (Also reported as difference in proportion (& 95% CI) b/w RNs and other intake clinicians).	**Quality rating:** Fair **Comments:** Secondary analysis, so study not designed to answer this question Missing important info that's reported in original study **Adequate randomization:** NR **Attrition rate:** NR

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Katz et al., 2004 **Geographic area:** US **Funding agency:** National Cancer Institute; University of Wisconsin; GlaxoSmithKline donated transdermal nicotine patches for use in trial **Study setting:** Provider-based	**Research objective:** To test the effectiveness of a multi-modality intervention to implement the AHRQ Smoking Cessation Clinical Practice Guideline in primary care settings **Population:** Adults **Study type:** RCT **Inclusion criteria:** Adults smoking at least one cigarette per day and having an appointment with a primary care clinician for routine, non-emergency care and willing to complete a brief exit interview immediately after the clinic appointment **Exclusion criteria:** NR	**Sampling plan:** • 12 eligible clinics were invited to participate; 9 clinics agreed to participate; 1 clinic participated only in the pilot phase • Matched clinic sites (8) by primary care discipline and health plan affiliation (if any) • For each pair of clinics, project statistician used a random number generator to randomly assign each clinic to receive either the intervention (test site, n=4) or usual care (control site, n=4) **Sample size:** **G1:** 4 clinics, 1141 patients **C1:** 4 clinics, 1022 patients **Definition of smoking:** 7-day point prevalence

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Multicomponent office based intervention **Intervention:** **G1:** Tutorial for intake clinicians, group and individual performance feedback for intake clinicians, use of a modified vital signs stamp, an offer of free nicotine replacement therapy and proactive telephone counseling. **C1:** Staff received only general information on the AHRQ Guideline **Method of assessment:** Self-reported by telephone interview at 2- and 6-month follow-up **Baseline data:** No statistically significant differences in smoking cessation rates between participants at test and control sites during the baseline period, except in educational level During the intervention period, patients at test sites were older, had more years of education and smoked more cigarettes per day than patients at control sites No significant differences between characteristics of intake clinicians at test sites and those at control sites with one exception, intake clinicians at control sites had more years of work experience than those at test sites	**Statistical analysis:** Hierarchical logistic regression models used to estimate the odds rations for treatment assignment after adjustment for patient characteristics **Data verification:** Self-report and confirmatory salivary cotinine for self-reported quitters **Dependent variables:** • Performance of recommended smoking cessation activities by clinic staff • Abstinence at 2 and 6 months after the initial clinic visit (7-day point prevalence) • Continuous abstinence at 2 and 6 months (self-reported abstinence at both 2 and 6 month assessments)	During the intervention period, more patients at test sites were asked about their smoking status (OR = 3.1; 95%,CI; 1.2 to 8.2; $P = 0.02$) or about their willingness to quit smoking (OR = 6.4, 95%, CI; 3.7 to 10.8; $P < 0.001$), were given literature about quitting (OR = 21, 95%, CI; 8.8to 49; $P < 0.001$), were assisted with setting quit date (OR = 33, 95%, CI;11 to 100; $P < 0.001$) or were engaged in a discussion about pharmacotherapy (OR = 3.9, 95%, CI; 2.5 to6.3; $P < 0.001$). Among participants treated during the intervention period, those at test sites were more likely than those at control sites to report being abstinent at the 2- month (16.4% vs. 5.8%, adjusted OR = 3.3, 95% CI, 1.9 –5.6, $P < 0.001$) and 6-months (15.4% vs 9.8%; adjusted OR = 1.7, (95% CI = 1.2-2.6), $P = 0.009$) follow-up assessments and to report continuous abstinence (10.9% vs 3.8%, adjusted OR = 3.4 (95% CI, 1.8-6.3), $P < 0.001$) With biochemically confirmed abstinence at 6 months, showed no difference between G1 and C1 Very low response rate for planned collection of confirmatory salivary cotinine tests of self-report cessation	**Quality rating:** Good **Comments:** Failed to reach original enrollment target resulting in slightly lower power than originally planned to detect differences in cessation outcomes. **Adequate randomization:** Yes **Attrition rate:** **G1:** 11% **C1:** 10%

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation

Study Characteristics	Study Design	Sample Design and Definitions
Author: Pbert et al., 2004 **Geographic area:** US **Funding agency:** NHLBI **Study setting:** Practice/provider settings	**Study objective:** To evaluate effect of a provider counseling and office systems intervention in obstetric, pediatric, and Special Supplemental Nutrition Program for WIC clinics on smoking and relapse rates in pregnant and postpartum wome **Population:** • Adults • Women (only) • Pregnant women **Study type:** RCT w/ cluster randomization **Inclusion criteria:** • Women receiving prenatal care and WIC services and planning to receive pediatric care at one of community health centers • Speaking English or Spanish • Having at least 2 months before their due date • Being a current smoker or spontaneous quitter (quit smoking after learning of pregnancy) • Planning to remain in area for at least 6 months following delivery **Exclusion criteria:** • NR	**Sampling plan:** • Five community health centers randomized to special intervention or usual care • Research assistants screened women in WIC offices **Sample size:** **G1:** 272 **C1:** 278 **Definition of smoking:** Cigarettes • Abstinence: not smoking within last 7 days • Spontaneous quitter: quit smoking since learning of pregnancy and not smoking for at least 7 days prior to baseline

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Individual Counseling by non Health Professional **Intervention:** **G1:** Clients visited community health centers and WIC offices that received: provider training to deliver a SIbased on national clinical practice guidelines tailored to woman's stage of change and delivered through three channels (obstetric, pediatric, and WIC providers); an office practice management system to routinely screen for smoking status, prompt/remind providers to intervene, document the encounter, distribute materials, and arrange followup; and establishment of program boards to coordinate transfer of documentation among clinics, including periodic meetings w/ representatives from all clinics **C1:** Usual care **Method of assessment:** Data collected from participants at five time points during regular WIC appointments or by telephone: baseline interview upon enrollment, 9-month interview before delivery, 1-month postpartum interview within 30 days after delivery, 3-month postpartum interview, and 6-month postpartum interview	**Statistical analysis:** • A mixed-effects linear modeling used to test hypotheses about txt conditions controlling for clustering of respondents within each community health center • Linear logistic regression analyses computed using GLIMMIX macro, which uses iteratively reweighted likelihoods to fit a logistic regression • PROC MIXED procedure in SAS used for analysis of number of cigarettes per day over time • Reported *P* values are for two-sided alternative hypotheses **Data verification:** Salivary cotinine levels ≤ 20 ng/ml assessed to confirm 7 day abstinence **Dependent variables:** Smoking status **Baseline data:** Groups similar at baseline	30-day abstinence rates at end of pregnancy among women who did not spontaneously quit upon learning of their pregnancy: **G1:** 26% **C1:** 12% OR = 2.57 *P* = 0.05 30-day abstinence rates at 1-month postpartum among women who did not spontaneously quit upon learning of their pregnancy: **G1:** 26% **C1:** 11% OR = 3.01 *P* = 0.04 All other effects not statistically significant No effect remained at 3 and 6 mo followup Intent to treat at 30 day followup: Non-spontaneous quitters: 2.02 *P* = 0.09 Spontaneous quitters 0.95 *P* = 0.95	**Quality rating:** Fair **Comments:** NR **Adequate randomization:** Yes **Attrition rate:** 20%

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation

Study Characteristics	Study Design	Sample Design and Definitions
Author: Pieterse, 2001 **Geographic area:** Western Europe **Funding agency:** Dutch Cancer Society **Study setting:** Practice/provider settings	**Study objective:** To test effectiveness of a minimal contact smoking cessation program implemented by Dutch general practitioners. **Population:** • Young adults • Adults **Study type:** • RCT w/ simple randomization • Randomization occurring within practice sites according to a "prestructured allocation list" **Inclusion criteria:** • 18 to 70 • Self-reported smoker **Exclusion criteria:** • Controls exposed to txt • Controls w/ severe tobacco-related health problems (thus given intervention)	**Sampling plan:** Smoking patients 18 to 70 recruited from participating Dutch general practitioners' clinics Only info regarding randomization process: • Occurred within clinics and used a prestructured allocation list **Sample size:** **G1:** 269 **C1:** 261 **Definition of smoking:** Cigarettes • Non-smokers at followup defined as consistently providing non-smoker responses to two questions 1) contact name for someone to verify smoking status and 2) self-reported smoking status

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Individual counseling by non health professional • Telephone counseling • Pharmaceuticals **Intervention:** **G1:** Brief (10-minute) counseling sessions w/ physician; self-help manual; followup sessions. **C1:** Usual txt - no counseling or advice on smoking except when initiated by patient or when indicated by the contact reason, in which case counseling limited to a straightforward stop-smoking advice and possibly a referral to local municipal health organization **Method of assessment:** Self-report by questionnaire	**Statistical analysis:** Logistic regression, backward stepwise procedures, univariate ANOVA, X^2 tests **Data verification:** Self-report. No biochemical verification **Dependent variables:** • Self-reported abstinence from smoking • Point prevalence of smoking • Consecutive abstinence from smoking (abstinent at both 6- and 12-month followups) **Baseline data:** Significant difference in G1 vsC1 in baseline measures of: Percent smoking ≤ 10 cigarettes per day (**G1:** 13.3, **C1:** 20.4; F = 4.3, *P* = 0.04) Motivation to quit score (**G1:** 14.8, **C1:** 13.8, F = 6.7, *P* = 0.01) Otherwise, population considered representative of average Dutch visitor of a general practice	1-month followup smoking abstinence rates greater among those in intervention compared to controls (OR = 2.56; CI, 1.8, 3.8) Similarly, 12-month follow up smoking abstinence rates were 13.4% (G1) vs 7.3% (C1), w/ an OR = 1.51 (CI, 1.1, 2.1), *P* < 0.05 Consecutive abstinence greater among intervention group (8.2%) than among C (3.1%); OR = 3.04 (CI, 1.7, 5.6), *P* < 0.001	**Quality rating:** Fair **Comments:** Not clear about randomization procedures because only vague information provided Important potential influence identified by authors -- implementation of national mass-media stop-smoking campaign, which started shortly before second followup **Adequate randomization:** Yes **Attrition rate:** 1 month: Overall: 26% **G1:** 33% **C1:** 19% 6 month: Overall: 26% (no info on each group). 12 month: Overall: 19% (no info on each group).

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Piper et al., 2003 **Geographic area:** US **Funding agency:** National Cancer Institute **Study setting:** Provider-based	**Research objective:** To test effectiveness of expanded vital sign stamp to identify smokers and reduce smoking rates **Population:** Adult smokers attending health care clinics **Study type:** Cluster RCT (clinics unit of randomization) **Inclusion criteria:** • Any adult smoker (older than 18 years) • Attended only one health care clinic **Exclusion criteria:** None reported	**Sampling plan:** • Convenience sample • Adults exiting health clinics (n = 5) were approached • Any adult smoker willing to participate was enrolled **Sample size:** **G1:** 5582 **C1:** 3857 **Definition of smoking:** NR

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Expanded vital sign stamps **Intervention:** **G1:** smoking status was added to the vital sign stamp **C1:** usual vital sign stamp without smoking status **Method of assessment:** Follow up questionnaire after 1 year (method NR) **Baseline data:** Similar at baseline	**Statistical analysis:** Chi square (response rates not reported) **Data verification:** NR **Dependent variables:** • Smoking cessation • Identification of smokers • Rates of smoking counseling by physicians	Proportion of all participants asked by any clinic staff person about smoking before and after implementation of vital sign stamp revealed an overall increase of 9.6% in control group and 30.9% in intervention clinics Mean increase in asking behavior of physicians at vital sign clinics was statistically greater than that of physicians at control clinics t = -3.61; *P* = 0.002) No statistically significant differences in abstinence rates (complete abstinence during past 7 days) between G1 and C1 after 1 year (*P* = 0.27).	**Quality rating:** Fair **Comments:** Response rates to follow up questionnaire at 1 year not reported **Adequate randomization:** NR **Attrition rate:** NR

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Russos et al., 1999 **Geographic area:** US **Funding agency:** Cigarette and Tobacco Surtax Fund of the State of Calif through the Tobacco-Related Disease Research Program of the University of Calif **Study setting:** Practice/provider settings	**Study objective:** To examine rate and determinants (especially as related to social learning factors) of tobacco prevention and cessation counseling by orthodontists participating in a controlled trial to decrease incidence of tobacco use among adolescents. **Population:** • Adults **Study type:** • Cross-sectional • Current study based on cross-sectional interview design survey of orthodontists randomized to intervention to enhance skills in delivering smoking prevention and cessation counseling to adolescent patients or to C (thus, interventions described relate to the RCT, not the cross-sectional survey) **Inclusion criteria:** • Orthodontist from an office in one of the selected Calif counties • Practiced at least 2 days a wk • Had at least 75 adolescent patients • Planned to remain in practice at least 2 yrs (for survey: participated in original study) **Exclusion criteria:** • Not meeting inclusion criteria	**Sampling plan:** Orthodontists recruited from 154 participating orthodontic offices within various southern Calif counties **Sample size:** **G1:** 63 **C1:** 63 **Definition of smoking:** NR

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by non health professional • Telephone counseling • Video • Media campaign **Intervention:** **G1:** Anti-tobacco materials (e.g., posters), 1.5 hr training session on tobacco prevention, written anti-tobacco prescriptions, reimbursement for anti-tobacco prescription given to patients, quarterly visits and calls; office staff asked to make office tobacco-free (remove ashtrays, distribute anti-tobacco materials and prescriptions to all youth, to remind patients not to begin tobacco use) **C1:** No training, materials, or visits, nor asked to change their offices or practices **Method of assessment:** Mailed survey requesting self-report from orthodontists	**Statistical analysis:** • Nonparametric statistics (Kendall, Mann-Whitney) used in bivariate analyses • Multivariate analysis **Data verification:** Telephone survey of orthodontists **Dependent variables:** • Provision of prevention and cessation counseling to patients • Counseling content • Counseling determinants **Baseline data:** No significant differences ($P > 0.05$) found b/w G1 and C1 in terms of demographics, clinical practices, office characteristics, history of tobacco use, nor training for tobacco counseling Mean age about 51, mean yrs in practice about 24 yrs, about 230 adolescent patients, mean gross annual income 445,000	**Outcome measures:** In a typical wk more clinicians in experimental vsC provided prevention counseling to patients (Mean: 25.4% v 3%, Mann-Whitney U = 696.5, z = -7.0, $P < 0.01$) and at least some cessation counseling (91% vs 72%, chi sq = 8.4, $P < 0.01$) G1 asked higher % (4.8) of their patients whether they use tobacco than C1 (2.9), (U = 1349.0, z = -3.3, $P < 0.01$) G1 more likely to report mostly positive reactions from tobacco users for cessation counseling (chi sq = 7.8, $P < 0.05$) C1 more likely than G1 to say they don't provide counseling because it's not their job or not expected of them (chi sq = 3.7, $P = 0.05$) G1 more likely to say lack of time is significant barrier to giving prevention counseling (chi sq = 4.2, $P < 0.05$) Demographic, office, and clinic practice variables not associated w/ prevention or cessation counseling ($P > 0.05$) Higher rates of prevention and cessation counseling associated ($P < 0.05$) w/: asking patients whether they used tobacco; belief that counseling is important; belief that clinicians should receive counseling training; intent to attend training; and to disagree that counseling is not part of their jobs	**Quality rating:** Fair **Comments:** Good, documentation of reasons for attrition and distribution of non-responders by group; things to consider when trying to improve providers' provision of tobacco use prevention and cessation advice Similar findings from comparison of results to other studies **Adequate randomization:** Yes **Attrition rate:** Survey: G1 and **C1:** 18% each

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Slama et al., 1999 **Geographic area:** Western Europe **Funding agency:** French Ministry of Health; European Union "Europe Against Cancer Programme"; French Committee for Health Education **Study setting:** Practice/provider settings	**Study objective:** To examine participation and effectiveness of GPs in offering a minimal smoking cessation intervention according to attitudinal and behavior variables **Population:** • Adults **Study type:** Cross-sectional survey w/ GPs who participated in a previous smoking cessation intervention **Inclusion criteria:** • Participated in previous smoking cessation intervention study **Exclusion criteria:** • NR	**Sampling plan:** • 2,860 GPs from France interviewed about their attitudes and behaviors • From this group, 170 of 371 randomly selected smoking GPs and 202 of 375 randomly selected non-smoking GPs participated in survey **Sample size:** Smokers: 170 smokers Non-smokers: 202 **C1:** NA **Definition of smoking:** Cigarettes • Abstinent: not smoking cigarettes

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Extra-curricular activities **Intervention:** **G1:** NA **G2:** NA **G3:** NA **C1:** NA **Method of assessment:** For GPs' attitudes and reported practices: self report obtained by telephone survey GPs' participation in intervention measured by patient information GP returned per protocol at 1 and 12 mo followups. Patient smoking status: self report at 1 and 12 mo followups	**Statistical analysis:** Chi sq tests Frequencies Proportions **Data verification:** Self report **Dependent variables:** • Rate of participation in cessation trial by GP's smoking status • Effect of GPs' smoking-related attitudes and reported practices **Baseline data:** 50% of eligible GPs participated (45% smoked; 54.1% did not; $X^2 = 5.147$, $P < 0.05$) Significant differences b/w participating and non-participating GPs in beliefs about usefulness of screening for cervical (96.2% vs 91.6%, $X^2 = 6.460$, $P < 0.011$) and breast cancer (98.1% v 94.8%, $X^2 = 5.918$, $P < 0.015$) Other differences NS	Doctors who were smokers less likely than non-smoking GPs to participate in the smoking cessation trial, despite having originally consented to do so (45% vs 54.1%, chi sq: 5.147, $P < 0.05$) None of the GPs' smoking related attitudes and reported behaviors significantly related to their participation in the study nor to their patients' rates of smoking cessation at 1 mo, 12 mos, or both Conclusion: When minimal advice has an effect, it is due more to systematic nature of the provision of intervention than to the attitudes or reported practices of practioner giving advice	**Quality rating:** Fair **Comments:** Interesting practical applications to understanding factors that might influence physicians' willingness to participate in interventions to address smoking cessation w/ patients; Limited discussion of intervention, though refers to previous article description **Adequate randomization:** NR **Attrition rate:** Smoking GPs (%): 1 wk: 11.8 2 wks: 8.2 3 wks: 12.9 4 wks: 32 Non-smoking GPs (%): 1 wk: 9.9 2 wks: 10.3 3 wks: 15.3 4 wks: 35.5

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation

Study Characteristics	Study Design	Sample Design and Definitions
Author: Smith et al., 2002 **Geographic area:** US **Funding agency:** NCI, Canadian Cancer Society **Study setting:** Hospital	**Study objective:** To assess effectiveness of a nurse case-managed smoking cessation program for general hospitalized patients, was continued for 3 yrs after completion of RCT **Population:** • Adults **Study type:** • Time series • Single group effectiveness study using a program put into standard hospital practice. • No comparison group for this study; instead, follows participants over time and assesses smoking status at various points postintervention **Inclusion criteria:** • Patients who smoked in month before hospital admission • Wanted to quit smoking • Agreed to participate in intervention **Exclusion criteria:** • Did not speak English • Impaired level of consciousness • Terminal • Primary reason for hospitalization was substance abuse • Hospital stay less than 36 hrs	**Sampling plan:** Patients admitted to Stanford (Calif.) Hospital who smoked any amount the month before admission were offered a smoking cessation program during hospitalization **Sample size:** 12 month sample = 720 **Definition of smoking:** Cigarettes • 7 day point-prevalence as defined by NHLBI (not even a puff for a minimum of 7 consecutive days prior to assessment

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Telephone counseling • Video • Pharmaceuticals **Intervention:** **G1:** Used multiple-reinforcement approach (multiple providers, components, and contacts) During hospitalization: Physician advice on smoking cessation; bedside education and counseling w/ specially trained nurse; take-home materials (video, workbook, relaxation audiotape), NRT if requested or indicated, 4 nurse-initiated postdischarge phone counseling calls (2,7,21, and 90 days postdischarge) **C1:** No control or comparison group **Method of assessment:** In-person survey for demographic information, and baseline smoking history and alcohol consumption Postdischarge data collected by telephone and involved self-report	**Statistical analysis:** • ANOVA • X^2 • Frequencies • Intent-to-treat analysis **Data verification:** • Self-report by telephone No biochemical assessment **Dependent variables:** 12 mo quit rate (7 day point prevalence at 12 mos) **Baseline data:** Mean age: 52 Males: 58% Race/ethnicity: • Caucasian: 79% • African American: 5% • Asian: 9% • Hispani**C1:** 1% • Other race: 6% Hospitalization reasons: • Cardiovascular: 41% • Cancer: 12% • Pulmonary: 6% • Gynecological: 4% • Internal medicine: 19% • Orthopedi**C1:** 10% • Other: 9% Significant ($P < 0.001$) differences in age, sex, ethnicity, primary reason for hospitalization b/w total smokers identified, ineligibles, participants, wanted to quit on own, and did not want to quit groups	Including only those who were reached at 12 mos, 49% reported being smoke free for previous 7 days Including 211 who were not reached at 12 mos (intent to treat) and counting them as smokers, self-reported smoking cessation rate is 35%.	**Quality rating:** Fair **Comments:** Though no comparison group in this study, it provides very good and detailed data regarding continuation of a smoking cessation program implemented previously as part of a RCT; only 52% of eligible patients participated, but this is considered fairly high acceptance rate for the population; it also presents data both w/ and without intent-to-treat approach; partial reasons for high attrition rate at 12 mos include nurse not having time to devote to trying to make follow up calls and only 3 attempts made to reach participants by phone. Study also addresses practical hospital-related issues to be considered when implementing an inpatient smoking cessation program **Adequate randomization:** No **Attrition rate:** Excluding 42 who died before assessment, 29% attrition rate (not reached or dropped out)

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Soulier-Parmeggiani et al., 1999 **Geographic area:** Western Europe **Funding agency:** NR **Study setting:** Hospital Practice/provider settings	**Study objective:** To evaluate effectiveness of a smoking cessation program for outpatients **Population:** • Adults **Study type:** • Before and after study • Patients participated in 1-hr consultation groups once a wk for 4 wks; patients interviewed at baseline and 3, 6, and 12 months after intervention **Inclusion criteria:** • NR **Exclusion criteria:** • NR	**Sampling plan:** NR **Sample size:** **G1:** 299 **Definition of smoking:** NR

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Individual counseling by health professional • Group counseling • Telephone counseling • Social support • Video • Pharmaceuticals **Intervention:** **G1:** One-hr group consultations once per wk for 4 wks; followup individual consultations by telephone at 1, 3, 6, and 12 mos after intervention; prescription of NRT; individual strategy for cessation discussed w/ a provider; family support recommended; video of benefits of cessation; dietitian-led session on preventing weight gain and individual diet recommendations; relapse prevention counseling **C1:** NR **Method of assessment:** • Questionnaires filled out by patients at baseline and 3, 6, and 12 mos postintervention • Patients' CO levels measured at each session and followup	**Statistical analysis:** Proportions of smokers calculated at baseline and followup intervals **Data verification:** Patients' CO levels measured at each session and followup **Dependent variables:** Smoking status **Baseline data:** Collected data on smoking history, addiction level as measured by FTQ, and motivation and confidence to quit smoking	Non-smokers at baseline and each followup: Baseline: 0% End of intervention: 54% 3-mo followup: 39.4% 6-mo followup: 25.8% 12-mo followup: 20.9%	**Quality rating:** Poor **Comments:** Sampling not explained, no C, limited generalizability **Adequate randomization:** NR **Attrition rate:** 10.4%

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation

Study Characteristics	Study Design	Sample Design and Definitions
Author: Stevens et al., 2000 **Geographic area:** US **Funding agency:** NCI **Study setting:** Hospital	**Study objective:** To evaluate implementation and effectiveness of hospital-based smoking cessation counseling delivered by respiratory therapists chosen from among hospital staff **Population:** • Adults **Study type:** RCT w/ simple randomization **Inclusion criteria:** • Between 18 to 70 yrs old • Being admitted to one of two participating Kaiser Permanente hospitals in Portland, OR • Reporting regular smoking anytime in 3 months preceding hospitalization **Exclusion criteria:** • Obstetric patients • < 18 or >70 yrs old • Hospitalized for psychiatric or drug or alcohol abuse diagnoses • Patients w/ hospital stays less than 36 hrs • Hospice patients	**Sampling plan:** • Smokers b/w 18 to 70 yrs old identified by questionnaire upon hospital admission • Eligible smokers assigned to txt or usual care by a random digit in their HMO member number **Sample size:** **G1:** 541 **C1:** 632 **Definition of smoking:** Cigarettes • Abstinence from smoking considered as ≥ 6 months • Second analysis included pipes or cigars

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Telephone counseling • Video **Intervention:** **G1:** If assigned to intervention but did not agree to participate, received smoking cessation brochure only If agreed to participate, watched 12 minute video for hospitalized smokers; offered one 20-minute counseling session w/ RT; choice of written materials (e.g., NCI's **C1:** no information **Method of assessment:** Mailed questionnaire and follow up by phone for non-responders	**Statistical analysis:** X^2 tests and one logistic regression **Data verification:** Relied on self-report of smoking status **Dependent variables:** 6 month abstinence from smoking **Baseline data:** • 57% women, mean age 47 yrs • Mean smoking rate before hospitalization: 19 cigarettes per day • Similar baseline characteristics among intervention and Cs No statistically significant differences b/w groups at baseline in terms of demographics or smoking, but race/ethnicity NR)	NR	**Quality rating:** Poor **Comments:** NR **Adequate randomization:** Yes **Attrition rate:** NR

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation

Study Characteristics	Study Design	Sample Design and Definitions
Author: Young et al., 2002 **Geographic area:** Australia **Funding agency:** CSAHS Tobacco Education Team. (NSW Quit Campaign supplied free "Quit Kits," Pharmacia Upjohn donated NRT starter packs; NSW Cancer Council supplied videos and workbooks at cost.) **Study setting:** Practice/provider settings	**Study objective:** To evaluate a multifaceted, practice-based intervention involving audit, feedback, and academic detailing to improve family physicians' smoking cessation advice **Population:** • Adults **Study type:** • RCT w/ cluster randomization • Each family practice, representing a cluster, randomly allocated to receive either intervention in smoking cessation advice (G1) or an intervention of identical format and intensity but about cervical screening (C1) • This constituted a 2 x 2 balanced incomplete block design, used to equalize nonspecific effects of research participation b/w groups and thereby minimize Hawthorne effect • Data from FPs' patients used to assess effectiveness of intervention by comparing baseline and posttest questionnaires **Inclusion criteria:** • Family physicians from practices located within a defined geographical area in 1999 • Patients: Aged 18 to 70 • Attending FPs during specified data collection periods • Spoke and read English • Could read questionnaire **Exclusion criteria:** FPs: • Ineligible if they worked < 2 days per wk • Planning to leave practice within 6 months • On extended or maternity leave • Did not employ a receptionist • Already participating in a clinical audit • More than 50% of their patients spoke a language other than English at home Patients: • Did not read or speak English • Were unable to read or understand questionnaire • Were too sick or distressed to participate • Had participated previously	**Sampling plan:** • All FPs in defined geographical area in 1999 were invited to participate • Following baseline data collection, practices stratified according to number of participating FPs at practice (1, 2-4, 5+) to ensure approximately equal numbers of FPs in each study group • Within each stratum, practices then randomly allocated to intervention or C using random numbers generated by SAS FP patients 18 to 70 recruited consecutively and invited to participate in a study about health care in a general practice. **Sample size:** **G1:** 30 (FPs) in 20 practices **C1:** 30 (FPs) in 19 practices **Definition of smoking:** Cigarettes • NA Smokless tobacco • NA

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Video • Pharmaceuticals **Intervention:** **G1:** FP received three academic detail visits which combined audit and feedback; resources for FPs (skills training video and workbook package, clinical practice guidelines, prompt sheet to assist w/ smokers' excuses and self-exceptions); resources for practices (patient-mediated prompts, reminders for medical records) and resources for patients (patient brochures and free starter packs of nicotine replacement gum) • Sessions 1 and 2 conducted by a medical peer • Session 3 conducted by a non-medical public health academic **C1:** Received similar intervention in terms of intensity and format, but w/ regard to cervical screening **Method of assessment:** • Baseline: Demographic questionnaires completed by participating FPs • Patients at participating practices also completed baseline and posttest questionnaires • Medical record audit	**Statistical analysis:** Frequencies, proportions, univariate analysis, bivariate analysis, X^2, Wilcoxon's rank sum tests, Fisher's exact test, McNemar's test for paired proportions, Wilcoxon's sign rank tests for paired ordinal data, logistic regression using GEE **Data verification:** Self-report of FP practices and patient recall of them, supplemented w/ patient medical chart review for verification **Dependent variables:** • Patient recall of smoking cessation-related interactions w/ FP during clinic visit • Recall of: question from FP about smoking status • Smokers' recall of specific smoking cessation advice • Discussion of health risks of smoking • Discussion of passive smoking • Providing practical advice • Setting a quit date • Providing written materials • Recommending nicotine replacement patches • Arranging follow up appointment; referring to a smoking clinic Medical record audit of patient smoking status and cessation advice in chart for index consultation (for smokers only).	Improvements b/w baseline and posttest in patient recall of FP advice about nicotine replacement patches and gum were significantly greater in intervention than C (P = 0.0056 and P = 0.0002, respectively) Substantial increases in patient recall of assessment of smoking status and FP use of quit dates, behavioral advice, written materials in intervention group, but changes not significantly greater than those in C Medical chart review indicated FP notation of smoking cessation advice remained suboptimal after intervention 100% of FPs found following intervention components	**Quality rating:** Fair **Comments:** • Low consent rate among FPs (35%), limiting generalizability of findings • Some significant differences b/w patients in G1 vs C1 • Though many comparisons of improvements in FPs' smoking cessation advice (G1 v C1) were NS, could be due to both groups being trained to be more mindful of addressing patients' health risks, thus reducing apparent effect of intervention • High rate of attrition in both groups and at both time points **Adequate randomization:** Yes **Attrition rate:** Baseline follow up: **G1:** 34% **C1:** 27% Posttest follow up: **G1:** 37% **C1:** 31%

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation

Study Characteristics	Study Design	Sample Design and Definitions
Author: Young et al., 2002 (continued)		

Evidence Table 7. Health care systems strategies to increase implementation of population-level tobacco use cessation (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
	• Also assessed FPs thoughts about usefulness of intervention components **Baseline data:** FPs: Representative of reference FP population except for participating FPs more likely to be full-time vs part-time Personal and professional characteristics of FPs allocated to each group were comparable G1 vs **C1:** Mean age 46.4 v. 49.8; Female (%): 43 v. 33; Mean yrs in practice: 18 vs 19 Patients: 77% consented to participate 70% response rate Less likely to respond: Smokers vs non-smokers (57% v 73%, chi sq = 35.3, *P* < 0.001) Males (65% v 73%, chi-sq = 11.8, *P* < 0.001) Those from intervention practices (66% v 73% chi sq = 11.2, *P* < 0.001)		

Evidence Table 8. Effect of smokeless tobacco product marketing and use on population harm from tobacco use

Study Characteristics	Study Design	Sample Design and Definitions
Author: Choi et al., 1995 **Geographic area:** US **Funding agency:** UCSF, Institute for Health and Aging **Study setting:** Population-based in Calif	**Study objective:** To assess trends in ST use and to identify risk factors that distinguish youths who use or who are at risk of using ST **Population:** • Adolescent males, ages 12 to 17 • Young adult males, ages 18 to 24 **Study design:** • Cross-sectional • Telephone survey using random digit dialing **Inclusion criteria:** Residing in Calif **Exclusion criteria:** NR	**Sampling plan:** Stratified random sample of adults and all 12 to 17 yr old adolescents **Sample size:** 1990: 3,912 1992: 883 1993: 2,814 **Definition of smoking:** Cigarettes • Current users: respondents who smoked a cigarette within last 30 days Smokeless tobacco • Current users: reported use of smokeless tobacco within last 30 days

Evidence Table 8. Effect of smokeless tobacco product marketing and use on population harm from tobacco use (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: NA **Intervention:** NA **Method of assessment:** Telephone survey	**Statistical analysis:** Multivariate logistic regression **Data verification:** NR **Dependent variables:** • Current use and susceptibility to use ST • Current cigarette use • Exposure to other ST users • Exposure to ST advertisements • Rebelliousness • Participation in team sports • Depression • Peer Use of drugs or alcohol • Peer norms **Baseline data:** NA	Ever experimented w/ ST: 1990: 15.2% (95% CI, 13.7-16.7) 1992: 12.3% (95% CI, 9.8 - 14.8) 1993: 13.8% (95% CI, 12.3-15.3) Current use of ST (%) 1993: • 12 to 13 yrs: OR = 0.3 (95% CI, 0.1 -0.05) • 14 to 15 yrs: OR = 2.6 (95% CI, 1.0 - 4.2) • 16 to 17 yrs: OR = 6.6 (95% CI, 4.1 - 9.1) Susceptibility to use ST (%) in 1993: • 12 to 13 yrs: OR = 16.8 (95% CI, 13.7 - 19.9) • 14 to 15 yrs: OR = 17.3 (95% CI, 14.8 - 19.8) • 16-17 yrs: OR = 18.8 (95% CI, 14.6 - 23.0) Exposure to SLT advertising (%) in 1993: • 12 to 13 yrs: OR = 21.0 (95% CI, 17.4 - 24.6) • 14 to 15 yrs: OR = 34.3 (95% CI, 30.3 - 38.3) • 16 to 17 yrs: OR = 43.8 (95% CI, 38.3 - 48.8) Recall of ST advertisements in 1993: AOR 7.5 (95% CI, 3.1 – 18.1), ($P < 0.001$) Susceptibility to use of ST in 1993: OR = 1.6 (95% CI, 1.2 – 2.0), ($P<.001$) Cigarette smokers risk of being ST users in 1993: OR = 3.3 (95% CI, 1.9 -5.7), ($P<.001$)	**Quality rating:** Fair **Comments:** Cross sectional study design; only reported analysis on 1993 data and youth subjects; no clear explanation of final sample size **Adequate randomization:** Yes **Attrition rate:** NR

Evidence Table 8. Effect of smokeless tobacco product marketing and use on population harm from tobacco use (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Tomar; 2003 **Geographic area:** US **Funding agency:** NR **Study setting:** Population-based	**Study objective:** To assess 4-yr initiation rates of ST use and cigarette smoking in relation to each other and examine switching b/w products **Population:** • Adolescents, ages 11 to 19 • Young adults • Men **Study design:** • Cross-sectional • Nationally-representative, cross-sectional telephone and mail survey **Inclusion criteria:** • 11 to 19 yrs of age at baseline • Reside in households interviewed for National Health Interview Survey • Male **Exclusion criteria:** NR	**Sampling plan:** 1989 TAPS-I and its 1993 followup TAPS-II: TAPS-I sampling frame consisted of all teenagers aged 12–18 yrs on November 1, 1989, who resided in households interviewed for the NHIS during last two quarters of 1988 and first two quarters of 1989 **Sample size:** Total: 3,996 **Definition of smoking:** Cigarettes • Current smoker: reported smoking at least 100 cigarettes in their lifetime and smoked at least 1 cigarette in 30 days preceding interview • Former smoker: smoked at least 100 cigarettes in their lifetime, but smoked no cigarettes in last 30 days preceding interview • Never smokers: had not smoked 100 cigarettes in their lifetime Smokeless tobacco groups: • never user of ST • used ST, but never regularly • used ST regularly but not currently • current, regular user of ST

Evidence Table 8. Effect of smokeless tobacco product marketing and use on population harm from tobacco use (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: NA **Intervention:** NA **Method of assessment:** • Computer-assisted telephone interviews • Traditional telephone interviews • Mailed surveys (TAPS-I 1989 data and TAPS-II 1993 data)	**Statistical analysis:** • Estimates of prevalence and initiation rates included 95% CI • Multiple logistic regression modeling used to adjust for age and race/ethnicity • OR estimate interpreted as significantly different from reference group, at 95% level of confidence, if its 95% CI, excluded 1.0 • All analyses of TAPS data conducted using sampling weights developed by National Center for Health Statistics **Data verification:** NR **Dependent variables:** • ST use • Cigarette use **Baseline data:** Prevalence of tobacco use at baseline (males only): • current smoker: 9% • former smoker: 1.6% • regular ST user at sometime: 6.1% • current regular ST user: 2.7%	At 4 yr followup: • current smokers: 21.2% • regular users of ST at sometime: 11.9% • current regular users: 5.7% After adjusting for age and race, males who had been regular users of ST were more than 3 times as likely as never users of ST to become smokers, OR = 3.45 (95% CI, = 1.84 -6.47) Current smokers not different from never smokers in rate of initiating current regular ST use OR = 1.45 (95% CI, = .5-4.22) NS Among males who were regular ST users but were not smokers at baseline: • continued to exclusively use ST at followup: 44.8% • had switched to smoking at followup: 25.5% • continued to use ST while also smoking at followup: 14.3% • no longer using tobacco: 15.2% Of smokers at baseline who were not ST users: • switched to ST exclusively: 8% • continued to smoke but also use ST: 3.6% • quit using tobacco: 16.9%	**Quality rating:** Fair **Comments:** • Self report without any biochemical verification; participants lost at followup may have been more difficult to capture because they were more likely to progress to current smoking or regular use of ST • Definition of ST use relied on respondents' self characterization of regular use **Adequate randomization:** NR **Attrition rate:** NR

Evidence Table 9. Tobacco cessation interventions for persons w/ co-occurring morbidities and risk behaviors

Study Characteristics	Study design	Sample Design and Definition
Author: Brown et al., 2001 **Geographic area:** US **Funding agency:** National Institute on Drug Abuse; American Cancer Society **Study setting:** Population-based	**Research objective:** To assess the efficacy of a standard, cognitive–behavioral smoking cessation treatment vs standard cessation treatment combined with CBT for depression in smokers with a positive history of MDD **Population:** • Smokers with a positive history of MDD **Study type:** RCT **Inclusion criteria:** • Ages of 18 and 70 years • Smoked for at least 1 year • Currently smoking at least 10 cigarettes per day • Had a history of MDD according to the DSM-III **Exclusion criteria:** • DSM–III–R diagnosis of current MDD, dysthymia, or other Axis I disorder • DSM–III–R diagnosis of psychoactive substance abuse or dependence within the past 6 months (other than nicotine) • Current use of psychotropic medication • Current weekly psychotherapy • Use of other tobacco products • Intent to use pharmacological aid to cessation	**Sampling plan:** • Potential participants screened by telephone prior to an intake interview to confirm eligibility • Eligible participants required to provide a $75 deposit, refunded incrementally on completion of follow-up procedures • 358 invited to study center for diagnostic interview to confirm eligibility; 100 did not show up • 258 participants completed informed consent and participated in the interview; 5 withdrew prior to being assigned to a treatment condition; 74 did not meet inclusion–exclusion criteria **Sample size:** **G1:** 86 **C1:** 93 **Definition of smoking:** • Smoked at least 10 cigarettes a day for at least 1 year

Evidence Table 9. Tobacco cessation interventions for persons w/ co-occurring morbidities and risk behaviors (continued)

Intervention Details	Statistical Analysis and Baseline Data	**Outcome Measures**	Quality Comments
Intervention methods: • Group counseling • Tailored cognitive behavioral therapy **Intervention:** **G1:** Eight 2-hr sessions over 6 weeks standard comprehensive CBT for smoking cessation, plus cognitive behavioral coping for depression **C1:** Eight 2-hr sessions over 6 weeks; comprehensive, standard CBT for smoking cessation **Method of assessment:** Assessment battery administered at pretreatment; questionnaires administered at each session during treatment; follow-up phone interviews occurred at 1, 6, and 12 months posttreatment, and self-reported abstinence was verified biochemically **Baseline data:** Groups were similar	**Statistical analysis:** • Chi-square analyses • Repeated measures analyses for categorical outcomes using generalized estimating equation **Data verification:** • Self report • CO and saliva cotinine **Dependent variables:** • Demographic characteristics (age, gender, marital status, and years of education) • Nicotine dependence severity (FTND score, number of years smoking, average daily smoking rate, and saliva cotinine) • Depression severity and chronicity	No statistical difference between groups were found for 7 day point prevalence abstinence rates at 1, 6 and 12 months for C1 = 30.1%, 24.7%, 24.7%, respectively; G1 = 39.5%, 24.4%, 32.5%. In the final step of the GEE analysis a significant interaction was found between treatment and heavy smoking (P = 0.02), and between treatment and recurrent depression (P = 0.02)	**Quality rating:** Fair **Adequate randomization:** NR **Attrition rate:** • 5% at 1 month • 8.9% at 6 months • 7.8% at 1 year

Evidence Table 9. Tobacco cessation interventions for persons w/ co-occurring morbidities and risk behaviors (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Brown et al., 2003 **Geographic area:** US **Funding agency:** None listed **Study setting:** Psychiatric hospital	**Study objective:** To test hypothesis that among adolescent smokers hospitalized for psychiatric and/or substance use disorders, MIwould lead to more and longer quit attempts, reduced smoking, and more abstinence from smoking over 12 mo followup **Population:** • Adolescents • Aged 13 to 17 from Providence, RI **Study type:** RCT w/ systematic cohort randomization **Inclusion criteria:** • Hospitalized for psychiatric and/or substance use disorder • Age 13 to 17 • Smoked at least 1 cigarette/wk for 4 wks prior to hospitalization • Access to phone **Exclusion criteria:** • DSM-IV criteria for psychotic disorder • Recent violent behavior • Recent participation in another study • Uncertain guardianship status • Language incompatibility • Sibling in study • Significant cognitive impairment • Residing too far away to complete followups • Patient or parent refusal	**Sampling plan:** Consecutive sample of eligible 13 to 17 yr olds hospitalized for psychiatric and/or substance use disorder but not psychotic **Sample size:** **G1:** 116 **G2:** 75 **Definition of smoking:** Cigarettes • Number of cigarettes smoked per day

Evidence Table 9. Tobacco cessation interventions for persons w/ co-occurring morbidities and risk behaviors (continued)

Intervention Details	Statistical Analysis and Baseline Data	Results	Quality Comments
Intervention methods: • Self-help • Individual counseling by health professional • Telephone counseling • Pharmaceuticals **Intervention:** **G1:** Two in-person 45-minute MI sessions during hospitalization or on outpatient basis; self-help pamphlet and manual; offer of up to two 8-wk courses of free transdermal NPtherapy if eligible; up to 6 postdischarge phone counseling sessions; up to 4 brief parent intervention phone counseling sessions. **G2:** 5-10 minute in-person advice to quit smoking; self-help pamphlet; offered one course of transdermal NPtxt if eligible **C1:** NA **Method of assessment:** Pre and postintervention assessment of various outcomes at 1, 3, 6, 9, and 12 mo follow ups Smoking: • Self-report and biochemical verification for those claiming abstinence Nicotine Dependence: • Fagerstrom tolerance questionnaire • Psychopathology dz: C-DISC • Intent to change: Self-report to single item • Self-efficacy: SCQ	**Statistical analysis:** Hierarchical Linear Modeling GEE Linear and Logistic Regression **Data verification:** Self-report plus biochemical verification (saliva cotinine) for those claiming tobacco use abstinence **Dependent variables:** • Point prevalence abstinence • Quit attempts • Changes in smoking rate • Longest quit attempt **Baseline data:** • Female: 62.3 • Mean age: 15.4 Race/ethnicity • White: 94.8 • Hispani**C1:** 1.6 • African American: 0 • Other Race: 3.6 Other • Mean age at first cigarette: 10.85 • Smoked on avg: 91.19% of previous 3 mos • Mean: 14.48 cigarettes on smoking days • Daily smokers: 63.9 • Mean Fagerstrom tolerance score: 4.9 • Met DSM-IV criteria for nicotine dependence: 68.6 • Mean length inpatient stay: 9.11 days • Used NRT during hospital stay: 26%	**Mean of anxiety disorders:** **G1:** 1.1 **G2:** 1.3 *P* = NS Odds for quit attempts AOR 1.99 (95% CI, 1.08, 3.71) Longest quit attempt, days: **G1:** 48.2 **G2:** 60.9 *P* > 0.05 NS Point prevalence abstinence at 1, 6 and 12 mos: *P* > 0.30, NS Smoking rate: (b = 0.05, SE = 0.16, *P* = 0.74, NS) Higher discharge scores on situational confidence questionnaire associated w/ significantly less smoking during followup (b = -0.02, SE = 0.007, *P* = 0.007)	**Quality rating:** Fair **Comments:** • High refusal rate • Due to slow participant flow, recruitment ended before all cohorts completed, resulting in imbalance of participants across conditions • Inconsistent txt implementation **Adequate randomization:** Yes **Attrition rate:** 20 (9%)

Evidence Table 9. Tobacco cessation interventions for persons w/ co-occurring morbidities and risk behaviors (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Hitsman et al., 1999 **Geographic area:** US **Funding agency:** VA Merit Review award by NIDA, and Eli Lilly and Company **Study setting:** Population-based	**Study objective:** To identify individual differences that predict cessation when fluoxetine is combined w/ CBT **Population:** • Adults **Study type:** RCT w/ simple randomization **Inclusion criteria:** Participants are: • 18 to 65 yrs of age • have smoked daily for at least one yr • exhibit a baseline expired CO level of greater than 8 ppm • agree to declare a quit date within 2 wks after second study visit (Source: Borrelli, et al. 1997) **Exclusion criteria:** • Clinically significant depression HDRS score greater than 14 • Pregnancy • Hypertension • Use of psychotropic medication or current psychiatric illness • Alcohol or drug abuse in past yr • Current use of nicotine replacement • Unstable medical condition or major health event in past 6 months • Use of ST, pipes or cigars • Recent experience of a major life event (e.g., divorce or major job change) • Suicidal ideation • History of bipolar disorder (Source: Borrelli, et al. 1997)	**Sampling plan:** Specific randomization scheme NR. **Sample size:** Total: 253 **Definition of smoking:** Cigarettes • Reported smoking • Expired CO greater than 8 ppm • Saliva continine value greater than 10 ng/ml

Evidence Table 9. Tobacco cessation interventions for persons w/ co-occurring morbidities and risk behaviors (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: • Individual counseling by health professional • Pharmaceuticals **Intervention:** **G1:** Nine, 1-hr individual CBT sessions + fluoxetine 30 mg for a total of 10 wks • Participants required to set a quit date within 2 wks after drug txt began • Participants quit smoking at 3rd CBT session • Medication stopped at 9th CBT session, at which time 6-month followup period began • CBT not explained • Patients w/ fluoxetine level less than or equal to 150 ng/ml considered compliant **G2:** Same as **G1:**, except fluoxetine dose of 60 mg and fluoxetine blood level less than or equal to 300ng/ml considered compliant **C1:** Same as G1, except given placebo **Method of assessment:** Self report of smoking, expired CO, and saliva continine Also used depresion scale, nicotine dependence, weight restraint scale, and self-efficacy questionnaire	**Statistical analysis:** Constructed predictive models using logistic regression w/ hierarchical approach to variable selection. Models evaluated w/ parallel analyses using stepwise selection procedure **Data verification:** Expired CO and saliva continine **Dependent variables:** Depression, nicotine dependence, weight concerns, self-efficacy about quitting smoking **Baseline data:** No significant difference b/w txt groups in baseline characteristics: age, gender, education, smoking history, baseline level of nicotine dependence, depression, weight concern, and self-efficacy	At 1 wk postcessation: higher levels of depression predicted failure to achieve abstinence (ITT analysis); higher levels of nicotine dependence and depression associated w/ decreasing likelihood of abstinence (analysis of txt-compliant patients) and likelihood of abstinence for participants on fluoxetine tended to be higher than for those on placebo (P = 0.06); At 1 month postcessation: higher levels of weight concern predicted lower abstinence (X^2 4.8, P = 0.78); patients on fluoxetine had positive association b/w degree of depression and likelihood of abstinence (highest quartile HRSD = 3, OR = 2, 95% CI, 0.85-4.70); At 3 months postcessation: patients treated w/ fluoxetine had positive association b/w HRSD scores and abstinence likelihood (highest quartile HRSD = 3, OR = 1.44, 95% CI, 0.53-3.91) Smoking characteristics predicting txt compliance were nicotine intake at baseline, saliva cotinine (X^2 = 11.4, P < 0.001), and expired CO (X^2 = 5.3, P < 0.05)	**Quality rating:** Fair **Comments:** • Authors didn't report numbers of participants per arm of study, baseline demographic characteristics of those groups, nor 6 month followup results • Inclusion/ exclusion criteria are described in companion article, Borrelli, et al. 1997 **Adequate randomization:** NR **Attrition rate:** NR

Evidence Table 9. Tobacco cessation interventions for persons w/ co-occurring morbidities and risk behaviors (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Joseph, 1993 **Geographic area:** US **Funding agency:** NR **Study setting:** Hospital	**Study objective:** To evaluate effect of smoke-free policies in in-patient alcohol txt wards and effect of these policies on long-term txt outcomes **Population:** • Adults **Study type:** Prospective cohort study **Inclusion criteria:** NR **Exclusion criteria:** Excluded patients admitted b/w May and July, 1988, because they would have overlapped w/ the implementation of smoke-free policy	**Sampling plan:** • Enrolled consecutive patients • Admitted to an inpatient substance abuse txt program prior to implementation of a smoke-free policy and those patients admitted after smoke-free policy was implemented **Sample size:** **G1:** 407 **G2:** 299 **Definition of smoking:** NR

Evidence Table 9. Tobacco cessation interventions for persons w/ co-occurring morbidities and risk behaviors (continued)

Intervention Details	Statistical Analysis and Baseline Data	Results	Quality Comments
Intervention methods: • Group counseling • Classroom instruction **Intervention:** **G1:** Patients not given specific information about smoking or cessation; smoking on the ward only permitted in 2 designated rooms and not allowed during group sessions **G2:** Patients required upon admission to acknowledge the smoke-free policy and sign a contract agreeing to abstain from nicotine during their stay; smoking cessation program designed for substance abusers delivered (didactic lectures on pharmacology of nicotine, films, and discussion group); Clonidine patches available but not studied in a systematic fashion **Method of assessment:** A one-pg, standardized, self-administered questionnaires given upon admission to hospital and third wk of hospitalization to assess smoking status and motivation to quit Structured telephone interviews at 1 yr posthospitalization (pre policy group interviewed at 16.2 mos and post policy group at 10.7 mos) conducted to assess use of substances other than nicotine Improvement in chemical dependency defined as less or no use of substance abuse they were treated for at hospital	**Statistical analysis:** NR **Data verification:** NR **Dependent variables:** Tobacco-use status; motivation to quit; use of substances other than nicotine **Baseline data:** Demographic data from both groups similar at baseline	Proportion of patients that want to quit smoking while in hospital at three-wk followup: **G1:** 24% **G2:** = 61% *P* = < 0.001 Proportion of patients that has abstained from smoking for > 1 wk: **G1:** 9% **G2:** 41% *P* = < 0.001 Proportion of patients that cut down smoking while in hospital: **G1:** 46% **G2:** 93% *P* = < 0.001 Quit smoking as reported at 1 yr followup interview: **G1:** 3% **G2:** 8% *P* < 0.05 quit smoking No significant difference found in 1-yr followup for non-nicotine substance use b/w groups	**Quality rating:** Fair **Comments:** • Statistical methods NR • No biochemical verification • High attrition **Adequate randomization:** NR **Attrition rate:** Attrition at 1-yr followup: **G1:** 61.7% **G2:** 45.5%

Evidence Table 9. Tobacco cessation interventions for persons w/ co-occurring morbidities and risk behaviors (continued)

Study Characteristics	Study design	Sample Design and Definition
Author: Joseph, Willenbring et al., 2004 **Geographic area:** US **Funding agency:** National Institute on Alcohol Abuse and Alcoholism; Health Services Research and Development Center for Chronic Disease Outcomes Research, Veterans Affairs **Study setting:** Residential treatment program	**Research objective:** To compare the effects of smoking treatment and intensive treatment for alcohol dependence, delivered concurrently, with treatment delayed by 6 months on smoking outcomes and alcohol use **Population:** Adult men and women ages 21-75 **Study type:** RCT Stratified random sampling **Inclusion criteria:** • Met criteria for alcohol dependence or abuse according to the Diagnostic and Statistical Manual of Mental Disorders, 4th ed. and who smoked more than 5 cigarettes per day for more than 1 year • Completed first week of alcoholism treatment **Exclusion criteria:** • No interest in stopping smoking • Diagnosis of dementia or schizophrenia • Inability to comply with the protocol due to severe psychiatric symptoms or cognitive deficits • Refusal to provide the name of a contact or source of collateral information • Unwillingness to attend visits as planned in the protocol	**Sampling plan:** • Treatment assignment accomplished by stratifying by substance use disorder treatment site and blocking within site in groups of 10. Computer generated random sequence was concealed from study personnel • Initial screening included questions about interest in participating in a research study, stage of change and potential concerns about participating. (Screen A) • Patients passing Screen A invited to do Screen B, a computerized self-administered Quick Diagnostic Interview Schedule to confirm that they met criteria for alcohol dependence. • 1,943 adults assessed for eligibility • 499 adults agreed to participate **Sample size:** **G1:** 251 **G2:** 248 **Definition of smoking:** Any smoking within past 7 days

Evidence Table 9. Tobacco cessation interventions for persons w/ co-occurring morbidities and risk behaviors (continued)

Intervention Details	Statistical Analysis and Baseline Data	Outcome Measures	Quality Comments
Intervention methods: Behavioral counseling and pharmacological treatment **Intervention:** G1 (concurrent treatment): Individual counseling (1-hour face-to-face session) and up to 3 follow-up sessions conducted in person or by telephone Participants in the action stage of change received a free prescription for NRT, unless they declined or had a medical contraindication Medication algorithm recommended nicotine patches (21 mg for 6 weeks, 14 mg for 2 weeks and 7 mg for 2 weeks). A combination of patches and nicotine gum was offered to participants who smoked more than 20 cigarettes per day. **Method of assessment:** • Data collected at treatment site, research study office or by telephone at 6, 12 and 18 months after study enrollment • Brief smoking outcome data were also collected at 3 and 9 months **Baseline data:** No baseline group differences	**Statistical analysis:** • Simple likelihood ratio chi-square tests compared rates of tobacco and alcohol abstinence • Logistic regression analyses modeled the odds of smoking abstinence and prolonged alcohol abstinence as a function of intervention group and baseline measures that might affect smoking and alcohol treatment outcomes **Data verification:** Self-report abstinence Smoking validated by expired carbon monoxide; alcohol by breath alcohol concentration. **Dependent variables:** • Smoking: 7 day point prevalence • Smoking abstinence at 3, 6 and 12 months • Prolonged (6-mo.) smoking abstinence at 18 months • Number of quit and relapse episodes • Participation in treatment • Alcohol: 6-months duration of alcohol • 1-months duration of alcohol abstinence and number of drinking days in the past 6 months • Relapse to alcohol	Smoking Cessation Outcomes Intention-to-Treat Analysis 7 day point prevalent smoking abstinence rates at 3 months were 15.5% in the concurrent treatment group and 4.4% in the delayed group ($P < 0.0001$); at 6 months, 10.5% vs. 5.2% ($P = 0.02$) (note that at 3 and 6 months the delayed treatment group had not received intervention). At 9,12 and 18 months there were no significant differences between treatment groups. **Alcohol Abstinence Outcomes** At 6- 12- and 18-month visits, point prevalent alcohol abstinence was lower in the concurrent treatment group than in the delayed treatment group ($P = 0.004$, $P = 0.11$, and $P = .001$, respectively)	**Quality rating:** Good **Comments:** • Very low participation rate in expired carbon monoxide testing, 34% at 12 months and 25% at 18 months • 6.6% failed to support self-reported abstinence rates **Adequate randomization:** Yes **Attrition rate:** 18% at 6 months 20% at 18 months

Evidence Table 9. Tobacco cessation interventions for persons w/ co-occurring morbidities and risk behaviors (continued)

Study Characteristics	Study Design	Sample Design and Definitions
Author: Murray et al., 1995 **Geographic area:** US Canada **Funding agency:** Division of Lung Diseases of the NHLBI **Study setting:** Practice/provider settings	**Study objective:** Explore relationship b/w alcohol consumption and smoking cessation **Population:** • Adults • Describe: aged 35 to 60 **Study type:** RCT w/ simple randomization Multi-center clinical trial **Inclusion criteria:** • Smokers • Age 35 to 60 w/ evidence of early stage COPD **Exclusion criteria:** • Serious health condition that is likely to affect lung function • Use of regular medications that might interfere w/ study results • Consumption of more than 25 alcohol drinks per wk or 8 drinks in one occasion once a mo or any consumption of alcohol in past yr for recovering alcoholics	**Sampling plan:** NR **Sample size:** **G1:** 2,649 **C1:** 1,327 **Definition of smoking:** Cigarettes Defined as smoking at any clinic visit

Evidence Table 9. Tobacco cessation interventions for persons w/ co-occurring morbidities and risk behaviors (continued)

Intervention Details	Statistical Analysis and Baseline Data	Results	Quality Comments
Intervention methods: • Group counseling • Pharmaceuticals **Intervention:** **G1:** Bronchodilator inhaler or placebo inhaler and multi-component counseling and nicotine gum; counseling intervention included a multi-component approach w/ standard cognitive-behavioral strategies such as stimulus control, avoidance, role playing, assertiveness training, reinforcement, and relaxation techniques • Following counseling program, regular maintenance program scheduled on at least a monthly basis • Maintenance programs included weight management and exercise • In addition an extended group intervention program offered to participants who relapsed and want to try and quit again; NRT available free of charge to study participants but not tracked systematically in relationship to quit rates **C1:** Usual care **Method of assessment:** • Baseline interviews using self-reported alcohol and tobacco use • Intervention group (only), contacted monthly for 1st yr then w/ clinic visits every 4 mos w/ alcohol used assessed at 12 mos	**Statistical analysis:** Polychotomous ordinal logistic regression **Data verification:** Self-report on CO in expired air **Dependent variables:** • Current alcohol use • History of alcoholism • History and current use of tobacco • Family smoking • Attitudes towards smoking and stopping smoking • Physical dependence on nicotine (Fagerstrom) **Baseline data:** Similar w/ an exception, less female alcoholics in C than in txt group (2.8% vs5.8%)	**Outcome measures:** No significant relationship b/w amount of alcohol consumed at baseline and smoking status after 1 yr for G1. In G2, women baseline drinkers more likely not to be smoking after 1 yr: **G1:**14% **G2:** 6.3% *P* = NR Currently drinking at end of intervention: **G1:** Smokers: 5.24 drinks/wk Nonsmokers: 4.46 drinks/wk (t = 1.94, 1,440df, *P* = 0.05) Within smoking cessation intervention (G1), those who drank eight or more drinks per occasion (binge drinkers) more likely to be current smokers (i.e., lower cessation rate) after 1 yr (men binge = 44.8%, no binge = 51%, *P* < 0.05) and (women binge = 27.3%, no binge = 41.8%, *P* < 0.01) Within intervention group, binge drinkers smoked more cigarettes per day than those without a history of binge drinking (Men binge = 12.5, no binge = 10.3, *P* < 0.05) and (women binge = 14.3, no binge = 10.7, *P* < 0.01) When volume of drinking and drinking of eight or more drinks per occasion were compared in polychotomous ordinal logistic regressions, only binge drinking for men predicted failure at smoking cessation (Chi sq = 4.11, 1 d.f. *P* < 0.05, OR = 0.76)	**Quality rating:** Poor **Comments:** • Changed exclusion criteria after recruiting 1/3 of participants • Post randomization of subjects (excluded recovering alcoholics) • No systematic control of NRT use • No information on attrition • Within txt group analysis **Adequate randomization:** Yes **Attrition rate:** NR

Evidence Table 10. Systematic and meta-analysis reviews

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Ebbert et al., 2004 **Geographic area** United Kingdom **Funding source** No source of support supplied **Time period covered** Databases searched systematically through March 2004	**Inclusion criteria** Randomized trials of behavioral or pharmacologicial interventions to help users of ST to quit, w/ a followup of at least 6 months **Population** Users of any tobacco product that is placed in mouth and not burned, including moist snuff, chewing tobacco and betel quid **Characteristics of studies (Interventions)** Interventions studies could be pharmacologicial (NRT or bupropion) or behavioral, either directed at individual ST users or a groups of users **Method of review** • One author examined all titles generated from search and obtained abstracts • Abstracts considerd by two authors for full text review • Differences of opinion resolved by consensus **Study design** Cochrane Systematic Review and meta analysis. **Studies included in meta-analysis** • Eight behavioral trials • Separate meta analyses performed on 4 studies that randomized individuals and on 4 studies that gave oral exams and feedback to ST users	**Aim of review** To assess effects of behavioral and pharmacotherapeutic interventions to treat ST use **Main results** No evidence of ST abstinence for trials using bupropion, NRT, or nicotine gum Three trials showed significant effects using behavioral interventions A subgroup of behavioral studies that randomized individuals showed a pooled significant effect (OR 1.43, 95% CI, 1.06 to 1.93); OR higher in trials that included an oral exam and feedback (OR 2.41, 95% CI, 1.79 to 3.24)	**Quality rating** Good **Adverse events** Yes All reported adverse events associated w/ NRT such as skin reactions, nausea, headache and gastro-intestinal distress

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Author, year	Study Characteristics	Main Results/ Aim of Review	Quality Rating
Author, year El-Guebaly et al., 2002 **Geographic area** Canada **Funding source** NR **Time period covered** Reveiwed the following databases between 1991 through 2001: Medline, CINAHL, PsycINFO, Best evidence, Healthstar, Cochrane Database of Systematic Reviews, Legal Trac, Bioethicsline, Philosopher's Index, and Dissertation abstracts	**Inclusion criteria** Studies that presented data on samples of people with diagnoses of specific mental illness or addictive disorders , with not restrictions as to methodology. Broader studies reporting symptomatic sub groups in their analysis were excluded **Population** People with diagnoses of specific mental illness or addictive disorders **Characteristics of studies (interventions)** Smoking cessation interventions targeted at people with diagnoses of specific mental illness or addictive disorders **Method of review** NR **Study design** Qualitative narrative synthesis **What studies are included in meta-analysis** NA	**Main results** Twenty-four studies, 8 included schizophrenia, 8 included depression, and 8 included persons with addictive disorders Interventins used a combination of medication, educational and cognitive-behavioral approaches Post-treatment quit rates for Schizphrenia ranged from 35% to 56%, and a 6 months quit rate of 12% Postreatment quit rates for depression ranged from 31% to 72%, and 12 months quit rates 11.8% to 46% Postreatment quit rates for addictive disorders ranged from 7% to 60%, and 12 months quit rates 13% to 27% **Aim of review** To assess the impact of smoking cessation approaches on individuals with mental illness or addictive disorders	**Quality rating** Fair **Comments** NR **Adverse events** NA

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Lancaster et al., 2005 **Geographic area** United Kingdom **Funding source** Internal: Department of Primary Health Care, University of Oxford UK External: NHS Research and Development Programme UK **Time period covered** Databases searched systematically through April 2005	**Inclusion criteria** Randomized trials of smoking cessation w/ followup of at least six months, where at least one arm tested a self-help intervention Self help defined as a structured program of smokers trying to quit without intensive contact w/ a therapist **Population** Any smoker except pregnant smokers and adolescent smokers. **Characteristics of studies (Interventions)** • Self-help interventions used by individual to assist a quit attempt not aided by health professionals, counsellors and group support • Included written materials, audio, videotape or computer programs **Method of review** • Two authors extracted data • Trials categorized according to amount of face to face contact provided to both txt and comparison intervention, and according to whether txt group received any written materials **Study design** Cochrane Systematic Review and meta analysis performed where appropriate **Studies included in meta-analysis** NR	**Aim of review** To detemine effectiveness of different forms of self-help materials, compared w/ no txt and w/ other minimal contact strategies; effectiveness of adjuncts to self-help, such as computer generated feedback, telephone hotlines, and pharmacotherapies **Main results** Self-help vs no intervention: OR favored self-help intevention, although C1 narrowly excluded 1 (N = 13,773; OR 1.24, 95% CI, 1.07 - 1.45) • Two trials excluded due to significant heterogeneity • Where controls received an alterative form of written materials -- no evidence of an effect (N = 4,807; OR .87, 95% CI, .68 to 1.12); • Failed to find evidence of an increased quit rate by adding self-help to advice or NRT • Based on 3 studies self-help tailored materials were better than no intervention (N = 7,790 OR 1.38, 95% CI, 1.15 - 1.66)	**Quality rating** Good **Adverse events** No

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Lancaster et al., 2005 **Geographic area** United Kingdom **Funding source** Internal: Oxford University of Primary Health Care UK; External: NHS Research and Development Programme UK **Time period covered** Databases systematically searched though Dec 2004	**Inclusion criteria** Randomized and quasi-randomized trials w/ a least one txt are consisting of face to face individual counseling from a health care worker not involved in routine clinical care and outcome of smoking cessation at least 6 months after intervention **Population** Any smoker except children, adolescents, and pregnant women. **Characteristics of studies (Interventions)** • Face to face encounter b/w a smoking patient and a counsellor trained in assisting smoking cessation • Excludes studies of counseling delivered by doctors or nurses involved in regular clinical care • Also excluded multiple risk factor interventions **Method of review** • Two authors extracted data • Studies summarized • Results reported as odds ratios • Meta analysis used when appropriate **Study design** Cochrane Systematic Review w/ meta analysis of pooled studies **Studies included in meta-analysis** NR	**Aim of review** To determine effects of individual counseling **Main results** • Studies comparing counseling w/ minimal contact controls reported counseling significantly increases likelihood of cessation compared to less intense support (OR 1.56 95% CI, 1.32-1.84) • No evidence of benefit from more intensive compared to brief counseling (OR .98, 95% CI, .61-1.56); • Cessation rates higher in trials that used NRT, and patients w/ coronary artery disease • No significant differences occured b/w the comparison of counseling approaches	**Quality rating** Good **Adverse events** No

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Lancaster et al., 2004 **Geographic area** United Kingdom **Funding source** NHS Research and Development Programme UK **Time period covered** Reviewed the following databases b/w 1972 and 2003. Tobacco Addiction Group Register, Medline, Embase, Psyclit and the Cochrane Central Register of Controlled Trials, handsearching of specialist journals, and conference proceedings	**Inclusion criteria** • Randomized trials of smoking cessation advice from a medical practitioner in which abstinence was assessed at least 6 months following advice. • For inclusion in meta analysis: 1) had to have at least 2 txt groups, and 2) allocation to groups must use formal randomization **Population** • Participants were smokers recruited in any setting • Pregnant smokers excluded **Characteristics of studies (Interventions)** Studies included physician advice to stop smoking vs no advice or comparing different levels of physician advice to stop smoking **Method of review** • Data extracted from published reports by 2 people independently • Disagreeements resolved by referral to a third party • Quality assessment performed on all studies **Study design** Cochrane systematic reivew and meta analysis **Studies included in meta-analysis** Seventeen trials of brief advice vs no advice were pooled	**Aim of review** To assess effectiveness of advice from physicians in promoting smoking cessation; to compare minimal interventions by physicians w/ more intensive interventions; to assess effectiveness of various aids to advice in prom **Main results** Small satistically significant increase in odds of quiting (OR 1.74, 95% CI,1.48 to 2.05); Intense advice vs no advice and minimal advice showed a small but significant advantage to more intense advice A subset of 10 trials of smoker NOT selected as having smoking related disease showed a marginal significant impact for more intensive interventions (OR 1.24, 95% CI, 1.02 to 1.50); Studies that included followup visits had a higher success rate vs no advice than those studies that didn't have followup visits (OR 2.55, 95% CI, 2.04 to 3.19) Lack of evidence as to effectiveness of aids used in addition to providing advice and motivational counseling vs brief advice did not increase cessation rates	**Quality rating** Good **Adverse events** NA

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Lancaster et al., 2000 **Geographic area** United Kingdom **Funding source** Internal: Department of Primary Health Care, University of Oxford UK; External: NHS Anglia and Oxford Region Research and Development Programme UK; NHS Research and Dvelopment National Cancer Programme UK **Time period covered** Database searched systematically through May 2000	**Inclusion criteria** • Randomized trials in which the intervention was training of health care professionals in smoking cessation • Only used trials w/ outcomes from patient smoking rates at least 6 months after intervention **Population** Health care practitioner or health care practice **Characteristics of studies (Interventions)** • Health care professionals trained in methods to promote smoking cessation among their patients • Allocated health care professionals into at least 2 groups by a formal method of randomization • Studies that compared trained professionals to C and studies that examined effectiveness of adding prompts and reminders to training **Method of review** • Two reviewers independently extracted data from published articles. Disagreement resolved by referral to another person **Study design** Cochrane Systematic Review using a narrative approach to synthesising data **Studies included in meta-analysis** NR	**Aim of review** To assess effectiveness of training health care professionals to deliver smoking cessation interventions to their patients, and to assess additional effects of prompts and reminders to the health professional to intervene **Main results** • 10 studies met criteria • Trained professionals about 1.5 to 2.5 times more likely to counsel patients about smoking • One study found a significant effect of training on sustained abstinence at one yr (8.8% trained group vs 6.1% and 4.4% in comparison groups $P < 0.001$) • Prompts increase frequency of health professions performing intervention but only 1 out of 3 studies reported significant abstinence rates	**Quality rating** Good **Adverse events** No

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Lumley et al., 2004 **Geographic area** United Kingdom **Funding source** NHS Central R & D Programme, Dept. of Health 1995-1996 UK; Victorian Health Promotion Foundation Australia; Dept. of Health, funding for EPI Center, London University UK; Public Health Branch Victoria Dept. of Human Services Australia; La Trobe University **Time period covered** Databases searched systematically though July 2003	**Inclusion criteria** Randomized and quasi-randomized trials of smoking cessation programs implemented during pregnancy in settings such as hopitals, and community clinics **Population** Healthy pregnant women, women seeking a pre pregnancy consultation, and health professionals. **Characteristics of studies (Interventions)** Interventions include programs providing information on risks of smoking to fetus and infant, benefits of quitting, recommendations to quit, setting quit date, feedback about fetus and harmful levels of cotinine or CO, teaching cognitive behavior strategies, advice tailored to stages of change model, rewards/incentives, social support or peer support, and NRT **Method of review** • Two reviewers independently extracted data from published reports • Quality review of methodology assessed • Heterogeneity tested In all pooled analyses **Study design** Cochrane Systematic Review and meta analysis **Studies included in meta-analysis** NR	**Aim of review** To assess effects of smoking cessation programs implemented during pregnancy on health of fetus, infant, mother, and family **Main results** • 48 trials revealed a significant reduction in smoking in late pregnancy for aintervention groups (RR.09, 95% CI, .93 - .95) this is an absolute difference of 6 out of 100 women continuing smoking • With biochemically validated studies, absolute difference was same (RR.94, 95% CI, .92 - .95) • Smoking cessation interventions signifcantly reduced low birth weight, preterm birth, and increase birth weight by 33 g (RR .81, 95% CI, .70 - .94), (RR .84, 95% CI, .72 - .98), and (95% CI, 11g - 55g) • Intervention strategy (reward + social support) showed significantly greater smoking reduction (RR .77, 95% CI, .72 - .82) • Stages of change and relapse showed no significant reduction in smoking	**Quality rating** Good **Adverse events** No

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Author, year	Study Characteristics	Main Results/ Aim of Review	Quality Rating
Author, year Melvin et al., 2003 **Geographic area** United States **Funding source** The Robert Wood Johnson Foundation **Time period covered** Databases systematically search from January 1994 through March 31 2002.	**Inclusion criteria:** Randomized, comparison-controlled intervention trials for pregnant smokers at the individual level **Population** Pregnant smokers **Characteristics of studies (interventions)** • Brief counseling approach for pregnant smokers • Improving disclosure of smoking status • Spontaneous quitting and eminence of cessation • Postpartum relapse prevention • Adjuncts to brief counseling • Exposure to second hand smoke around time of pregnancy • Disclosure of second hand smoke around time of pregnancy • Increasing compliance with best practice **Method of review** Pre-screened published articles for relevance, two reviewers assessed studies independently for inclusion, data extracted by 1 reviewer and checked by a second, and used narrative synthese **Study design** Systematic review of literature **What studies are included in meta-analysis** NA	**Aim of review** To review the recommendations made in 2000 regarding treatment for pregnant and parenting **Main results** The 5 A's approach is still the best treatment for light and moderate smokers Clinicians offering care to postpartum women and parents should asses smoking status and second hand smoke exposure For parents willing to quit, the use of pharmacotherapy should be used to help To assess compliance of practice guidelines with best practice guide evaluation of effectiveness, assessment of financial incentives, and identification of methods is needed Additional research is recommended on ways to improve disclosure, safety and efficacy of pharmacotherapy, use of biomarker feedback or incentives, partner involvement, and interventions to reduce second hand smoke	**Quality rating** Good **Adverse events** NR

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Moher et al., 2005 **Geographic area** United Kingdom **Funding source** Internal: Department of Primary Health Care, Oxford University, External: NHS Research and Development Program UK **Time period covered** Databases searched systematically through October 2004.	**Inclusion criteria** Interventions categorized into two groups: 1)Interventions aimed at individual to promote smoking cessation in the workplace setting (included randomized control trials) 2) Interventions aimed at workplace as a whole (included controlled trials w/ baseline and post interventionoutcomes and interrrupted times series studies) **Population** Adults, over 18 yrs of age, in employment, who smoked. **Characteristics of studies (Interventions)** • Smoking cessation programs aimed at individual in workplace including individual and group counseling, self help materials, advice from physicians and NRT • Interventions aimed at workforce population to assess a comprehensive approach to workers health, including smoking cessation **Method of review** • Prescreened published articles for relevance • Two reviewers assessed studies independently for inclusion • Data extracted by 1 reviewer and checked by a second • Because of considerable heterogeneity studies were combined using qualitative narrative synthesis **Study design** Cochrane Systematic Review **Studies included in meta-analysis** NR	**Aim of review** To assess extent to which different kinds of workplace smoking programs help smokers to reduce or stop cigarette consumption. **Main results** • Group and individual counseling (particularly by a physician), and NRT significantly increased cessation rates vs no txt or minimal intervention controls • Self-help interventions less effective • Tobacco bans aimed at workplace as a whole decreased cigarette consumption at work but no evidence that total consumption decreased • Quit rates not increased by adding social or environmental support to workplace programs Competitions and incentives increased attempts to quit but less evidence for actual quitting	**Quality rating** Good **Adverse events** No

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Prochaska et al., 2004 **Geographic area** US **Funding source** Calif Tobacco-Related Disease Research Program, and National Institute on Drug Abuse **Time period covered** January 1966 through September 2003	**Inclusion criteria** Randomized controlled designs of evaluations of a smoking cessation intervention where study participants were in addiction txt or recovery Studies used quantitative assessment **Population** Adults aged 18 yrs and older. **Characteristics of studies (Interventions)** • Psychosocial smoking cessation interventions provided in all but 1 study and included the following: brief advice, educational information, skill based, behavioral, cognitive behavioral, motivational, or staged based interventions • Eleven studies provided NRT, one evaluated bupropion, and another fluoxetine **Method of review** • Two reviewers independently conducted article abstraction • One reviewer blinded to study author, institution, artile title, journal, and yr of publication • Qualilty assessment used a 3 pt scale • Discrepancies settled though discussion or consulting a third reviewer **Study design** • Abstinence ratios used to measure effect for smoking and substance use • Meta Analysis performed using 2X2 tables for txt and Cs • To reduce bias .5 was added to every cell in the table containing a zero • Abstinence rates expressed as relative risk w/ 95% CI; RR > 1.0 indicated favoring of intervention for increased abstinence **Studies included in meta-analysis** • 19 studies • 12 conducted w/ 1,410 participants in addiction txt and 7 studies w/ 638 participants in recovery	**Aim of review** To examine outcomes of smoking cessastion interventions evaluated w/ individual in current addictions txt or recovery **Main results** • Abstinence rates for addictions txt were 12% vs 3% in intervention and Cs • Abstinence rates for recovery were 38% vs 22% in intervention and Cs • Summary RR for addiction txt 2.03 (95% CI, 1.21 - 3.39; heterogeneity, *P* = 0.519) indicated a significant increase in likelihood of abstinence in intervention group • Summary RR for recovery 1.77 (95%CI, 1.37-2.30; heterogeneity, *P* = 0.878) indicated a significant increase in likelihood of abstinence in intervention group • ANOVA comparing addiction and recovery intervention effects were NS • Long term follow up no significant differences in smoking outcomes by condition • Significant increase of drug and alcohol abstinence occurred in intervention groups RR = 1.25 (95% CI, 1.07 – 1.46, heterogeneity, *P* = 0.496) • NRT studies revealed stronger effects and more recently published	**Quality rating** Good **Adverse events** No

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Author, year	Study Characteristics	Main Results/ Aim of Review	Quality Rating
Author, year Rigotti et al., 2002 **Geographic area** United Kingdom **Funding source** NHS Research and Development Programme UK and Department of Primary Health Care, Oxford University,UK **Time period covered** Databases systematically searched through March 2002	**Inclusion criteria:** • Randomized and quasi-randomized trials of behavioral, pharmacological or multicomponent interventions to help patients to stop smoking conducted with hospitalized patients • Trials of secondary prevention or cardiac rehabilitation that did not recruit on the basis of smoking history and trials in patients hospitalized for psychiatric disorders or substance abuse (including inpatient tobacco addiction programs) were excluded. **Population** Patients who were hospitalized, or about to be hospitalized and who were currently smoking or had recently quit. **Characteristics of studies (interventions)** Any intervention to increase motivation to quit, to assist a quit attempt or to help recent quitters avoid relapse. Interventions during the hospital stay were categorized according to whether they included follow-up after discharge and by level of intensity leading to four categories of intervention intensity: • Single contact in hospital lasting ≤ 15 minutes, no follow-up support • One of more contacts in hospital lasting in total > 15 minutes, no follow-up support • Any hospital contact plus follow-up ≤ 1 month • Any hospital contact plus follow-up ≥ 1 month **Method of review** Pre-screened published articles for relevance, three reviewers assessed studies independently for inclusion, data extracted by 1 reviewer and checked by a second, and used statistical methods for pooling described by Peto's group (Yusuf 1985) **Study design** Cochrane Systematic Review **What studies are included in meta-analysis** 17 trials conducted in the US, the UK, Canada and Spain between 1990 and 2002	**Aim of review** To determine the effectiveness of interventions for smoking cessation in hospitalized patients. **Main results** Intensive intervention (inpatient contact plus follow-up for at least 1 month) was associated with a significantly higher quit rate compared to control (Peto Odds Ratio = 1.82 (95% CI, 1.49-2.22, six trials). Inteventions with less than a month of follow-up did not show evidence of significant benefit (Peto Odds Ratio 1.99, (95%CI, 0.91-1.31, seven trials). There was no evidence to judge the effect of very brief (<20 minutes) interventions delivered only during rhe hospital stay. Longer inteventions delivered only during the hospital stay were not significantly associated with a higher quit rate (Peto Odds Ratio 1.07 (95% CI, 0.79-1.44, three trials). Although the interventions increased quit rates irrespective of whether nicotine replacement therapy (NRT) was used, the results for NRT were compatible with other data indicating that it increases quit rates. There was no strong evidence that clincial diagnosis affected the likelihood of quitting.	**Quality rating** Good **Adverse events** No

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Secker-Walker et al., 2002 **Geographic area** United Kingdom **Funding source** No source of support supplied **Time period covered** Databases searched systematically through August, 2001	**Inclusion criteria** Controlled trials of community interventions for reducing smoking prevalence in adult smokers where primary outcome measure was smoking behavior **Population** Adults, 18 yrs and older **Characteristics of studies (Interventions)** Coordinated, multidimensional programs aimed at changing adult smoking behavior involving several segments of the community and conducted in a defined geographical area such as a town, city, county, or administrative district **Method of review** • Prescreened published articles for relevance • Two reviewers assessed studies independently for inclusion • Data extracted by 1 reviewer and checked by a second • Studies combined using qualitative narrative synthesis **Study design** Cochrane Systematic Review **Studies included in meta-analysis** NR	**Aim of review** To assess effectiveness of community interventions for reducing prevalence of smoking **Main results** • Changes in smoking prevalence measured using cross sectional data in 27 studies • Net decline ranged from -1.0% to 3.0%/yr; for women -.2% to 3.5%/yr; for men -.4% to 1.6%/yr • Two rigorous studies found significant results:1) change in smoking prevalence among light/moderate smokers, 2) greater quit rates among men but community level changes not found • Projects that address smoking alone scarcely more effective than general health prevention projects • Longer project, projects using formative research, and projects w/ higher levels of participation and awareness were more effective	**Quality rating** Good **Adverse events** No

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Sinclair et al., 2005 **Geographic area** United Kingdom **Funding source** University of Aberdeen UK **Time period covered** Databases systematically searched through March 2003.	**Inclusion criteria** Randomized trials which compared interventions by community pharmacy personnel to promote smoking cessation amongst their clients who were smokers compared to usual pharmacy support or any less intensive program **Population** Community pharmacy clients who are smokers and wish to stop. **Characteristics of studies (Interventions)** Any intervention by community pharmacy personnel to promote smoking cessation amongst their clients Pharmaceutical trials which compared only NRT w/ a control in the community pharmacy setting did not fall within scope of this review **Method of review** • Studies generated by search strategy reviewed by two authors, according to inclusion criteria • Data extracted by one author and checked by a second **Study design** Cochrane Systematic Review **Studies included in meta-analysis** NR	**Aim of review** To assess effectiveness of interventions by community pharmacy personnel to assist clients to stop smoking **Main results** • Two trials met the criteria w/ a total of 976 smokers • Both studies involved training using stages of change model, and compared a support program of counseling and record keeping w/ a C who recieved normal services • Significant result for study 1 showed cotinine-validated continuous abstinence at 12 months of 14.3% in intervention group and 2.7% in C • Study 2 did not show a statistically significant effect at any followup, but there was a consistent trend toward benefits fro intervention • Using a random effects model to pool results showed no evidence of significant benefits	**Quality rating** Good **Adverse events** NA

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Sowden et al., 2003 **Geographic area** United Kingdom **Funding source** NHS Center for Reviews and Dissemination, UK **Time period covered** Databases searched systematically through September 2002	**Inclusion criteria** Randomized and non RCTs that assessed effectiveness of multi-component community (geographical or school district) interventions to prevent uptake of smoking in young people **Population** Young people aged less than 25 yrs **Characteristics of studies (Interventions)** Interventions targeted at entire or parts of entire communities or lage ares w/ intention of influencing smoking behaviors of young people **Method of review** • Prescreened published articles for relevance • Two reviewers assessed studies independently for inclusion • Data extracted by 1 reviewer and checked by a second, • Studies combined using qulitative narrative synthesis **Study design** Cochrane Systematic Review **Studies included in meta-analysis** NR	**Aim of review** To determine effectiveness of community interventions in preventing initation of smoking in young people. **Main results** • Community interventions vs no intervention controls reported lower smoking prevalence; • Community interventions vs school-based only intervention found a significant smoking prevalence in one study • Community interventions vs community w/ school-based component found no differences in smoking cessation rates • Community intervention w/ media component vs media alone found significantly lower rate of increased smoking in community and media intervention	**Quality rating** Good **Adverse events** No

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Sowden et al., 1998 **Geographic area** United Kingdom **Funding source** Internal: NHS Centre for Reviews and Dissemination UK; External: NHS Research and Development National Cancer Programme, England UK **Time period covered** Databases searched systematically through June 1998	**Inclusion criteria** Studies that evaluated effectiveness of mass media campaigns influencing smoking behaviors in young people using the following designs: 1) RCT w/ unit of analysis as school, community or geographic area, 2) controlled trial w/o randomization, 3) time series **Population** Young people aged less than 25 yrs. **Characteristics of studies (Interventions)** • Mass media interventions using communication channels such as TV, radio, newspapers, bill boards, posters, leaflets or booklets intended to prevent uptake of smoking in young people • Also mass media campaigns combined w/ school-based programs designed to influence smoking behaviors were included **Method of review** • Stage 1: Reports of evaluations prescreened for relevance by at least one reviewer • Stage 2: Relevant studies assessed independently by 2 reviewers • Stage 3: Data extracted from included studies by one reviewer and checked by a second reviewer • Stage 4: Studies combined using qualitative narrative synthesis **Study design** • Cochrane Systematic Review • Studies combined using qualitative narrative synthesis **Studies included in meta-analysis** NR	**Aim of review** To determine effectiveness of mass media campaigns in preventing uptake of smoking in young people. **Main results** • Two of these six control trial design interventions found to be associated w/ reductions in smoking behavior • A media campaign aimed at girls found 4% lower smoking rates for girls in the media county (8.6% vs 12.4%, $P < 0.01$); OR of being a smoker in intervention county compared w/ being a smoker in control was .74 (95% CI, .64 to .86) after adjusting for baseline and gender • A media campaign combined w/ a school-based program vs school based program alone found a lower risk for weekly smoking at 2 yr in communities w/ combined intervention (OR .62, 95% CI, .49 to .78) • Both studies had effective campaigns w/ solid theoretical basis, used formative research in designing messages, and message broadcasts were intense over a extensive period of time • Problems w/ other studies: allocation of communities, areas and schools, unit of analysis, differences in baseline measure, and high attrition	**Quality rating** Good **Adverse events** NA

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Stead et al., 2005 **Geographic area** United Kingdom **Funding source** Internal: Department of Primary Helath Care, Oxford University UK, External: NHS Research and Development National Cancer Programme UK **Time period covered** Database searched sytematically through February 2005	**Inclusion criteria** Randomized trials w/ a minimum of two group meetings and followup at least 6 months **Population** Smokers of either gender irrespective of initial level of nicotine dependency, except for pregnant smokers. **Characteristics of studies (Interventions)** Studies where smokers met for scheduled meetings and received some form of behavioral therapy delivered over at least 2 sessions **Method of review** • Studies idenified and reviewed independently by 2 authors and disagreements referred to a third party • If 2 group methods were compared w/ another method the groups were combined and compared w/ the non group method **Study design** Cochrane Systematic Review and meta analysis performed if appropriate **Studies included in meta-analysis** NR	**Aim of review** To determine effects of smoking cessation programs delivered in a group format compared to self-help materials, no intervention, individual counseling, advice from Physician, and NRT **Main results** • Group therapy significantly increased cessation vs self-help using same or different content (N = 4395, OR 2.04, 95% CI, 1.60 - 2.60) • Higher quit rates comparing group to no intervention N = 815, OR 2.17, 95% CI, 1.37 - 3.45); No significant difference comparing group w/ individual therapy and only limited evidence that group produces extra benefits when combined w/ physician advice and NRT	**Quality rating** Good **Adverse events** No

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Stead, 2003 **Geographic area** United Kingdom **Funding source** NHS Research and Development Programme UK **Time period covered** Databases searched systematically through September 2002	**Inclusion criteria** Randomized or quasi-RCTs in which proactive or reactive telephone counseling to assist smoking cessation was offered to smokers or recent quitters **Population** Smokers or recent quitters **Characteristics of studies (Interventions)** • Proactive or reactive telephone counseling to assist smoking cessation to any population • Also studies that combined telephone counseling w/ self-help materials **Method of review** Relevant studies identified by one person and checked for inclusion or exclusion by a second person Data extracted by one author and checked by a second **Study design** Cochrane Systematic Review and if no signficant heterogeneity studies pooled for a meta analysis **Studies included in meta-analysis** NR	**Aim of review** To evaluate effect of proactive and reactive telephone support to help smokers quit **Main results** • Procative phone counseling + minimal intervention vs minimal intervention only: indicted a significant benefit from addition of phone counseling when minimal intervention used standard self-help material (OR 1.56, 95% CI, 1.38 - 1.77) • Proactive phone counseling increasec quit rates from 4.1% to 7.5% when compared to self-help or reactive counseling; Adding telephone counseling to face to face interventions failed to significantly increase OR (OR 1.08, 95% CI, .87- 1.33) • Adding proactive counseling to NRT did not signficantly increasequit rates; proactive counseling compared to group counseling showed no differences • Access to a hotline or reactive phone counseling showed a significant benefit in one out of 3 trials	**Quality rating** Good **Adverse events** No

Evidence Table 10. Systematic and meta-analysis reviews (continued)

Study Demographics	Study Characteristics	Aim of Review Main Results	Quality Rating
Author, yr Thomas et al., 2002 **Geographic area** United Kingdom **Funding source** No source of support supplied **Time period covered** Databases systematically searched through January 2002	**Inclusion criteria** Studies where individual students, classes, schools, or school districts were randomised to intervention or Cs and followed for at least 6 months **Population** Children (aged 5 to 12) or adolescents (aged 13 to 18) in school settings **Characteristics of studies (Interventions)** Classroom programs or curricula, including those associated w/ family or community interventions, intended to deter use of tobacco **Method of review** • Prescreened published articles for relevance • Two reviewers assessed studies independently for inclusion • Data extracted by 1 reviewer and checked by a second • Because of considerable heterogeneity the studies were combined using qualitative narrative synthesis **Study design** Cochrane Systematic Reveiw **Studies included in meta-analysis** NR	**Aim of review** To review all RCTs of behavioural interventions in schools to prevent children and adolescents starting smoking **Main results** • Information curriculum interventions less effective or showed no difference compared to other models of delivery • SLT (most widely used theory) had 8 studies w/ positive effects and 7 w/o positive effects and HSPP study had no effect • SLT lacks evidences about effectiveness • Limited evidence that combining social influence models w/ other components improves effectiveness	**Quality rating** Good **Adverse events** No

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Appendix D
List of Excluded Studies

Exclusion Codes:

X1: Foreign language
X2: Wrong outcome/off topic
X3: Sample size too small
X4: Outside specified geographic area
X5: Wrong publication type
X6: Wrong study design
X7: Follow-up too short
X8: Wrong date

Excluded articles

Oral snuff: a preventable carcinogenic hazard. Lancet 1986; 2(8500):198-200.
Notes: 2873443
KQ4 Search Editorial
User Define 1: I
User Define 2: X5

Smokeless tobacco sales increasing. ASDC J Dent Child 1991; 58(2):90.
Notes: 2050882
KQ4 Search News
User Define 1: I
User Define 2: X5

Smoking--getting the message across. Midwives Chron 1989; 102(1215):110.
Notes: 2761435
KQ3 Search Journal Article
User Define 1: I
User Define 2: X5

Summary for patients. Effect of a training program for resident physicians in improving success rate in helping patients quit smoking. Ann Intern Med 2002; 136(6):I31.
Notes: 11900514
KQ1 Search Clinical Trial
User Define 1: I
User Define 2: X5

Tobacco and health. CMAJ 1997; 156(2):240A-F.
Notes: 9012730
KQ4 Search Journal Article
User Define 1: I
User Define 2: X5

Tobacco-use prevention and cessation. For infants, children, adolescents, and adults. Institute for Clinical Systems Integration. Postgrad Med 1997; 101(3):292-300, 302.
Notes: 9074566
KQ3 Search Guideline
User Define 1: I
User Define 2: X5

Abel M. Substance misuse among young people in the Pacific. Promot Educ 1997; 4(3):41-2.
Notes: 9438308
KQ2 Search Journal Article KQ2 Search
User Define 1: I
User Define 2: X5

Abernathy TJ. Compliance for Kids: a community-based tobacco prevention project. Can J Public Health 1994; 85(2):82-4.
Notes: 8012922
KQ2 Search Journal Article KQ2 Search
User Define 1: I
User Define 2: X8

Adelman WP, Duggan AK, Hauptman P, Joffe A. Effectiveness of a high school smoking cessation program. Pediatrics 2001; 107(4):E50.
Notes: 11335771
KQ1 Search Clinical Trial
User Define 1: I
User Define 2: X7

Allen TW. Eliminating tobacco use, a continuing challenge. J Am Osteopath Assoc 2004; 104(8):313.
Notes: 15345698
KQ3 Search Comment
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Author	Title	Year
Stevens VJ, H. Severson, E. Lichtenstein, S. J. Little and J. Leben	Making the most of a teachable moment: a smokeless-tobacco cessation intervention in the dental office	1995
Walsh MM, J. F. Hilton, C. M. Masouredis, L. Gee, M. A. Chesney and V. L. Ernster	Smokeless tobacco cessation intervention for college athletes: results after 1 year	1999
Walsh MM, J. F. Hilton, J. A. Ellison, L. Gee, M. A. Chesney, S. L. Tomar and V. L. Ernster	Spit (Smokeless) Tobacco Intervention for High School Athletes: results after 1 year	2003

COCHRANE: Lancaster T, Stead LF, "Individual behavioural counselling for smoking cessation," 2005

Author	Title	Year
Leed-Kelly, A, K. S. Russell, J. K. Bobo and H. McIlvain	Feasibility of smoking cessation counseling by phone with alcohol treatment center graduates	1996
Malchodi, C. S., C. Oncken, et al.	The effects of peer counseling on smoking cessation and reduction	2003
McLeod, D., S. Pullon, et al.	Can support and education for smoking cessation and reduction be provided effectively by midwives within primary maternity care	2004
Molyneux, A, S. Lewis, U. Leivers, A. Anderton, M. Antoniak, A. Brackenridge, F. Nilsson, A. McNeill, R. West, J. Moxham and J. Britton	Clinical trial comparing nicotine replacement therapy (NRT) plus brief counselling, brief counselling alone, and minimal intervention on smoking cessation in hospital inpatients	2003
Simon, J. A., T. P. Carmody, et al.	Intensive smoking cessation counseling versus minimal counseling among hospitalized smokers treated with transdermal nicotine replacement: a randomized trial	2003

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Author	Title	Year
Richman PB, Dinowitz S, et al	The emergency department as a potential site for smoking cessation intervention : a randomized controlled trial	2000
Schnoll RA, Zhang B, et al	Brief physician-initiated quit-smoking strategies for clinical oncology settings: a trial coordinated by the Eastern Cooperative Oncology Group	2003
Willams GC, Gagne M, et al	Facilitating autonomous motivation for smoking cessation	2001
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Becona, E and F. L. Vazque	Effectiveness of personalized written feedback through a mail intervention for smoking cessation: A randomized-controlled trial in Spanish smokers	2001
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Catley, D., J. S. Ahluwalia, et al.	Depressive symptoms and smoking cessation among inner-city African Americans using the nicotine patch	2003
Etter, JF and T. V. Perneger	Effectiveness of a computer-tailored smoking cessation program: a randomized trial	2001
Fortmann SP, J. D. Killen, M. J. Telch and B. Newman	Minimal contact treatment for smoking cessation. A placebo controlled trial of nicotine polacrilex and self-directed relapse prevention: initial results of the Stanford Stop Smoking Project	1988
Lennox, AS, L. M. Osman, E. Reiter, R. Robertson, J. Friend, I. McCann, D. Skatun and P. T. Donnan	Cost effectiveness of computer tailored and non-tailored smoking cessation letters in general practice: randomised controlled trial	2001
Pallonen UE, L. Leskinen, J. O. Prochaska, C. J. Willey and et al.	A 2-year self-help smoking cessation manual intervention among middle-aged Finnish men: An application of the transtheoretical model	1994
Sykes, C. M. and D. F. Marks	Effectiveness of a cognitive behaviour therapy self-help programme for smokers in London, UK	2001

COCHRANE: Lumley J, Oliver SS, Chamberlain C, Oakley L., "Interventions for promoting smoking cessation during pregnancy," 2004

Author	Title	Year
Albrecht A, B. Cassidy, D. Salamie and M. D. Reynolds	A smoking cessation intervention for pregnant adolescents: implications for nurse practitioners	1999
Donatelle, R. J., S. L. Prows, et al.	Randomised controlled trial using social support and financial incentives for high risk pregnant smokers: significant other supporter (SOS) program	2000
Ershoff, D. H., V. P. Quinn, et al.	The Kaiser Permanente prenatal smoking-cessation trial: when more isn't better, what is enough?	1999
Hegaard, H. K., H. Kjaergaard, et al.	Multimodal intervention raises smoking cessation rate during pregnancy	2003
Moore L, R. Campbell, A. Whelan, N. Mills, P. Lupton, E. Misselbrook and J. Frohlich	Self help smoking cessation in pregnancy: cluster randomised controlled trial	2002
Tappin, D. M., M. A. Lumsden, et al.	A pilot study to establish a randomized trial methodology to test the efficacy of a behavioural intervention	2000
Tappin, DM, M. A. Lumsden, D. McIntyre, C. McKay, W. Gilmour, R. Webber, S. Cowan, F. Crawford and F. Currie	A pilot study to establish a randomized trial methodology to test the efficacy of a behavioural intervention	2000
Wisborg, K., T. B. Henriksen, et al.	Nicotine patches for pregnant smokers: a randomized controlled study	2000

COCHRANE: Moher M, Hey K, Lancaster T, "Workplace interventions for smoking cessation," 2005

Author	Title	Year
Emmons, K. M., L. A. Linnan, et al.	The Working Healthy Project: a worksite health-promotion trial targeting physical activity, diet, and smoking	1999
Hennrikus, D. J., R. W. Jeffery, et al.	The SUCCESS project: the effect of program format and incentives on participation and cessation in worksite smoking cessation programs	2002
Lang T, V. Nicaud, K. Slama, A. Hirsch, E. Imbernon, M. Goldberg, L. Calvel, P. Desobry, J. P. Favre-Trosson, C. Lhopital, P. Mathevon, D. Miara, A. Miliani, F. Panthier, G. Pons, C. Roitg and M. Thoores	Smoking cessation at the workplace. Results of a randomised controlled intervention study. Worksite physicians from the AIREL group	2000
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Sorensen, G, B. Thompson, K. Glanz, Z. Feng and et al.	Work site-based cancer prevention: Primary results from the Working Well Trial	1996
Sorensen, G., A. M. Stoddard, et al.	A comprehensive worksite cancer prevention intervention: behavior change results from a randomized controlled trial (United States	2002
Sorensen, G., A. M. Stoddard, et al.	A comprehensive worksite cancer prevention intervention: behavior change results from a randomized controlled trial (United States	2003

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Author	Title	Year
Feeney, G. F., A. McPherson, et al.	Randomized controlled trial of two cigarette quit programmes in coronary care patients after acute myocardial infarction	2001
Galvin, K., C. Webb, et al.	Galvin, K., C. Webb, et al. (2001). "Assessing the impact of a nurse-led health education intervention for people with peripheral vascular disease who smoke: the use of physiological markers, nicotine dependence and withdrawal	2001
Hajek, P., T. Z. Taylor, et al.	Brief intervention during hospital admission to help patients to give up smoking after myocardial infarction and bypass surgery: randomised controlled trial	2002
McHugh, F., G. M. Lindsay, et al.	Nurse led shared care for patients on the waiting list for coronary artery bypass surgery: a randomised controlled trial	2001

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Author	Title	Year
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COCHRANE: Sowden A, Arblaster L, Stead L, "Community Interventions for preventing smoking in young people," 2003

Author	Title	Year
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COCHRANE: Stead LF, Lancaster T, Perera R, "Telephone counselling for smoking cessation," 2003

Author	Title	Year
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Lipkus, IM, P. R. Lyna and B. K. Rimer	Using tailored interventions to enhance smoking cessation among African-Americans at a community health center	1999
McBride, CM, D. Scholes, L. C. Grothaus, S. J. Curry, E. Ludman and J. Albright	Evaluation of a minimal self-help smoking cessation intervention following cervical cancer screening	1999
McFall SL, A. Michener, D. Rubin, B. R. Flay, R. J. Mermelstein, D. Burton, P. Jelen and R. B. Warnecke	The effects and use of maintenance newsletters in a smoking cessation intervention	1993
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Author	Title	Year
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McBride, CM, D. Scholes, L. C. Grothaus, S. J. Curry, E. Ludman and J. Albright	Evaluation of a minimal self-help smoking cessation intervention following cervical cancer screening	1999
McFall SL, A. Michener, D. Rubin, B. R. Flay, R. J. Mermelstein, D. Burton, P. Jelen and R. B. Warnecke	The effects and use of maintenance newsletters in a smoking cessation intervention	1993
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Appendix E
Acknowledgments

Appendix E. Acknowledgments

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Technical Expert Panel

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Peer Reviewers

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