Evidence Report/Technology Assessment

Number 214

Smoking Cessation Interventions in Pregnancy and Postpartum Care

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Evidence-Based Practice

Evidence Report/Technology Assessment

Number 214

Smoking Cessation Interventions in Pregnancy and Postpartum Care

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This report is based on research conducted by the Vanderbilt Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2007-10065-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—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. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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This report may periodically be assessed for the urgency to update. If an assessment is done, the resulting surveillance report describing the methodology and findings will be found on the Effective Health Care Program Web site at: www.effectivehealthcare.ahrq.gov. Search on the title of the report.

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None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. 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 email to epc@ahrq.hhs.gov.

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Ms. Sanura Latham and Ms. Hollie Black assisted with formatting, data entry, and article retrieval. Ms. Nila Sathe provided guidance on logistics of the review process and organization of the report.

Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives are sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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Smoking Cessation Interventions in Pregnancy and Postpartum Care

Structured Abstract

Objective. The Vanderbilt Evidence-based Practice Center systematically reviewed evidence about smoking cessation interventions in pregnant and postpartum women.

Data sources. We searched MEDLINE®, CINAHL®, and PsycINFO® for randomized controlled trials (RCTs) on interventions and prospective studies on patient characteristics published in English.

Review methods. We dually reviewed abstracts and full texts. Studies were excluded if they did not address a Key Question, were not an eligible study design, or did not report biochemically validated smoking cessation outcomes. Data were extracted into evidence tables and summarized qualitatively. A meta-analysis of effectiveness data assessed relative impact of components in smoking cessation interventions.

Results. We included 59 unique studies reported in 72 publications. Of the 56 RCTs, 13 were good, 15 fair, and 28 poor quality. Studies evaluated counseling-based interventions, educational materials, nicotine replacement therapy (NRT), peer support, multicomponent interventions, and other unique interventions. Multicomponent approaches were most likely to be effective, but results were inconsistent. In the meta-analysis, incentives demonstrated the strongest effect; other components with a greater than 80-percent likelihood of success were feedback about biologic measures, information, personal followup, NRT, and quit guides. Findings regarding infant outcomes were inconsistent or did not reach statistical significance. No serious harms were identified in four studies that reported adverse events.

Conclusions. Across interventions, data are sparse to evaluate sustained cessation among pregnant and postpartum women. This review suggests that approaches that combine multiple components will have the best likelihood of success. Selecting which components to include is more complex and should be based on the particular considerations of the clinical setting, including patient characteristics and resource allocation, but incentives demonstrated the greatest effect among components studied. Infant outcomes are limited to data collected at time of birth; no studies assessed longer term or child outcomes. Harms data were rarely reported.

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Executive Summary

Background

Nearly 443,000 U.S. deaths are attributable annually to cigarette smoking, which makes tobacco, including secondhand smoke, the most preventable cause of disease, disability, and death in the United States.[1,2] An estimated 19.8 million women in the United States smoke.[3] Nationally, 23 percent of women report smoking in the 3 months before pregnancy, while 13 percent report smoking in the last 3 months of pregnancy. Rates vary significantly by State, with up to 30 percent of women in some States reporting continued tobacco use in the third trimester. Fewer than half of pregnant smokers report successfully quitting during pregnancy,[1] and self-report leads to an overestimation of cessation rates in pregnancy.[4] Nondisclosure of smoking status among pregnant smokers is common and ranges from 23[5] to 49 percent[6] in published reports.

Smoking during pregnancy can result in significant complications for the pregnant woman, her fetus, and members of the woman's household who are exposed to secondhand smoke. Smoking is associated with increased risk of placental abruption, anemia, preterm birth, chronic hypertension, and placenta previa.[7-10] Health risks to the fetus include low birth weight, restricted growth, and fetal death.[9,11-17]

Multiple interventions to promote smoking cessation exist. They include advice and counseling, self-help materials, nicotine replacement therapy (NRT), antidepressants including bupropion (Zyban®), and pharmacologic cessation aids such as varenicline (Chantix®). While these pharmacologic aids may limit the exposure to tobacco smoke, little is known about their potential adverse effects on short- and long-term reproductive outcomes. The U.S. Food and Drug Administration places the transdermal nicotine patch in pregnancy category D, which indicates there are known risks to the fetus, but potential benefits may outweigh risks in some cases. The other nicotine replacement products, as well as varenicline and bupropion, are category C medications, meaning animal studies have shown adverse fetal effects and no adequate human studies are available, but potential benefits may outweigh risks.[18-22] The American College of Obstetricians and Gynecologists does not recommend pharmacologic interventions as first-line therapies in pregnant women due to lack of evidence on safety and efficacy.[23,24]

Overall, the findings from existing systematic reviews suggest that NRT, behavioral and educational cessation strategies, and multicomponent interventions may be beneficial to women who smoke in pregnancy or the postpartum period, but to date, evidence has been mixed.[25-29] Despite these previous systematic review efforts, however, the efficacy of specific components and the impact of these various strategies on smoking and infant outcomes in pregnant and postpartum women remain unclear.

Scope and Key Questions

This review is focused on the evidence available to inform the provision of smoking cessation strategies for health care providers. The relevant population for this review consists of pregnant and postpartum woman who are current smokers or recent quitters. The literature reflects various strategies to promote smoking cessation and relapse prevention. Interventions include any behavioral, psychosocial, pharmacologic, or educational intervention intended to

promote individual changes in cigarette consumption among pregnant smokers and recent quitters in the prenatal and postpartum period. Interventions targeting the behavior of smokers' partners or health care providers exclusively were not included. Interventions of interest are those that were conducted in or originated from a health care setting. The review does not include public health initiatives or system-level smoking cessation research.

Smoking outcomes are limited to biochemically validated reports of smoking cessation during pregnancy or in the postpartum period. Biochemical validation of smoking status includes measures of cotinine from saliva, urine, or serum; expired carbon monoxide; or serum thiocyanate. Although these measures do not verify continuous abstinence, they are accepted standards for evaluating point prevalence of smoking status. The review does not report smoking reduction.

We addressed the following Key Questions:

Key Question 1: What is the effectiveness of interventions intended to achieve or maintain smoking cessation in women who are pregnant or postpartum for promoting smoking cessation, relapse prevention, and continuous abstinence?

Key Question 2: What is the effectiveness of interventions intended to achieve or maintain smoking cessation in women who are pregnant or postpartum for improving infant and child outcomes?

Key Question 3: What are the harms of interventions intended to achieve or maintain smoking cessation in women who are pregnant or postpartum?

Key Question 4: What is the effect of components of the smoking cessation intervention, including who delivered the intervention (physician, nurse, midwife, etc.), the intervention itself, and where the intervention was delivered (clinic, hospital setting, etc.), on cessation of smoking or durability of cessation in women who are pregnant or postpartum?

Key Question 5: What is the effect of patient characteristics on outcomes of smoking cessation interventions (successful/unsuccessful cessation, relapse) in women who are pregnant or postpartum?

Because there is a high risk of relapse among individuals who attempt to quit smoking, we assessed relapse prevention outcomes in pregnancy and after parturition from studies of smoking cessation interventions for women defined as recent quitters. The review also reports infant and/or child outcomes (Key Question 2) from studies evaluating smoking cessation interventions, but does not include analysis of information about the effects of maternal smoking on child health. Data on harms or adverse effects of included interventions are captured in Key Question 3. The aim of Key Question 4 is to obtain information on components of the interventions that may have an impact on patient outcomes, while Key Question 5 is included to capture characteristics that potentially modify outcomes from eligible studies. We explicitly

defined eligibility criteria using a PICOTS (population, intervention, comparator, outcome, timing, and setting) structure (Table A).

Table A. PICOTS

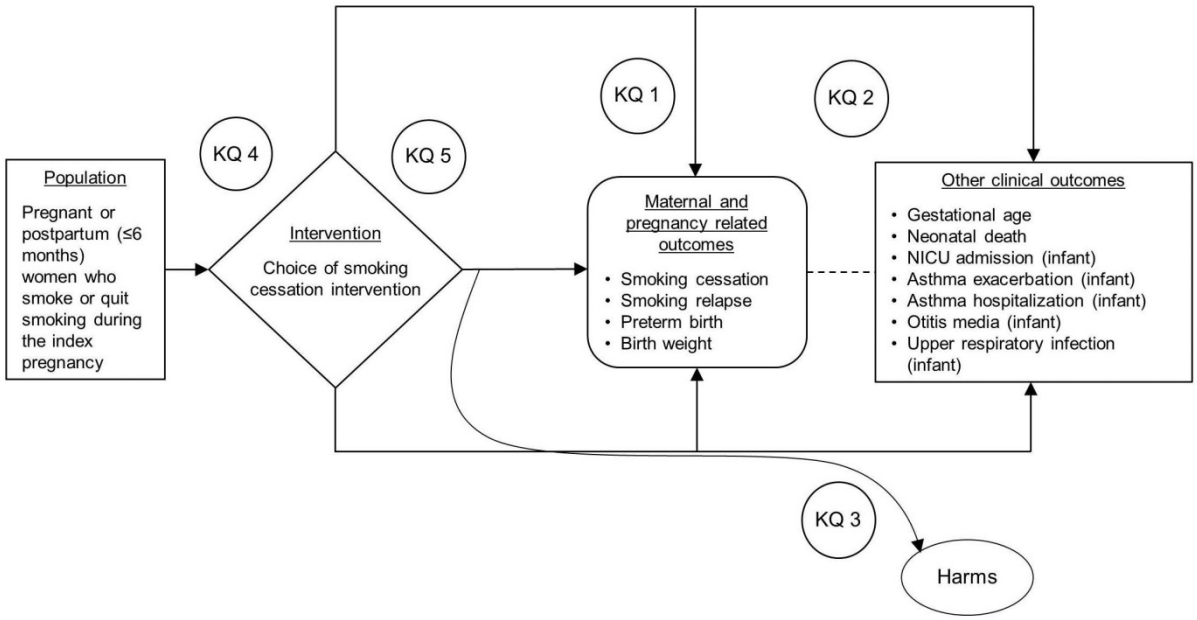
PICOTS	Criteria
Population	• Pregnant or postpartum (≤6 months post-birth) women who smoke or quit smoking in the index pregnancy • Infants and children of pregnant or postpartum (≤ 6 months post-birth) women receiving smoking cessation interventions • Subgroups of pregnant and/or postpartum women by level of nicotine dependence, prior quit attempts, concomitant substance or alcohol abuse, partner smoking status, and/or employment
Intervention	Any smoking cessation intervention, including pharmacologic and nonpharmacologic interventions
Comparator	• Different intervention • Usual care • Placebo
Outcomes	**KQ1** • Smoking cessation (biochemically validated) • Continuous abstinence (biochemically validated) • Relapse **KQ2** • Preterm birth • Gestational age • Birth weight • Neonatal death • NICU admission • Asthma exacerbation • Asthma hospitalization • Otitis media • Upper respiratory infection **KQ3** Harms (e.g., weight gain, emotional stress, adverse events associated with medication to the mother or fetus) **KQs 4 and 5** • Smoking cessation (biochemically validated) • Continuous abstinence (biochemically validated) • Relapse
Timing	Any length of followup
Setting	Clinician-initiated intervention or an intervention that intersects clinical care

Abbreviations: KQ = Key Question; NICU = neonatal intensive care unit; PICOTS = population, intervention, comparator, outcome, timing, setting.

Analytic Framework

We developed the analytic framework (Figure A) illustrating the population, interventions, and outcomes that guided the literature search, study eligibility, screening, and synthesis.

Figure A. Analytic framework



Abbreviations: KQ = Key Question; NICU = neonatal intensive care unit.

Methods

Literature Search Strategy

We searched MEDLINE®, CINAHL®, and PsycINFO®. Search results were limited to papers published in English. Search strategies used a combination of subject headings (i.e., controlled vocabulary) and keywords (Appendix A of full report). Searches were executed between October 2012 and January 2013. We also searched the reference lists of included publications and recent systematic reviews related to smoking cessation interventions for pregnant women.

Inclusion and Exclusion Criteria

The inclusion and exclusion criteria for the review (Table B) were derived from our understanding of the literature and refinement of the review topic with the Task Order Officer and the topic nominators. We included studies of pregnant or postpartum (within 6 months of birth) women who currently smoked or who had quit during the index pregnancy.

We did not limit the search to studies conducted during any specific time period. We included studies published in English only. Two team members independently reviewed the titles and abstracts of the non–English-language literature published since 1990 located via the MEDLINE search (Appendix A of the full report) and determined that few studies would meet the inclusion criteria. Most non–English-language studies were cross-sectional or were not original research.

Studies were required to include a minimum of 20 participants with data in each study arm. The team established this minimum sample size to balance the need for smaller studies of specialized populations (e.g., studies in specific ethnic groups) with the need to preserve methodologic rigor.

Table B. Inclusion and exclusion criteria

Category	Criteria
Study population	Pregnant or postpartum (up to 6 months post-birth at initiation of the intervention) women who smoke or quit smoking during the index pregnancy
Time period	Database inception to present
Publication languages	English only

Admissible evidence (study design and other criteria)	Admissible designs
	• KQs 1–5: RCT
	• KQs 3–5: Prospective cohort study
	
	Other criteria
	• Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results
	• Studies targeting women who smoke and meet the population criteria described above
	• Studies that address one or both of the following:
	  o Treatment modality aimed at smoking cessation in a relevant population
	  o Outcomes related to interventions; primary outcomes of interest include smoking cessation, continuous abstinence, smoking relapse, harms of intervention to the mother or fetus, gestational age, NICU admission, birth weight, and preterm birth
	• Studies that include extractable data presented in text or tables (as opposed to solely in figures) on relevant outcomes

Abbreviations: KQ = Key Question; NICU = neonatal intensive care unit; RCT = randomized controlled trial.

Study Selection

We developed screening forms to assess eligibility for inclusion in the review (Appendix B of the full report). We revised the forms following testing by the team. We conducted screening in two phases: abstract and full-text screening. Publications were promoted to full-text review when one reviewer indicated that the publication met all inclusion criteria or when the title and abstract did not provide adequate information to make a determination. Two reviewers independently reviewed each publication at the full-text screening phase. Discordant classifications were resolved in team meetings including senior investigators.

Data Extraction

Two reviewers independently extracted relevant data from all included publications using a predefined evidence table shell. A senior investigator reviewed the evidence tables for accuracy and completeness. The final evidence tables are provided in Appendix H of the full report.

Risk-of-Bias Assessment

We assessed quality of randomized controlled trials (RCTs) using the Cochrane Collaboration Risk of Bias Tool,[30] which evaluates domains, including sequence generation, allocation concealment, blinding, outcome data reporting, and reporting bias. Two reviewers independently assessed risk of bias as low, high, or unclear for each domain. Differences were resolved though discussion, review of the publications, and consensus with the team. We rated studies as good, fair, or poor quality and retained poor studies as part of the evidence base but did not include them in our assessment of strength of evidence.

Data Synthesis

To synthesize the data, we first divided the studies into broad categories and described the studies qualitatively within this organization (Key Question 1). These categories were established a priori as accepted approaches to intervening during pregnancy to encourage women to stop smoking. The categories reflect broad approaches to cessation intervention, and the studies within a category are often very heterogeneous.

While studies may purport to examine effects of an individual intervention component, interventions are almost always multicomponent in practice. In addition, even usual care often includes an intervention, such as some level of counseling. Thus, we also conducted a meta-analysis, using a Bayesian approach to a logistic mixed-effects model to quantify the relative influence of each component within the interventions across the body of literature. This served in part to answer Key Question 4. It also provided a quantitative basis for assessing strength of evidence (see below), in addition to providing a basis for users of the report to make intervention decisions.

Data for Key Questions 2, 3, and 5 were described qualitatively. Key Question 2 was organized by the infant outcomes being assessed, Key Question 3 was organized by the categories of interventions used in Key Question 1, and Key Question 5 was organized by factors that modify success of the intervention and factors related to probability of cessation.

Strength of the Body of Evidence

Two senior investigators graded the body of evidence based on the "Methods Guide for Effectiveness and Comparative Effectiveness Reviews,"[31,32] and the final assignment was reviewed with the project team.

We assessed the strength of evidence for effectiveness, infant outcomes, and harms of interventions. Because of the heterogeneity of interventions within categories of approaches, we focused our strength-of-evidence assessment on the components that could be meta-analyzed and thus contributed quantitative data to our understanding of smoking cessation in pregnancy. We used the standard Evidence-based Practice Center approach to strength of evidence with this exception: if the posterior probabilities based on the Bayesian credible intervals (BCIs) suggested greater than 80-percent likelihood that the true effect was greater than the null, we considered the estimate of the effect to be positive and therefore assessed the strength of the evidence that there was benefit from the intervention.

Only studies of good quality were considered to be low risk of bias. For consistency, we required that the BCI of the estimate not cross the null. All outcomes were direct because they were biochemically validated. For precision, we considered a difference of less than 3 between the lower and upper BCI of the estimate to be precise. For effectiveness, we assessed strength of evidence based on the good and fair included RCTs because there were enough of these studies to form a "best evidence" set that would not be obscured by biased and poorly conducted studies.

To support this decision, we also assessed the likelihood that the poor studies would change our determination of strength of evidence. For infant outcomes and harms of interventions, we included poor-quality studies in the strength-of-evidence assessment. These Key Questions warrant a more expansive assessment of the literature because they focus on outcomes that are rarely reported.

Applicability

Assessments of applicability describe elements of the literature that would affect end-users' ability to apply our findings in a real-world setting. We assessed applicability by identifying potential factors from the PICOTS framework likely to affect the generalizability of the synthesized results. For this particular review, the most likely factors that could affect applicability are the patient population (e.g. whether or not results are available to assess the utility of given interventions in target populations) and the intervention (e.g., the difficulty of applying the intervention in a nonresearch setting given available resources). We noted where data were available for specific populations and made relative assessments of applicability for intervention components in the context of resource considerations.

Results

We identified 2,454 titles and abstracts for screening; 417 publications were identified as potentially eligible for inclusion and were promoted for full-text review. We identified 72 publications from 59 unique studies that met criteria for inclusion. Of these, 56 were RCTs and 3 were prospective cohort studies. The complete list of excluded papers and exclusion reasons is provided in Appendix G of the full report. A summary of all component items and overall risk of bias/quality score for each included study is provided in Appendix I of the full report.

Key Question 1. Intervention Outcomes for Pregnant and Postpartum Women

Fifty-six RCTs evaluated one or more interventions designed to reduce smoking or prevent relapse in pregnant or postpartum women. These RCTs had as their primary focus counseling (14 studies), educational materials (10 studies), multicomponent interventions (14 studies), NRT (5 studies), peer support (4 studies), and other interventions (9 studies). We assessed individual study quality as good for 13 studies, fair for 15 studies, and poor for 28 studies. Fifty-two studies enrolled women who were pregnant, and four RCTs enrolled women in the postpartum period (within 6 months of giving birth). Eight studies restricted enrollment to women who had recently quit smoking. Forty studies included current smokers only, and seven studies included both current smokers and women who had quit smoking immediately prior to or during pregnancy.

The duration of followup was generally short and usually limited to the prenatal period. Only 15 studies reported biochemically validated cessation after birth. Among studies evaluating an intervention delivered in the postpartum period, the longest period of followup was 6 months postpartum.

Eight of 24 studies of good or fair quality demonstrated effectiveness for cessation, with a difference in cessation between intervention and control groups ranging from 5.8 percent to 31.0 percent (Table C). Four of these studies used multicomponent interventions. Counseling, educational materials, peer support, and voucher incentives were each the primary intervention in one study showing positive effects. This qualitative synthesis suggests that, generally speaking, multicomponent approaches were most effective, but does not provide evidence to drive selection of specific components to form those interventions. The most common interventions in successful multicomponent studies were also common in studies that failed to demonstrate effectiveness. For each study with a primary intervention that demonstrated effectiveness, there were other studies of this intervention that did not demonstrate effectiveness.

Table C. Evidence map: smoking cessation

Intervention	Good Quality: Total Number of Studies (Number of Studies Showing Effectiveness)	Fair Quality: Total Number of Studies (Number of Studies Showing Effectiveness)	Poor Quality: Total Number of Studies (Number of Studies Showing Effectiveness)
Counseling	1 (0)	3 (1)[a]	6 (0)
Education	3 (1)	2 (0)	4 (2)[b]
NRT	1 (0)	1 (0)	3 (2)
Peer Support	2 (1)	1 (0)	1 (0)
Other	1 (0)	2 (1)	5 (2)
Multicomponent	3 (1)	4 (3)	5 (1)

Abbreviations: NRT = nicotine replacement therapy.
[a]Demonstrated effectiveness at end of pregnancy but was no longer significant at 6 months postpartum.
[b]No demonstrated effectiveness at end of pregnancy. Smoking cessation was higher at 8 weeks postpartum for group who received quit guides.

One of five studies of good or fair quality demonstrated effectiveness for relapse prevention with a 35-percent higher cessation in the intervention group than in the control group (Table D). This study evaluated a unique intervention to promote mother-infant bonding. Additional studies are needed to confirm the effectiveness of this intervention, as the study included only 54 participants and cessation outcomes were not reported beyond 8 weeks postpartum.

Table D. Evidence map: relapse prevention

Intervention	Good Quality: Total Number of Studies (Number of Studies Showing Effectiveness)	Fair Quality: Total Number of Studies (Number of Studies Showing Effectiveness)	Poor Quality: Total Number of Studies (Number of Studies Showing Effectiveness)
Counseling	1 (0)	0 (NA)	5 (0)
Education	0 (NA)	1 (0)	0 (NA)
NRT	0 (NA)	0 (NA)	0 (NA)
Peer Support	0 (NA)	0 (NA)	0 (NA)
Other	1 (1)	0 (NA)	1 (0)
Multicomponent	1 (0)	1 (0)	3 (0)

Abbreviations: NA = not applicable; NRT = nicotine replacement therapy.

Key Question 2. Intervention Effects on Infant Outcomes

We identified 13 studies that reported infant outcomes associated with smoking cessation and/or relapse prevention interventions among pregnant women. The interventions represented include counseling (3studies), educational materials (2 studies), NRT (4 studies), incentives (3 studies), and one study each of a multicomponent intervention and point-of-care nicotine testing. One study is of good quality, three of fair quality, and nine of poor quality. All studies focused

on infant outcomes during the immediate postpartum period; none of the studies included infant outcomes after hospital discharge or further followup of any child-related outcomes.

Findings regarding mean birth weight were inconsistent, and no clinically meaningful differences were identified. Only one of the seven studies that reported gestational age had statistically significant results, with women who received NRT in addition to cognitive behavioral therapy giving birth an average of 1 week later than women who received cognitive behavioral therapy only. No studies found statistically significant differences in the incidence of preterm birth, neonatal deaths, or neonatal intensive care unit (NICU) admissions between the intervention and control groups.

Key Question 3. Intervention Harms for Pregnant and Postpartum Women

We identified four studies that reported harms or adverse events associated with smoking cessation interventions. The interventions included NRT (3 studies) and educational materials (1 study). None of the studies reported a higher incidence of adverse events in women receiving interventions than in the control groups; however, there were low numbers of participants and low adherence rates in NRT trials that assessed harms. None of the studies that evaluated relapse prevention interventions reported harms data.

Key Question 4. Effectiveness of Intervention Components

Twenty-eight good- and fair-quality RCTs were available for this Key Question. Three studies targeted postpartum women, and the rest enrolled pregnant women. Twenty-two focused on current smokers, four focused on recent quitters, and two included both smokers and quitters. We did not find any cohort studies that had appropriate information for inclusion in the meta-analysis, which is the basis for this Key Question. We determined that inclusion of poor-quality studies in the analysis would not have modified our assessment.

We were able to combine 23 of these studies into a robust random-effects meta-analysis to quantify the relative impact of components of the interventions on smoking cessation. One study was excluded because outcomes for smoking cessation and relapse prevention were reported together and could not be calculated separately. Nine components were evaluated individually: clinic reinforcement, feedback, incentives, information, NRT, peer support, personal followup, prescription to quit, and quit guides and "other." "Other" combined relatively rarer components, such as groups and quit contracts. Counseling was ubiquitous in both intervention and control arms of the studies; thus it could not be assessed as a driver of effect.

The use of incentives was most clearly associated with substantially increased smoking cessation. The odds of quitting with the use of incentives were three times the odds of quitting in the absence of incentives, holding all other interventions constant (odds ratio = 3.23; 95% BCI, 1.98 to 4.59). Additional intervention components that may have some positive effect, as demonstrated by 80-percent or greater probability that the odds are higher than the null for the intervention increasing smoking cessation, include feedback about biologic measures, information, personal followup, NRT, and quit guides. Data were not available to specifically address the impact of who delivered the intervention or where the intervention was delivered.

Key Question 5. Effect of Patient Characteristics on Effectiveness

In total, studies from 18 populations provide information about how participant characteristics related to success in quitting smoking. This includes 14 randomized trials of which 4 are from studies with interventions proven effective, and 3 cohort studies. Across intervention types there were commonalities.

Predictors of achieving and maintaining cessation included lower levels of tobacco dependence at baseline, as measured by biomarkers and questions gauging dependence and cigarettes per day. Data were sparse to document the influence of maternal age, parity, other smokers in the home, a nonsmoking partner, and smoke-free policies in the home. Data were less consistent for the effects of education, prior experience with cessation, readiness to change, and self-reported motivation to quit.

Younger maternal age, which is correlated with fewer years of smoking, was reported to be associated with improved chance of cessation. No studies of interventions found to be effective addressed the influence of maternal education or of parity. Partner smoking status and household exposure to tobacco smoke are characteristics that are often considered predictors in the health behavior literature and in cohort analyses. We found three trials that commented on the influence of partner or household smoking status, and of these, only two addressed cessation during pregnancy. Neither study showed that the intervention in the trial was effective.

Biomarkers and quantity of smoking were found to play a role in predicting cessation in a successful trial of a multicomponent intervention that centered on a pregnancy-specific quit guide. Five other trials, for which the intervention was not demonstrated to be more effective than the comparison group, reported similar findings: lower cigarette use at baseline improved chances of cessation. Self-reported readiness or motivation to quit, as well as confidence in one's own ability to do so, were evaluated in multiple studies as markers of being able to successfully quit. The only trial with an effective intervention reported that baseline self-efficacy did not predict who would be able to quit.

Discussion

As clinicians and policymakers consider implementing smoking cessation interventions, their primary consideration is choosing those approaches that are most likely to be effective and feasible. Qualitatively, this review suggests that approaches that combine multiple components will have the best likelihood of success. Selecting which components to include is more complex and should be based on the particular considerations of the interventions and clinical setting. Efficacy is foremost in choosing the combination of interventions in a multicomponent strategy. The meta-analysis presented in this review allowed us to calculate the posterior probability that specific intervention components contributed to success in smoking cessation. Multiple components had a greater than 80-percent probability of having a positive effect, with incentives demonstrating the strongest effect. While incentives require a financial investment, they are not time intensive. In addition, prior research in other fields, such as weight loss, suggests that modest incentives can be adequate to change behavior.[33] The other components with high probability of success were feedback about biologic measures, information, personal followup, NRT, and quit guides. Our meta-analysis results suggested that clinic reinforcement, peer support, and prescriptions to quit contributed little in multicomponent interventions. With the exception of medications, for which limited data are available, the safety of smoking cessation interventions makes it reasonable to include a number of interventions in a multicomponent

approach. Other important considerations in selecting which smoking cessation interventions to implement include the availability of financial and human resources. It may also be helpful to end-users to understand whether specific populations of patients are more amenable to behavior change. Although few data are available to guide targeting of services, the research reviewed in this report suggests that women who are less tobacco dependent and younger may have a greater chance of successfully quitting. More intensive interventions are worth considering for women who are less likely to successfully quit smoking.

Key Findings and Strength of Evidence

Overall the evidence to answer Key Questions about smoking cessation and relapse prevention interventions for pregnant and postpartum women did not reach standards for high strength of evidence. The strength-of-evidence tables (Table E and Tables 28–30 in the full report) summarize the total number of studies and, within those studies, the number of participants randomized. The tables also provide the assessment of the risk of bias, consistency of findings across trials, directness of the evidence, and precision of the estimate provided by the literature.

We assessed the strength of evidence for the effectiveness of intervention components using the meta-analysis (Table E) and using the approach described in our Methods section. Strength of evidence was moderate for the effectiveness of incentives and low for all other intervention components.

Table E. Strength of evidence for effectiveness of intervention components for smoking cessation among current smokers in pregnancy

Intervention Component	Risk of Bias	Consistency	Directness	Precision	OR (BCI) Posterior Probability[a] Strength of Evidence[b]
Incentives	Medium	Consistent	Direct	Precise	3.23 (1.98 to 4.59) 100% Moderate for effect
Feedback	Medium	Inconsistent	Direct	Precise	1.43 (0.88 to 2.03) 95% Low for effect
Information	Medium	Inconsistent	Direct	Precise	1.32 (0.88 to 1.79) 93% Low for effect
Personal followup	Medium	Inconsistent	Direct	Precise	1.25 (0.94 to 1.57) 95% Low for effect
Nicotine replacement therapy	Medium	Inconsistent	Direct	Precise	1.24 (0.84 to 1.68) 87% Low for effect
Quit guide	Medium	Inconsistent	Direct	Precise	1.18 (0.82 to 1.56) 83% Low for effect
Prescription to quit	Medium	Inconsistent	Direct	Precise	1.13 (0.46 to 1.95) 57% Low for no effect
Peer support	Medium	Inconsistent	Direct	Precise	1.07 (0.70 to 1.46) 60% Low for no effect

Table E. Strength of evidence for effectiveness of intervention components for smoking cessation among current smokers in pregnancy (continued)

Intervention Component	Risk of Bias	Consistency	Directness	Precision	OR (BCI) Posterior Probability[a] Strength of Evidence[b]
Clinic reinforcement	Medium	Inconsistent	Direct	Precise	1.05 (0.65 to 1.49) 55% Low for no effect

Abbreviations: BCI = Bayesian credible interval; OR = odds ratio.
Note: Table shows data from 8, 086 participants randomized in 23 RCTs**.** BCI = Bayesian credible interval; OR = odds ratio.
[a]Probability that the OR is greater than the null.
[b]The effect is positive if the posterior probability is 80% or greater.

There is insufficient strength of evidence to determine the effect of smoking cessation interventions on birth weight, gestational age, and neonatal deaths. There is low strength of evidence for no significant effect on preterm birth and NICU admission. There is also insufficient strength of evidence to determine the harms of smoking cessation interventions.

Applicability

Applicability for this literature is largely dependent on the target population and the feasibility of the interventions in the clinical setting. The target populations are defined by whether women were pregnant or postpartum, whether they were current smokers or recent quitters, and whether they were selected from at-risk populations. Interventions could be resource intensive across axes of time, money and personnel. Thus, to ascertain the applicability of any given intervention, potential end-users must consider whether research on the intervention has been conducted in their target population, and whether the intervention is appropriate and feasible in terms of resource allocation.

The majority of studies (55 studies) included in this review recruited pregnant women; 4 studies were conducted in the postpartum period. Most studies (42) were conducted in the United States and thus should be applicable to the U.S. health system. Studies enrolled women who were all current smokers (42 studies), all recent quitters (8 studies), or both types (9 studies). The duration of followup in the studies included in this review was generally short, and thus little is known about durability of effects.

It would be particularly helpful to end-users to know whether certain interventions were effective in high-risk populations. However, studies targeting high-risk populations were limited. One study enrolled adolescents only, six studies targeted income-specific groups, and one study specifically selected participants from the Medicaid population. Interventions were generally more effective among participants with lower levels of tobacco dependence, so even the more effective approaches may be less applicable in populations with extremely high levels of nicotine dependence. Younger maternal age, which is correlated with fewer years of smoking, was reported to be associated with improved chance of cessation.

Smoking cessation and relapse prevention interventions, both prenatal and postpartum, were overwhelmingly multifaceted. Studies deployed multiple components in the intervention being compared with usual care or an alternative level of standard cessation services. As described earlier, incentives had the highest independent effect, but given that the statistical model underlying the meta-analysis was additive and that the likelihood of positive effects was high for a number of intervention components, it would be reasonable for providers to select the set of

components that might have greatest applicability in their setting and develop those into a multicomponent intervention. To that end, we have made relative assessments in the full report of the resources and considerations that end-users might have around implementation of the components assessed in this report.

Limitations of the Evidence

Nearly half of the studies (n=28) were of poor quality, and the most common reason for high risk of bias was incomplete outcome data. Losses to followup varied by intervention, but the reasons for this variation and its impact on the results are unclear. Studies were most commonly rated fair quality (n=15) due to unclear risk of bias associated with allocation concealment and random sequence generation.

Research Gaps

Future research needs around smoking cessation in pregnancy are both substantive and methodologic. Several interventions warrant additional research and replication, including better assessments. Priorities for future research about interventions include—

- Conducting additional studies of incentives, including the amount needed and under what circumstances they are effective.
- Replicating the evaluation of the mother-infant bonding intervention that was found to be effective in the relapse prevention study.
- Developing much more rigorous studies that isolate counseling and its components. Counseling was ubiquitous, and studies were heterogeneous in their approach.
- Studying intervention components, either in isolation or in multicomponent studies with very high rigor, identified in the meta-analysis as having a high probability of being effective so that the effect of individual components, or specific combinations of components, can be measured.

Methodologic and study design considerations for future research include —

- Clear characterization of the components of both the intervention and comparator.
- A plan for assessment and reporting of fidelity of intervention implementation and the potential for crossover of the intervention into the comparator group.
- Use of biochemically validated outcomes. Self-report is known to underestimate smoking prevalence. A sustained measure of smoking abstinence, as opposed to a point prevalence measure, would be ideal.
- Assessment of the degree to which timing matters in successfully achieving cessation. Intervention timing varies substantially across studies, including early and late in pregnancy. Some studies suggest that interventions may have potential for getting women to stop earlier in pregnancy even when overall differences are not significant.
- Adequate sample sizes with long-term followup. Current studies are short term and have no ability to assess effectiveness over time, including long-term health implications. This is in part due to the need for large numbers at study inception in order to maintain adequate power over time. Larger sample sizes are needed to assess comprehensively infant and longer term child outcomes as well as events and harms.
- Identification of the underlying study purpose. There is a lack of clarity overall in this body of research about whether encouraging women to stop smoking in pregnancy is for the purpose of optimizing fetal growth or creating a smoke-free home by the end

of pregnancy. While both goals are important, identifying the specific underlying rationale for a study can help in intervention development in a way that is targeted and potentially more effective.

Conclusions

Across interventions, data are sparse to evaluate sustained cessation among pregnant and postpartum women. This review suggests that approaches that combine multiple components will have the best likelihood of success. Selecting which components to include is more complex and should be based on the particular considerations of the clinical setting, including patient characteristics and resource allocation, but incentives demonstrated the greatest effect among components studied. Infant outcomes are limited to data collected at time of birth; no studies assessed longer term or child outcomes. Harms data were rarely reported.

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Introduction

Background

Nearly 443,000 U.S. deaths are attributable annually to cigarette smoking, which makes tobacco, including secondhand smoke, the most preventable cause of disease, disability, and death in the United States.[1, 2] Smoking is also associated with staggering estimates of 5.1 million years of potential life lost and $96.8 billion in lost productivity per year in the United States alone.[3] Globally, smoking-related deaths are estimated to exceed 8 million by 2030.[4] Smoking is linked to cancer, heart disease, lung disease, and stroke[1] and places women at greater overall risk for disease than men.[5, 6] Smoking also raises a woman's risk for breast, cervical, and ovarian cancer; infertility; and early menopause.[7] Leading causes of smoking-related deaths among women are lung cancer, heart disease, and chronic lung disease.[2]

An estimated 19.8 million women in the United States smoke.[8] Nationally, 23 percent of women report smoking in the 3 months before pregnancy, while 13 percent report smoking in the last 3 months of pregnancy. Rates vary significantly by state, with up to 30 percent of women in some states reporting continued tobacco use in the third trimester. Fewer than half of pregnant smokers report successfully quitting during pregnancy.[1] Furthermore, self-report leads to an overestimation of cessation rates in pregnancy.[9] Nondisclosure of smoking status among pregnant smokers is common and ranges from 25[10] to 49 percent[11] in published reports.

Compared with nonsmokers, those who smoked around the time of their pregnancy were more likely to be younger (<25 years old), be non-Hispanic white, have 12 or fewer years of education, be unmarried, have an annual income of less than $15,000, be underweight, have an unintended pregnancy, be first-time mothers, initiate prenatal care later, be Medicaid-enrolled, and receive WIC during pregnancy.[12] These national data are compatible with similar reports from states, health systems, and from smoking intervention studies.

Adverse Outcomes Associated With Smoking During Pregnancy

Smoking during pregnancy can result in significant complications for the pregnant woman, her fetus, and members of the woman's household who are exposed to secondhand smoke. Smoking is associated with increased risk of placental abruption, anemia, preterm birth, chronic hypertension, and placenta previa.[13-16] Health risks to the fetus include low birth weight, restricted growth, and fetal death.[15, 17-23]

Maternal smoking also remains a significant issue of concern after birth; estimates from the research literature indicate that 60 to 80 percent of women who quit smoking during pregnancy resume tobacco use in the first six to 12 months postpartum.[24] Infants and children of women who smoke during pregnancy face a higher risk of sudden infant death syndrome[25, 26] and other conditions including respiratory infections, impaired lung growth, otitis media, necrotizing enterocolitis, and infectious diseases.[27-31] Infants and children are also affected by secondhand or environmental tobacco smoke, including significant nicotine exposure via breast milk among breastfed children. The 2006 U.S. Surgeon General's report, Health Consequences of Involuntary Exposure to Tobacco Smoke, noted that exposed children are at increased risk for sudden infant death syndrome, acute respiratory infections, otitis media, and more severe asthma.[32] Passive smoke exposure has also been associated with bronchiolitis and bronchitis.[33, 34] Recent global estimates suggest that 165,000 children under age 5 die annually from lower respiratory infection caused by exposure to secondhand smoke.[35]

Measurement of Tobacco Exposure During Pregnancy

Measurement of smoking status is commonly assessed through self-report and can be confirmed using biological markers. Pregnant women are more likely to underreport their smoking status than nonpregnant women[10] likely due to the stigmatization of smoking during pregnancy.[36] Multiple studies of representative samples of pregnant women using biochemical measurements have confirmed high levels of patient non-disclosure.[9, 11, 37-41] Therefore it is important to use biochemical validation of smoking status rather than relying solely on self-report.

Biochemical validation of smoking includes measures of cotinine from saliva, urine or serum, thiocyanate, or expired carbon monoxide. Although these measures do not verify continuous abstinence they are accepted standards for evaluating point prevalence smoking status. Cotinine, the major proximate metabolite of nicotine, is the most useful and popular marker. It has a half-life of 15 to 40 hours, and measured cotinine levels in the body correlate with the quantity of nicotine absorbed.[36] Cotinine can be measured in serum, but saliva and urine sample collection is easier and less invasive. Cotinine is measured in nanograms per milliliter (ng/ml). The cut point for smoking status depends upon the type of sample (plasma or saliva: 15 ng/ml; urine: 50 ng/ml).[42] Thiocyanate, a metabolite of hydrogen cyanide gas, can be measured in blood, urine, and saliva. It has a half-life of 10 to 14 days but has low sensitivity and specificity making it less useful.[36] Cotinine and thiocyanate cannot be used in studies of NRT. Expired carbon monoxide can be assessed using a handheld breath analyzer and is reported in parts per million (ppm). Carbon monoxide has a short half-life of 4 to 5 hours. The cut point for smoking status is generally between 8 to 10 ppm,[42] however, environmental sources can produce levels comparable to those of current smokers.[36]

Interventions

Multiple interventions to promote smoking cessation exist and include advice and counseling, self-help materials, nicotine replacement therapy (NRT), antidepressants including bupropion (Zyban®), and pharmacologic cessation aids such as varenicline (Chantix®). While these pharmacologic aids may limit the exposure of tobacco smoke, little is known about the potential adverse effects on short- and long-term reproductive outcomes. The U.S. Food and Drug Administration (FDA) places the transdermal nicotine patch in pregnancy category D, which indicates there are known risks to the fetus, but potential benefits may outweigh risks in some cases. The other nicotine replacement products, as well as varenicline and bupropion are category C medications, meaning animal studies have shown adverse fetal effects and no adequate human studies are available, but potential benefit may outweigh risk.[43-47] The American College of Obstetricians and Gynecologists does not recommend pharmacologic interventions as first-line therapies in pregnant women due to lack of evidence on safety and efficacy.[48, 49]

Previous systematic reviews have typically reported limited effectiveness for most interventions in pregnant smokers, though some have reported positive results. Overall, the findings from existing systematic reviews[50-54] suggest that NRT, behavioral and educational cessation strategies, and multicomponent interventions may be beneficial to women who smoke in pregnancy or the postpartum period. Despite these previous systematic review efforts, however, the efficacy of specific components and the impact of these various strategies on smoking and infant outcomes in pregnant and postpartum women remain unclear.

Other research has also shown that characteristics of women most likely to quit before or during pregnancy and to sustain cessation postpartum differ in important and predictable ways from those who do not attempt cessation or who relapse at various points.[55-67] Factors that can potentially predict successful smoking cessation include level of nicotine dependence, number and duration of prior quit attempts, concomitant substance or alcohol use, partner smoking status, and employment and timing of return to work. Previous reviews have not adequately characterized how such factors may modify the effects of interventions on cessation, birth weight, gestational age, and longer term outcomes such as childhood asthma exacerbations. Better understanding of these potential effect modifiers is key to optimal implementation of cessation strategies in pregnant and postpartum populations.

Scope and Key Questions

This review evaluates the effectiveness of interventions intended to achieve smoking cessation during pregnancy and the postpartum period. The current review stems from an interest in better understanding how cessation interventions may affect critical outcomes. The added value of this review is that it updates the evidence from prior systematic reviews, includes child outcomes, and identifies patient and intervention characteristics that modify the effects of interventions.

Scope of the Review

This review is focused on the evidence available to inform health care providers regarding the provision of smoking cessation strategies for their patients. The relevant population for this review includes pregnant and postpartum woman who are current smokers or recent quitters. The literature reflects various strategies to promote smoking cessation and relapse prevention. Interventions of interest include any behavioral, psychosocial, pharmacologic, or educational intervention intended to promote individual changes in cigarette consumption among pregnant smokers and recent quitters in prenatal and postpartum period. Interventions targeting the behavior of smokers' partners or providers exclusively were not included. Interventions of interest are those that were conducted in or originated from a health care setting. The review does not include public health initiatives or system-level smoking cessation research.

Smoking outcomes are limited to biochemically validated reports of smoking cessation during pregnancy or in the postpartum period. Biochemical validation of smoking status includes measures of cotinine from saliva, urine or serum, expired carbon monoxide, or serum thiocyanate. Although these measures do not verify continuous abstinence they are accepted standards for evaluating point prevalence of smoking status. The review does not report smoking reduction.

Because there is a high risk of relapse among individuals who attempt to quit smoking, we assessed relapse prevention outcomes in pregnancy and after parturition from studies of smoking cessation interventions for women defined as recent quitters. The review also reports infant and/or child outcomes (Key Question 2) from studies evaluating smoking cessation interventions, but does not include analysis of information about the effects of maternal smoking on child health. Data on harms or adverse effects of included interventions were captured in Key Question 3. The aim of Key Question 4 is to obtain information on components of the interventions that may have an impact on patient outcomes, while Key Question 5 is included to capture characteristics that potentially modify outcomes from eligible studies. We explicitly

defined eligibility criteria for these Key Questions using a PICOTS (population, intervention, comparator(s), outcome, timing, and setting) structure (Table 1).

Table 1. PICOTS

PICOTS	Criteria
Population	• Pregnant or postpartum (≤6 months post-birth) women who smoke or quit smoking in the index pregnancy • Infants and children of pregnant or postpartum (≤ 6 months post-birth) women receiving smoking cessation interventions • Subgroups of pregnant and/or postpartum women by level of nicotine dependence, prior quit attempts, concomitant substance or alcohol abuse, partner smoking status, and/or employment
Intervention	Any smoking cessation intervention, including pharmacologic and nonpharmacologic interventions
Comparator	• Different intervention • Usual care • Placebo
Outcomes	**KQ1** • Smoking cessation (biochemically validated) • Continuous abstinence (biochemically validated) • Relapse **KQ2** • Preterm birth • Gestational age • Birth weight • Neonatal death • NICU admission • Asthma exacerbation • Asthma hospitalization • Otitis media • Upper respiratory infection **KQ3** Harms (e.g., weight gain, emotional stress, adverse events associated with medication to the mother or fetus) **KQs 4 and 5** • Smoking cessation (biochemically validated) • Continuous abstinence (biochemically validated) • Relapse
Timing	Any length of followup
Setting	Clinician-initiated intervention or an intervention that intersects clinical care

Abbreviations: KQ = Key Question; NICU = neonatal intensive care unit; PICOTS = population, intervention, comparator, outcome, timing, setting.

Key Questions

Key Question 1:

What is the effectiveness of interventions intended to achieve or maintain smoking cessation in women who are pregnant or postpartum for promoting smoking cessation, relapse prevention, and continuous abstinence?

Key Question 2:

What is the effectiveness of interventions intended to achieve or maintain smoking cessation in women who are pregnant or postpartum for improving infant and child outcomes?

Key Question 3:

What are the harms of interventions intended to achieve or maintain smoking cessation in women who are pregnant or postpartum?

Key Question 4:

What is the effect of components of the smoking cessation intervention, including who delivered the intervention (physician, nurse, midwife, etc.), the intervention itself, and where the intervention was delivered (clinic, hospital setting, etc.) on cessation of smoking or durability of cessation in women who are pregnant or postpartum?

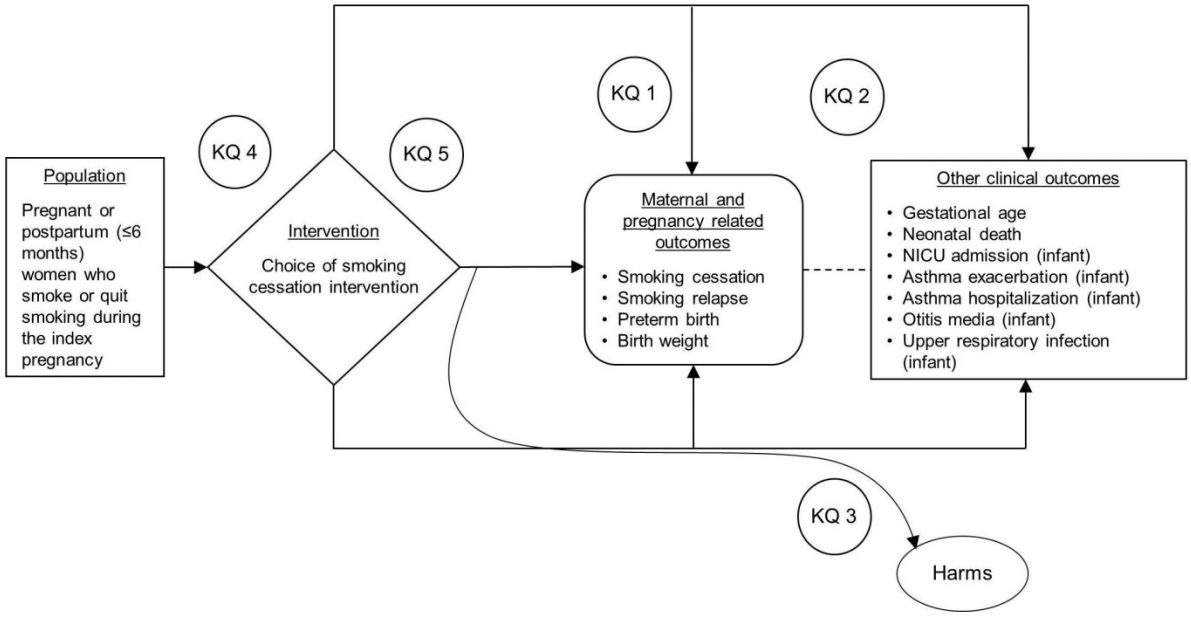
Key Question 5:

What is the effect of patient characteristics on outcomes of smoking cessation interventions (successful/unsuccessful cessation, relapse) in women who are pregnant or postpartum?

Analytic Framework

We developed the analytic framework (Figure 1) illustrating the population, interventions, and outcomes that guided the literature search, study eligibility, screening, and synthesis.

Figure 1. Analytic framework



Abbreviations: KQ = Key Question; NICU = neonatal intensive care unit.

Organization of This Report

In addition to this introductory chapter, this report documents the review methodology (Chapter 2) and presents the key findings and synthesis of study data for all five Key Questions (Chapter 3). We discuss these findings in the context of what is known, discuss limitations of the evidence and this review, and suggest opportunities for future research in Chapter 4. We also provide an assessment of the strength of evidence for the effectiveness of individual intervention components as well as for infant outcomes and harms in the final Chapter.

We have included a list of the abbreviation and acronyms used throughout the report and appendices at the end of the Discussion Chapter and preceding the list of references. Supplementary material, including screening forms, search strategies, complete study data, and a list of excluded studies is available in eight appendices.

Methods

The methods for this Evidence Report follow those suggested in the Agency for Healthcare Research and Quality (AHRQ) "Methods Guide for Effectiveness and Comparative Effectiveness Reviews."[68] The main sections in this chapter reflect the elements of established protocol; certain methods map to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.[69]

Review Protocol

We prepared final Key Questions and submitted them to AHRQ for review. We identified Technical Experts on the topic to provide assistance during the project. The Technical Expert Panel (TEP) included individuals with expertise in smoking cessation strategies in pregnant women, lead authors of ongoing reviews of cessation interventions, and maternal-child experts from the federal government. The TEP included 10 members serving as technical or clinical experts. TEP members participated in conference calls and discussions through e-mail to:

- Refine the analytic framework and Key Questions;
- Discuss the preliminary assessment of the literature, including inclusion/exclusion criteria;
- Provide input on the information and domains included in evidence tables.

Literature Search Strategy

Search Strategy

We searched MEDLINE®, CINAHL®, and PsycINFO®. Search results were limited to papers published in English. Search strategies used a combination of subject headings (i.e., controlled vocabulary) and keywords. (Appendix A). We also searched the reference lists of included publications and recent systematic reviews related to smoking cessation interventions for pregnant women. Searches were executed between October 2012 and January 2013.

The Scientific Resource Center requested published and/or unpublished information from companies that currently manufacture pharmacologic aids, including nicotine replacement products, for smoking cessation.

Search Terms

Each search strategy used a combination of subject headings (i.e., controlled vocabulary) and keywords appropriate for each database (Appendix A). The search strategies included terms related to the range of interventions used to promote and maintain smoking cessation during pregnancy and the postpartum period. We excluded undesired publication types (e.g. case reports, letters). We did not restrict to any particular study design to allow capture of all desired study types, including randomized controlled trials (RCTs) to address all Key Questions and prospective cohort studies relevant to Key Questions 3, 4, and 5.

Inclusion and Exclusion Criteria

The inclusion and exclusion criteria for the review were derived from our understanding of the literature and refinement of the review topic with the Task Order Officer and the topic nominators. We sought studies that evaluated that impact of smoking cessation interventions on

smoking cessation in pregnancy (Table 2). Thus, for this review, the population of interest was pregnant or postpartum (i.e., within 6 months of birth) women who currently smoked or who had quit smoking during the index pregnancy with a biochemically validated measure of cessation, as self-reported cessation tends to be overstated. We placed no limits on publication dates but required that studies be published in English. Two team members independently reviewed the titles and abstracts of the non-English-language literature published since 1990 located via the MEDLINE search (Appendix A) and determined that few studies would meet the inclusion criteria. Most non-English-language studies were cross sectional or were not original research.

Studies were required to include a minimum of 20 participants with data in each study arm. The team established this minimum sample size to balance the need for smaller studies of specialized populations (e.g., studies in specific ethnic groups) with the need to preserve methodologic rigor.

For Key Questions 1 and 2, we accepted only RCTs. Prospective cohort studies were admitted for Key Questions 3, 4, and 5.

Table 2. Inclusion and exclusion criteria

Category	Criteria
Study population	Pregnant or postpartum (up to 6 months post-birth at initiation of the intervention) women who smoke or quit smoking during the index pregnancy
Time period	Database inception to present
Publication languages	English only
Admissible evidence (study design and other criteria)	Admissible designs • KQs 1–5: RCT • KQs 3–5: Prospective cohort study Other criteria • Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results • Studies targeting women who smoke and meet the population criteria as described above • Studies that address one or both of the following: o Treatment modality aimed at smoking cessation in a relevant population o Outcomes related to interventions; primary outcomes of interest include smoking cessation, continuous abstinence, smoking relapse, harms of intervention to the mother or fetus, gestational age, NICU admission, birth weight, and preterm birth. • Studies must include extractable data presented in text or tables (vs. solely in figures) on relevant outcomes

Abbreviations: KQ = Key Question; NICU = neonatal intensive care unit; RCT = randomized controlled trial.

Study Selection

We developed individual abstract and full-text screening forms for the Key Questions (Appendix B and C). We revised the forms following testing by the team. The forms were adapted for use in the Web-based systematic review product, DistillerSR (Evidence Partners, Ottawa, Canada). We conducted screening in two phases: abstract and full-text screening. Publications were promoted to full-text review when one reviewer indicated that the publication met all inclusion criteria or when the title and abstract did not provide adequate information to make a determination. Two reviewers independently reviewed each publication at the full-text screening phase. Discordant classifications were resolved in team meetings with senior investigators.

Quality (Risk of Bias) Assessment of Individual Studies

Two senior team members independently assessed risk of bias in the included studies; disagreements were resolved through discussion or adjudication by a senior investigator. We used the Cochrane Risk of Bias Tool[70, 71] (Appendix C) to assess methodological quality of RCTs and the Newcastle-Ottawa Assessment Scale[72] (Appendix E) to assess quality of nonrandomized studies (i.e., cohort studies). The Newcastle-Ottawa Quality Assessment Scale includes three broad perspectives for assessment of observational studies: selection of study groups, comparability of study groups, and ascertainment of the outcome of interest. The Cochrane Risk of Bias tool includes criteria for judging risk of bias in RCTs for specific elements from five fundamental domains: sequence generation, allocation concealment, blinding, outcome data, and selective reporting (Appendix D).

To account for inherent limitations of the literature and our prespecified criterion for acceptable outcomes (i.e., biochemically validated smoking status), we modified criteria for judging risk of bias in the "selective outcome reporting" domain. Selective outcome reporting refers to the selection of a subset of analyses for publication based on results.[73] Risk of bias may be present if study authors fail to report or incompletely report prespecified outcomes.[74] In the case of this review, we included studies on the basis of their reporting of validated outcomes rather than on the basis of an intervention that arguably could affect a range of outcomes. Whether other outcomes were also collected and presented was not germane to our analysis. Therefore, we uniformly assessed the risk of bias as "low" for "selective outcome reporting" for all included studies. Studies that used intention-to-treat analyses were generally judged to have a low risk of bias for the "incomplete outcome data" domain. As we do not contact study authors for information, risk of bias for this domain was downgraded for studies that did not clearly report an intention-to-treat analysis or provide an explanation for missing data.

From the final assessment of risk of bias for the individual domains for RCTs, an overall assessment of risk of bias was calculated based on prespecified thresholds. The overall risk of bias assessment was then expressed as one of three final study quality ratings: studies assessed as having a high risk of bias were categorized as "poor" quality studies; studies having a medium risk of bias were categorized as "fair" quality studies; and studies assessed as low risk of bias were categorized as "good" quality studies. The conversion thresholds for "good," "fair," and "poor" quality designations are presented in Appendix F. A summary of all component items and overall risk of bias/quality score for each included study is provided in Appendix I.

Data Extraction

We created uniform evidence tables to extract data and facilitate data synthesis. We collected data related to population characteristics, intervention characteristics, and outcomes. Outcome data that relied exclusively on self-report were not included, given strong existing evidence on variability and relatively low accuracy of self-assessed smoking status among pregnant women.[12, 75] The outcome of interest (smoking cessation) had to be confirmed by one or more biochemical measurements (e.g., urinary, salivary, or serum cotinine, expired carbon monoxide, serum thiocyanate). Where possible, we extracted data on possible confounders, including age, parity, and baseline smoking levels. The final evidence tables are provided in Appendix H.

Data Synthesis

We analyzed the effectiveness data in two ways. First, we divided the studies into categories reflecting broad approaches to cessation intervention and described the studies qualitatively within Key Question 1. The categories were established a priori as accepted approaches to intervening during pregnancy to encourage women to stop smoking.[54] During data extraction it became apparent that study interventions were often heterogeneous, consisting of numerous and varied approaches. Studies that purport to evaluate the effects of a single intervention are almost always multicomponent in practice. Furthermore, the control arm (e.g., treatment as usual, control group, placebo) frequently receives some level of care, such as cessation counseling, that is a typical component of a smoking intervention.

As an alternative approach to the analysis of the effectiveness data, we conducted a meta-analysis using data from the good and fair quality RCTs to quantify the relative influence of intervention components across the body of literature. This analysis served in part to answer Key Question 4 and to provide a quantitative basis for assessing strength of evidence (see below), in addition to providing a basis for users of the report to make intervention decisions.

The association of smoking cessation intervention components with quit rates was meta-analyzed using a logistic mixed-effects model, estimated using Markov chain Monte Carlo methods.[76]The model was used to characterize quit rates across studies and estimate factors associated with intervention efficacy. Thus, we treat y_i, the number of quitters in some study arm i, as a binomial random variable:

$$y_i \sim Bin(n_i, p_i)$$

where n_i is the number of individuals in the arm and p_i the latent quit probability. This probability, in turn, is modeled as a function of several components:

$$logit(p_i) = \mu_{j[i]} + \alpha \times stage_i + X_i \beta$$

Here, μj[i] is a baseline random effect belonging to the study j corresponding to arm I, which accounts for the heterogeneity among studies. This random effect was modeled using a t-distribution, which is more robust than a typical Gaussian random effects. Xi is a matrix of indicators corresponding to each of the intervention factors included in the analysis (Clinic Reinforcement, Feedback, Incentives, Information, Peer Support, Personal Followup, Quit Guide, NRT, Prescription to Quit, and Other) and β is a vector of associated parameters describing their effect on expected quit rate. Finally, α describes the effect of the pregnancy stage at which the intervention is applied, which was divided into four intervals: prenatal; 0 to 3 months postpartum; 3 to 6 months postpartum; and 6 to 12 months postpartum.

This model was coded in PyMC version 3 (https://github.com/pymc-devs/pymc), which implements several MCMC algorithms for fitting Bayesian hierarchical models. All model parameters were assigned non-informative prior distributions, and the model was run for 100,000 iterations using a slice sampler.[76] Convergence of the chain was checked through visual inspection of the traces of all parameters, and via the Gelman-Rubin diagnostic. The fit of the model was checked via posterior predictive checks, which compare data simulated from the posterior distribution to the observed data. This exercise showed no substantial lack of fit for any of the studies included in the dataset.

Data for Key Questions 2, 3, and 5 were described qualitatively. Key Question 2 was organized by the infant outcomes being assessed, Key Question 3 was organized by the categories of interventions used in Key Question 1, and Key Question 5 was organized by factors that modify success of the intervention and factors related to probability of cessation.

Strength of the Body of Evidence

Two senior investigators graded the body of evidence and the final assignment was reviewed with the project team. We achieved alignment through group discussion with careful attention to application of consistent standards across each area item being graded. As indicated in the "Methods Guide for Effectiveness and Comparative Effectiveness Reviews"[68, 77] we assessed strength of evidence as "high," "moderate," or "low" based on four major domains: risk of bias (low, medium, high); consistency (inconsistency not present, inconsistency present, unknown or not applicable); directness (direct, indirect); and precision (precise, imprecise) of the evidence. When no studies were available for an outcome or comparison of interest or if the available evidence was weak (i.e. from studies with high risk of bias), we graded the evidence as insufficient. The strength of evidence grades and definitions are presented in Table 3.

For risk of bias, we started our assessment at "low" because only RCTs were included in the assessment. We reduced the strength of evidence risk of bias to "medium" when the evidence was from a mix of good and fair quality studies. For consistency, we required the majority of studies to report outcomes in the same direction. Precision was assessed based on the confidence bounds. Because we only accepted studies that used biochemically validated outcome measures, all outcomes were considered "direct."

We assessed the strength of evidence for effectiveness, infant outcomes, and harms of interventions. Because of the heterogeneity of interventions within categories of approaches, we focused our strength of evidence assessment on the components that could be meta-analyzed, and thus contributed quantitative data to our understanding of smoking cessation in pregnancy. We used the standard EPC approach to strength of evidence with the exception that Bayesian confidence bounds do not carry the same interpretation as classical (non-Bayesian) confidence intervals.

If the posterior probabilities based on the Bayesian credible intervals (BCIs) suggested greater than 80 percent likelihood that the true effect was greater than the null, we considered the estimate of the effect to be positive and therefore assessed the strength of the evidence that there was benefit from the intervention.

We required all studies to be good quality to be considered low risk of bias. For consistency, we required that the BCI of the estimate not cross the null. All outcomes were assessed as direct because we stipulated that all smoking cessation outcomes had to be confirmed by biochemical validation. For precision, we considered a difference of less than three between the lower and upper BCI of the estimate to be precise. For effectiveness, we assessed strength of evidence based on the good and fair quality included studies because there were enough of these studies to form a "best evidence" set that would not be obscured by biased and poorly conducted studies. To support this decision, we assessed the likelihood that inclusion of the poor quality studies would change the strength of evidence determination.

For infant outcomes (KQ2) and harms of interventions (KQ3) we included poor-quality studies in the strength-of-evidence assessment. These Key Questions warrant a more expansive assessment of the literature because they focus on outcomes that are rarely reported.

Table 3. Strength of evidence grades and definitions

Grade	Definition
High	We are very confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has few or no deficiencies. We believe that the findings are stable.
Moderate	We are moderately confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
Low	We have limited confidence that the estimate of effect lies close to the true effect for this outcome. The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
Insufficient	We have no evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome. No evidence is available or the body of evidence has unacceptable deficiencies, precluding judgment.

Applicability

We assessed applicability of results according to EPC methods guidance[78] by describing elements of the literature that would affect end users' ability to apply our findings in a real-world setting. We used the PICOTS (population, intervention, comparator(s), outcome, timing, and setting) framework to identify the factors likely to affect the generalizability of the synthesized results.

For this particular review, the most likely factors to affect applicability are the patient population (e.g. whether or not results are available to assess the utility of given interventions in target populations) and the intervention (e.g., the difficulty of applying the intervention in a nonresearch setting given available resources). We summarized the applicability of the body of evidence by noting where data were available for specific populations and making relative assessments of applicability for intervention components in the context of resource considerations.

Peer Review and Public Commentary

Experts in smoking cessation and care of pregnant and postpartum women were invited to provide external peer review. The draft report was posted for 4 weeks to elicit public comment. We addressed all reviewer comments by revising the text as appropriate. Responses to peer and public review comments are itemized in a “Disposition of Comments” report, which will be available on the AHRQ Web site approximately 3 months after the posting of this final review.

Results

Introduction

This chapter presents the results of the systematic review of the literature on smoking cessation interventions for pregnant and postpartum women. We begin with the results of our literature searches and an overview of the included studies as a whole. This is followed by results and detailed analysis for each Key Question.

Within Key Question 1 (KQ1) we have attempted to group together studies according to the primary component of the intervention. Virtually no studies were truly unimodal; however, we placed studies into one of six broad categories based on the description by the authors for the primary intervention of interest. Results are presented by primary intervention in the following order: counseling; educational materials; NRT; peer support; other interventions; and multicomponent interventions. For each category, we include a description of the included studies, a table summarizing the characteristics of the good and fair quality studies, a detailed synthesis, and a table of key outcomes for all included studies. When there were a sufficient number of studies with outcome data for postpartum interventions or relapse prevention, we included these under a separate subheading.

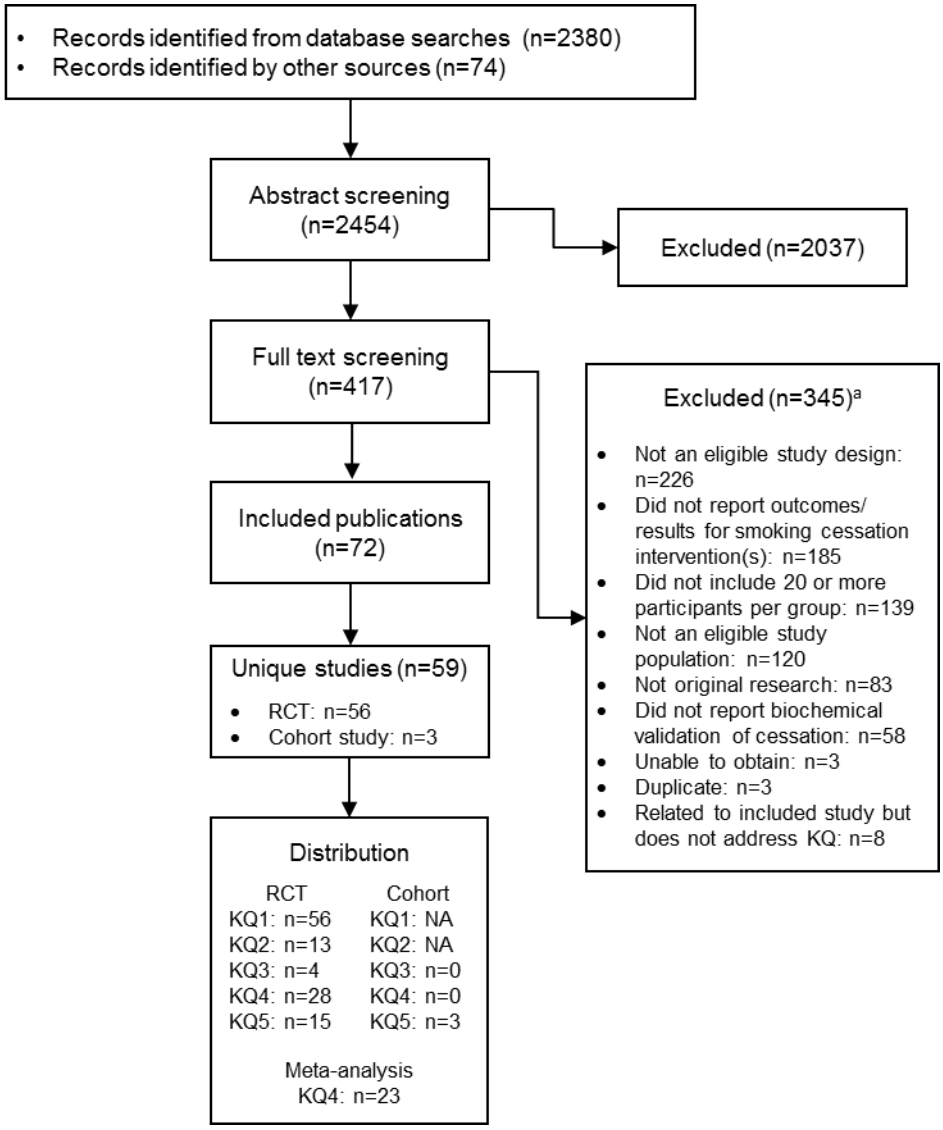
Key Question 2 (KQ2) is organized by infant outcomes. These analyses are followed by a review of the studies addressing Key Question 3 (KQ3), which pertains to harms associated with the interventions identified for KQ1. Key Question 4 (KQ4) focuses on the components of the interventions, which are organized by smoking cessation and relapse prevention, and include the meta-analysis results. These are the primary effectiveness results used for strength-of-evidence assessments in Chapter 4. For Key Question 5 (KQ5), we organize patient characteristics by factors that modify success of the intervention and those related to the probability of cessation.

We also describe studies in summary tables, generally organized to present validated smoking cessation outcomes in a single summary in the relevant section of text. Details on quality assessment for individual studies can be found in Appendix I. Information about the overall strength of evidence supporting the effectiveness of specific interventions is summarized in the Discussion chapter.

Results of Literature Searches

We identified 2,454 titles and abstracts for screening. Of these, 417 publications were promoted for full-text review. At full-text review, we excluded 345 publications. We found 72 publications from 59 unique studies that met criteria for inclusion. Of these, three were prospective cohort studies retained for KQ3, KQ4, and/or KQ5. We extracted data from the remaining 56 randomized controlled trials (RCTs) to address the Key Questions. The literature search and screening results are summarized in Figure 2. The complete list of references excluded at full-text review and exclusion reasons is provided in Appendix G. We received no published or unpublished data from the requests to manufacturers of the pharmacologic smoking cessation aids.

Figure 2. Flow diagram of literature search and screening



Abbreviations: KQ = Key Question; RCT = randomized controlled trial.

Description of Included Studies

We included 59 unique studies that address our Key Questions: 56 RCTs and three prospective controlled cohort studies. Included studies evaluated interventions based on behavioral, educational, medical, and other approaches to promote smoking cessation or relapse prevention among pregnant or postpartum women using at least one comparator or usual care. The majority of studies (55 studies) included in this review recruited pregnant women; four studies were conducted in the postpartum period. Studies enrolled women who were current smokers (42 studies), recent quitters (8 studies) or both (9 studies). The duration of followup in the studies included in this review was generally short. Most studies that delivered an intervention during pregnancy limited followup to the prenatal period. Only 15 studies reported biochemically validated cessation after birth. For studies evaluating an intervention delivered in the postpartum period, one study reported cessation at 6 weeks postpartum,[79] one at 8 weeks

postpartum,[80] one at 3 months postpartum,[81] and one at 6 months postpartum.[82] For RCTs, we assessed individual study quality as good for 13 studies, fair for 15 studies, and poor for 28 studies. The cohort studies were assessed as fair (2 studies) and poor (1 study) quality. A summary of all component items and overall risk of bias/quality score for each included study is provided in Appendix I.

For KQ2, we did not identify any publications that explicitly focused on infant outcomes in the context of treating maternal smoking behavior. The publications included for KQ2 are focused on smoking cessation patterns in mothers, with infant outcomes as a secondary outcome. Included studies evaluated the effect of these interventions on birth weight, gestational age, preterm birth, neonatal death, and neonatal intensive care unit (NICU) admission. For KQ3, we identified four studies reporting on harms of the included interventions. For KQ4 we extracted relevant data from 24 good and fair quality RCTs. Patient characteristics reported in 14 RCTs,[39, 82-94] and three cohort studies[38, 95, 96] are described in KQ5.

Key Question 1: Intervention Outcomes for Pregnant and Postpartum Women

Of the 59 included studies, 56 RCTs (13 good quality, 15 fair quality, 28 poor quality) evaluated one or more interventions designed to reduce smoking or to prevent relapse in pregnant or postpartum women. The majority of the studies were conducted in the United States (39 studies);[11, 39, 79, 80, 83-87, 89-94, 97-121] six in the United Kingdom;[88, 122-126] four were conducted in Australia;[127-130] two in Canada;[82, 131] and one each in Spain,[81] Scotland,[132] Denmark,[133] and Sweden.[134] Fifty-two studies enrolled women who were pregnant.[11, 39, 83-94, 97-134] Four of the RCTs enrolled women in the postpartum period.[79-82]

Eight studies[79, 80, 82, 94, 99, 111, 112, 114] restricted enrollment to women who had recently quit smoking. Forty-one studies[39, 83-87, 89-93, 97, 98, 100-104, 107-110, 113, 115-125, 128-134] included current smokers only, and seven studies[11, 81, 88, 105, 106, 126, 127] included both current smokers and women who had quit smoking immediately prior to or during pregnancy. Biochemical validation methods for smoking cessation included: expired carbon monoxide (9 studies);[82, 86, 88, 92, 102, 113, 116, 118, 119] cotinine measured in saliva, urine, or blood (31 studies);[11, 39, 79, 81, 83, 85, 87, 89, 91, 94, 97, 98, 101, 103-106, 108, 109, 111, 117, 120, 123-127, 129, 130, 132, 133] cotinine-creatinine ratio (3 studies);[114, 115, 131] and thiocyanate (4 studies).[93, 110, 112, 134] Multiple validation methods were used in nine studies.[80, 84, 90, 99, 100, 107, 121, 122, 128]

Smoking cessation and relapse prevention interventions, both prenatal and postpartum, were overwhelmingly multifaceted. Studies deployed multiple components in the intervention being compared with usual care or an alternative level of standard cessation services, both of which were also typically multicomponent. We have grouped studies by the predominant component of the intervention, which included counseling (14 studies);[81, 82, 86, 87, 89, 90, 99, 105, 108, 111, 114, 115, 129, 132] educational materials (10 studies);[94, 97, 113, 116, 117, 119, 123, 125, 126, 134] NRT (5 studies);[102, 104, 120, 122, 128] peer support (4 studies);[85, 101, 107, 109] other (9 studies),[80, 83, 84, 100, 106, 118, #3597, 124, 131] which consisted of various unique studies; and multicomponent interventions (14 studies).[11, 39, 79, 88, 91-93, 98, 103, 110, 112, 127, 130, 133] Descriptions of smoking cessation intervention components can be found in Table 4.

Table 4. Descriptions of smoking cessation intervention components

Component	Description
Clinic Reinforcement	Identifying participants at followup visits (usually by flagging patient charts) to remind staff to address smoking (e.g., assessment of smoking status, encouragement to achieve or maintain cessation).
Counseling	Any form of individual counseling (e.g., in person, by telephone), however brief, delivered by a range of practitioners (e.g., obstetrician, peers).
Feedback About Biologic Measures	Pregnant woman's ultrasound images, stress tests, biochemical tests for smoking (e.g., carbon monoxide, cotinine), or other biologic data presented to her to promote and/or sustain smoking cessation.
Groups	Support groups or group counseling to promote and/or sustain smoking cessation.
Incentives	Both financial and symbolic rewards (baby gifts, t-shirts, mugs, awards) contingent upon smoking reduction or cessation. This does not include gifts given at study enrollment or incentives for study visits.
Information	Education about pregnancy and smoking in the form of pamphlet, video, or other educational material. This includes factual or educational material only as distinguished from a Quit Guide which contains practical information and/or directions that the patient can use.
NRT	Pharmacological nicotine replacement therapy (e.g., patches, gum).
Partner/ Household/ Social Context	Identification of the smoking patterns of the partner, friends, and family as key aspects of the assessment process because these patterns potentially influence the woman's smoking behaviors. This may include household members.
Peer Support	Encouraging the identification and involvement of a peer or "buddy" for the pregnant woman as ongoing social support during the cessation process. This includes buddy contracts and lay health advisors.
Personal Followup	Followup with the purpose of sustaining the impact of the other components and offering encouragement (e.g., calls, postcards, congratulations letters).
Prescription To Quit	A written "prescription" from care provider typically including a target quit date.
Quit Guide	A take-home, patient-focused guide to quitting, usually incorporating some skill building, tips on reduction and cessation, and practical advice. This includes practical information and/or directions that the patient can use or do as distinguished from Information which provides factual or educational material only.
Stop Smoking Contract	Contract or formalized commitment to a specific quit date.
Usual Care	Described as such by study authors without specific details about what this entails.
Other	Unique component that cannot be grouped.

Overall, effects of individual studies were mixed, with nine of the good and fair quality studies reporting statistically significant positive results. In all cases where types of interventions were suggested to have positive results in some studies, other studies appear to contradict those results, even among higher quality studies. Among positive studies, most were multicomponent and form a heterogeneous set of interventions. The meta-analysis presented in KQ4 provides a detailed exploration of the individual components that may promote the apparent success of interventions. Table 5 presents individual difference in smoking cessation at the end of pregnancy for the good and fair quality studies and is followed by Table 6, which presents the difference in smoking relapse at last followup. Relapse prevention indicates the woman has not resumed smoking and is synonymous with continued cessation

Table 5. Difference in smoking cessation at end of pregnancy

Author, Year Country (Number Randomized)	Quality	Intervention (number analyzed)	Cessation, %	Cessation, %Δ	Significance (association)
Heil et al., 2008[84] U.S. (82)	Fair	Contingent vouchers (37) Control (40)	41.0 10.0	31.0	*(p=0.003)
Ondersma et al., 2012[97] U.S. (110)	Good	Educational materials (CD-5A's) (23) Usual care (23)	43.5 17.4	26.1	*(p<0.05) (OR=10.1,[a] 95% CI: 1.4 to 75.0)
Donatelle et al., 2000[110] U.S. (220)	Fair	Multicomponent (105) Usual care (102)	32.0 9.0	23.0	*(p<0.0001)
Dornelas et al., 2006[86] U.S. (105)	Fair	Counseling (53) Usual care (52)	28.3 9.6	18.7	*(p=0.02)
Windsor et al., 1985[93] U.S. (309)	Fair	Multicomponent (102) Usual care (104)	14.0 2.0	12.0	*(RR=0.12, 95% CI: 0.05 to 0.19)
Walsh et al., 1997[130] U.S. (293)	Good	Multicomponent (127) Control (125)	13.0 6.0	7.0	*(p=0.0353)
Windsor et al., 1993[39] U.S. (994)	Fair	Multicomponent (400) Usual care (414)	14.3 8.5	5.8	*(p=0.01)
Albrecht et al., 2006[85] U.S. (142)	Good	Peer Support (TFS-B) (45) Usual care (50)	NR	NR	*(p=0.01) (OR=3.73, 99% CI: 1.00 to 13.89)
Hartmann et al., 1996[92] U.S. (250)	Good	Multicomponent (107) Usual care (100)	20.0 10.0	10.0	NS (p=0.052) (OR=2.20, 95% CI: 0.98 to 4.94)
Hennrikus et al., 2010[101] U.S. (82)	Fair	Peer Support (54) Usual care (28)	13.0 3.6	9.4	NS
Ershoff et al., 1989[117] U.S. (323)	Fair	Educational materials (126) Usual care (116)	26.2 17.2	9.0	NS (p=0.09)[b]
Windsor et al., 1985[93] U.S. (309)	Fair	Multicomponent (Windsor Guide) (102) Multicomponent (ALA Guide) (103)	14.0 6.0	8.0	NS (RR=0.08, 95% CI: −0.00 to 0.16)
Stotts et al., 2009[83] U.S. (360)	Fair	Biologic feedback (MI + US) (120) Usual care (BP) (120)	18.3 10.8	7.5	NS (p=0.30)[c]
Burling et al., 1991[119] U.S. (139)	Fair	Educational materials (70) Usual care (69)	13.0 5.7	7.3	NS
Naughton et al., 2012[123] U.K. (207)	Good	Educational materials (96) Usual care (102)	12.5 7.8	4.7	NS (OR=1.68, 95% CI: 0.66 to 4.31)
Secker-Walker et al., 1998[90] U.S. (399)	Fair	Counseling (135) Usual care (141)	14.1 9.9	4.2	NS (OR=1.49, 95% CI: 0.71 to 3.10)
Ershoff et al., 1999[89] U.S. (390)	Fair	Counseling (MI) (101) Counseling (IVR) (120)	20.8 16.7	4.1	NS

Table 5. Difference in smoking cessation at end of pregnancy

Author, Year Country (Number Randomized)	Quality	Intervention (number analyzed)	Cessation, %	Cessation, %Δ	Significance (association)
Windsor et al., 1985[93] U.S. (309)	Fair	Multicomponent (103) Usual care (104)	6.0 2.0	4.0	NS (RR=0.04, 95% CI: −0.01 to 0.09)
Stotts et al., 2009[83] U.S. (360)	Fair	Biologic feedback (BP + US) (120) Usual care (BP) (120)	14.2 10.8	3.4	NS (p=0.30)[d]
Oncken et al., 2008[102] U.S. (194)	Fair	NRT (100) Placebo (94)	18.0 14.9	3.1	NS (p=0.56)
Malchodi et al., 2003[107] U.S. (142)	Good	Peer Support (67) Usual care (75)	24.0 21.0	3.0	NS (p=0.84)
Rigotti et al., 2006[87] U.S. (442)	Good	Counseling (209) Usual care (212)	10.0 7.5	2.5	NS (p=0.39) (OR=1.37, 95% CI: 0.69 to 2.70)
Coleman et al., 2012[122] U.K. (1050)	Good	NRT (521) Placebo (529)	9.4 7.6	1.8	NS (OR=1.26, 95% CI: 0.82 to 1.96)
Cinciripini et al., 2010[100] U.S. (266)	Good	Other (CBT) (128) Usual care (129)	18.0 16.3	1.7	NS (OR=1.1, 95% CI: 0.6 to 2.2)
Gielen et al., 1997[91] U.S. (467)	Fair	Multicomponent (193) Usual care (198)	6.2 5.6	0.6	NS
Hajek et al., 2001[88] U.K. (1120)[e]	Good	Multicomponent (431) Usual care (440)	6.0 7.0	(1.0)	NS
Ershoff et al., 1999[89] U.S. (390)	Fair	Counseling (MI) (101) Booklet (111)	20.8 22.5	(1.7)	NS
Moore et al., 2002[126] U.K. (1527)	Good	Educational materials (600) Usual care (695)	18.8 20.7	(1.9)	NS (95% CI: −3.5% to 7.3%)
Ondersma et al., 2012[97] U.S. (110)	Good	Educational materials (CD-5A's + CM-Lite) (26) Usual care (23)	15.4 17.4	(2.0)	NS
Ondersma et al., 2012[97] U.S. (110)	Good	Educational materials (CM-Lite) (22) Usual care (23)	13.6 17.4	(3.8)	NS
Ershoff et al., 1999[89] U.S. (390)	Fair	Counseling (IVR) (120) Booklet (111)	16.7 22.5	(5.8)	NS
Albrecht et al., 2006[85] U.S. (142)	Good	Peer Support (TFS) (47) Usual care (50)	NR	NR	NS (p=0.16) (OR=2.11, 99% CI: 0.54 to 8.19)
Albrecht et al., 2006[85] U.S. (142)	Good	Peer Support (TFS) (47) Peer Support (TFS-B) (45)	NR	NR	NS (p=0.21) (OR=1.77, 99% CI: 0.55 to 5.71)

Abbreviations: BP = best practice; CBT = cognitive behavioral therapy; CI = confidence interval; CD-5A's = computer delivered 5A's; CM-Lite = low intensity contingency management; NS = not significant; NR = not reported; NRT = nicotine replacement therapy; OR = odds ratio; RR = relative risk; TFS = Teen FreshStart; TFS-B = Teen FreshStart plus buddy; IVR = interactive voice response; MI = motivational interviewing; US = ultrasound; U.S. = United States.**Notes**: Includes good and fair quality studies only; includes a separate row for each comparison of multiple intervention studies; does not include studies that reported cessation at postpartum only; does not include studies that enrolled recent quitters only; rows ordered by significance and then by difference in cessation; asterisk (*) indicates statistical significance.

[a] Odds ratio adjusted for minority status and baseline smoking status; unadjusted OR=3.7 (95% CI: 0.94 to 14.2) p=NS.
[b] When combining early, middle, and late quitters to calculate overall quit rates, 26.2 percent of women in the intervention arm and 17.2 percent of control women were considered quit over the study period. The difference is not significant as calculated by the review team. Study reports differences as adjusted for "Early Quitting" (OR=2.80, 95% CI: 1.17 to 6.69); outcome selected post hoc upon seeing the difference in proportions among the subgroup, and assigns a smoking status to individuals who were later quitters, more of whom were in the control group, thus inflating the observed effect in terms of overall quit rates.
[c] P-value for 3-way comparison
[d] P-value for 3-way comparison
[e] Enrolled smokers (n=871) and quitters (n=249); relapse prevention for quitters reported in table 6.

Table 6. Difference in smoking relapse at last followup

Author, Year Country (Number randomized)	Quality	Intervention (number analyzed)	Relapse prevention,[a] %	Relapse prevention, %Δ	Significance (association)
Phillips et al., 2012[80] U.S. (54)	Good	Mother-infant bonding (21) Usual care (28)	81.0[b] 46.0	35.0	*(p<0.001)
Suplee, 2005[79] U.S. (62)	Fair	Multicomponent (30) Usual care (32)	37.0[c] 25.0	12.0	NS (p=0.319)
Johnson et al., 2000[82] Canada (254)	Good	Counseling (125) Usual care (126)	37.6[d] 27.0	10.6	NS (p=0.1) (OR=1.63, 95% CI: 0.96 to 2.78)
Ershoff et al., 1995[94] U.S. (218)	Fair	Educational materials (87) Usual care (84)	83.9 79.8	4.1	NS
Hajek et al., 2001[88] U.K. (1120)[e]	Good	Multicomponent (114) Usual care (135)	23.0[f] 25.0	(2.0)	NS

Abbreviations: CI=confidence interval; NS=not significant; OR=odds ratio; U.K.=United Kingdom; U.S.=United States.
Notes: Includes good and fair quality studies only; does not include studies that enrolled current smokers only; rows ordered by significance and then by difference in relapse prevention; asterisk (*) indicates statistical significance.
[a] Relapse prevention indicates the woman has not resumed smoking and is synonymous with continued cessation.
[b] 8 weeks postpartum
[c] 4 to 8 weeks postpartum
[d] 6 months postpartum
[e] Enrolled smokers (n=871) and quitters (n=249); cessation for current smokers reported in table 5
[f] 6 months postpartum

Counseling

Key Points

- Fourteen studies attempted to assess counseling interventions as the primary intervention, although counseling was ubiquitous in the overall literature: two of these were good quality, three of fair quality, and nine of poor quality.
- Counseling interventions included motivational interviewing, cognitive behavioral therapy (CBT), and psychotherapy.
- Nine studies enrolled pregnant women who were current smokers. One fair-quality study found a significant effect of the intervention at the end of pregnancy; however, the difference in the intervention and control groups did not persist at six months postpartum.
- Four studies enrolled pregnant women who had quit smoking prior to study entry, and none of these studies found statistically significant differences in maintaining cessation between the intervention and control groups.
- Two studies evaluated counseling for postpartum women who were not smoking at the time of birth, and neither had an effective intervention.

- Postpartum relapse rates were high and increased over time.

Description of Included Studies

We identified 14 RCTs[81, 82, 86, 87, 89, 90, 99, 105, 108, 111, 114, 115, 129, 132] that examined effectiveness of counseling interventions in getting smokers to quit or helping quitters avoid relapse. Ten of the studies were conducted in the United States,[86, 87, 89, 90, 99, 105, 108, 111, 114, 115] and one each in Canada,[82] Scotland,[132] Spain,[81] and Australia.[129] The majority (12) of the studies included pregnant women,[86, 87, 89, 90, 99, 105, 108, 111, 114, 115, 129, 132] and two studies enrolled women during their postpartum hospitalization.[81, 82] Eight studies were conducted in pregnant women who were currently smoking,[86, 87, 89, 90, 108, 115, 129, 132] four studies enrolled women who had quit smoking prior to the study (recent quitters),[82, 99, 111, 114] and two studies enrolled both current and former smokers.[81, 105] These 14 studies included a total of 5,499 participants at randomization (range 105 to 1,065) and 4,371 participants at analysis (range 92 to 762). Eleven studies reported outcomes at the end of pregnancy, and six studies reported postpartum outcomes with the latest followup at 12 months postpartum. Two studies were good quality,[82, 87] three fair quality,[86, 89, 90] and the remaining nine were scored poor quality.[81, 99, 105, 108, 111, 114, 115, 129, 132] Table 7 provides an overview of the good and fair quality studies.

The type of counseling and provider varied among the studies. Motivational interviewing, defined as "a collaborative, person-centered form of guiding to elicit and strengthen motivation for change,"[135] was used in seven studies, either alone or in combination with cognitive behavioral methods.[81, 87, 89, 99, 105, 108, 132] Two studies[82, 129] evaluated CBT, a therapy that focuses on changing an individual's thoughts in order to promote behavior change. Psychotherapy, which assumes behavioral change is more likely when the patient experiences affective arousal during the counseling with a high degree of interpersonal engagement with the therapist, was used in one study.[86] Four studies evaluated individualized smoking behavior change counseling for cessation[90, 115] or relapse prevention.[111, 114]

Seven studies evaluated individual in-person counseling,[90, 111, 114, 115, 129] including two studies that provided home visits,[105, 132] and five studies that used telephone counseling.[81, 87, 89, 99, 108] In two studies, the intervention was a combination of an in-person counseling session with followup telephone sessions.[82, 86] Treatment providers included therapists, bachelor or masters level counselors, trained midwives, public health nurses, and nurse educators.

Table 7. Overview of good and fair quality studies for counseling interventions

Study, Year Number Randomized Quality	Intervention	Components of Intervention Arm(s)	Time Point for Final Validated Cessation Measure	Population	Effect
Rigotti et al., 2006[87] 442 Good	Telephone counseling vs. "best practice" brief counseling	Counseling, clinic reinforcement, information, and personal followup	Pregnancy: 28 weeks to term Postpartum: 3 months	Pregnant smokers, mean gestation 12.6 weeks, mean age 28.5, 87.5% White, 73% private insurance	No difference at either time point

Table 7. Overview of good and fair quality studies for counseling interventions (continued)

Study, Year Number Randomized Quality	Intervention	Components of Intervention Arm(s)	Time Point for Final Validated Cessation Measure	Population	Effect
Johnson et al., 2000[82] 254 Good	In-hospital counseling sessions and telephone followup vs. usual care	Counseling, personal followup, and quit guide	Pregnancy: NA Postpartum: 6 months	Women enrolled after birth, recent quitters, mean age 27.6 years, 75% Canadian born	No difference
Dornelas et al., 2006[86] 105 Fair	In-person counseling and telephone followup vs. usual care	Counseling, clinic reinforcement, information, and personal followup	Pregnancy: 36 weeks Postpartum: 6 months	Pregnant smokers,≤ 30 weeks' gestation, low-income, 66% Hispanic	Cessation significantly (p=0.02) higher for intervention vs. control at end of pregnancy; no difference at 6 months postpartum
Ershoff et al., 1999[89] 390 Fair	Motivational interviewing telephone counseling and booklet vs. computerized cessation program and booklet vs. booklet only	Counseling, personal followup, and quit guide vs. quit guide and other	Pregnancy: 32 to 36 weeks Postpartum: NR	Pregnant smokers, age ≥ 18 years, 60% White, 50% at least some college, 100% HMO	No difference
Secker-Walker et al., 1998[90] 399 Fair	Structured physician advice and referral to individualized behavior change counseling vs. usual care	Counseling, clinic reinforcement, and feedback about biologic measures	Pregnancy: 36 weeks Postpartum: NR	Pregnant smokers, mean age 22.5 years, 72% Medicaid	No difference

Abbreviations: NA = not applicable; NR = not reported.

Detailed Synthesis

Pregnant Women

Smoking Cessation

Nine counseling studies, one good quality,[87] three fair quality,[86, 89, 90] and five poor quality,[105, 108, 115, 129, 132] enrolled pregnant women who were currently smoking. Four of the counseling interventions were based on motivational interviewing techniques,[89, 105, 108, 132] one study used CBT,[129] one study used CBT and motivational interviewing,[87] and one study evaluated a 90-minute psychotherapy session.[86] Two studies provided individualized smoking behavior change counseling.[90, 115] Counseling was conducted in-person in five studies, either at the clinic[90, 115, 129] or at the patient's home,[105, 132] and delivered by telephone in three studies.[87, 89, 108] One study combined a clinic in-person session with telephone followup.[86] The number of

scheduled counseling sessions ranged from one to six, though treatment fidelity varied widely within studies.

The proportions of reported cessation at the end of pregnancy ranged from less than 5 percent up to 34 percent. There were no statistically significant differences in cessation between groups in six studies that only reported a validated cessation measure at the end of pregnancy.[89, 90, 108, 115, 129, 132] Three studies reported validated cessation measured at 3 months[87] and 6 months[86, 105] postpartum, ranging from 4 to 10 percent, in addition to the end of pregnancy. Although one of these studies reported higher cessation in the women randomized to the counseling intervention at the end of pregnancy, the difference between groups was not sustained by 6 months postpartum.[86] Cessation declined in the postpartum period in both studies that reported validated outcomes from the end of pregnancy and postpartum.[86, 87] Outcomes of these studies are summarized in Table 8.

A good-quality study in 442 U.S. women recruited from a health maintenance organization (HMO) and community clinics evaluated a motivational interviewing and cognitive-behavioral counseling intervention delivered by trained counselors via telephone.[87] The mean number of calls was five (range 0 to 20), and 96 percent of the women received at least one call. The control group received a brief smoking counseling call at enrollment consistent with best practices. The cotinine validated quit proportions at the end of pregnancy were 10 percent for the intervention group and 7.5 percent for the control group (OR=1.37; 95% CI: 0.69 to 2.70). These declined to 6.7 percent and 7.1 percent respectively at the 3-month postpartum visit (OR=0.93; 95% CI: 0.44 to 1.99).

The three studies of fair quality were conducted in the United States.[86, 89, 90] Ershoff et al randomized 390 HMO members into one of three groups: motivational interviewing telephone counseling plus a quit guide booklet, a computerized cessation program plus booklet, and a control group who only received the booklet.[89] The cotinine validated quit rates in late pregnancy were similar in all three groups (20.8%, 16.7%, and 22.5% respectively). A fair-quality study in 105 low-income predominantly Hispanic women compared a 90-minute in-person psychotherapy session administered by a trained counselor with telephone followup to usual care which included standard cessation advice from a health care provider.[86] Cessation was significantly higher among women who were randomized to the intervention compared with the usual care group at the end of pregnancy verified by carbon monoxide levels, (28.3% vs. 9.6%, p=0.015) but these proportions fell by 6 months postpartum to 9.4 percent and 3.8 percent respectively (p=0.251). Only 68 percent of the women who were randomized to the intervention group received the counseling session, and telephone followup averaged 2.6 calls for this subset.

A fair-quality study that recruited women from a State maternal infant care clinic for underserved women and an adolescent clinic in Vermont randomized 197 women to receive structured physician advice and referral to individual relapse prevention counseling at their first, second, third, and fifth prenatal visits and 202 women to usual care.[90] At the 36-week prenatal visit, 14.1 percent of women in the intervention group and 9.9 percent in the control group were not smoking (OR=1.49; 95% CI: 0.71 to 3.10).

The five studies of poorer quality did not report statistically significant benefits of counseling interventions.[105, 108, 115, 129, 132]

Table 8. Smoking cessation outcomes of counseling interventions for pregnant women

Author, Year Country Population Quality	Comparison Groups (number randomized/ analyzed)	Key Cessation Outcomes
Rigotti et al., 2006[87] U.S. Pregnant smokers Good	**G1:** Telephone counseling intervention (220/209) **G2:** Brief counseling ("best practice") call (222/212)	• No significant difference in cessation between groups at the end of pregnancy (10% in G1 vs. 7.5% in G2) or at 3 months postpartum (6.7% in G1 vs. 7.1% in G2). • Very few women had sustained abstinence at both time points (4.8% in G1 and 3.3% in G2). • Smoking fewer than 10 cigarettes per day and younger (< 25 years) age were predictors of cessation.
Dornelas et al., 2006[86] U.S. Pregnant smokers Fair	**G1:** One in-person counseling session and telephone followup (53/53) **G2:** Usual care (52/52)	• Biochemically confirmed cessation in G1 was significantly higher than in G2 (28.3% vs. 9.6%, p=0.015) at the end of pregnancy. • Cessation declined in both groups (9.4% in G1 vs. 3.8% in G2, p=0.251) at 6 months postpartum.
Ershoff et al., 1999[89] U.S. Pregnant smokers Fair	**G1:** Motivational interviewing telephone counseling and booklet (126/101) **G2:** Computerized telephone cessation program plus booklet (133/120) **G3:** Booklet only (131/111)	• Urinary cotinine confirmed cessation was comparable in the three groups at the end of pregnancy: 20.8% (G1) vs. 16.7% (G2) vs. 22.5% (G3).
Secker-Walker et al., 1998[90] U.S. Pregnant smokers Fair	**G1:** Structured physician advice and referral to individual smoking behavior change counseling (197/135) **G2:** Usual care (202)	• Cessation at the 36-week prenatal visit confirmed by carbon monoxide exhalation was similar in both groups (14.1% in G1 vs. 9.9% in G2).
Reitzel et al., 2010[99] U.S. Pregnant quitters Poor	**G1:** Motivation and Problem solving (MAPS) counseling- 6 telephone sessions (68/68) **G2:** MAPS plus two additional in-person counseling sessions (68/68) **G3:** Usual care (115/115)	• The authors combined the findings from women in G1 and G2 for analyses. • Smoking cessation was not significantly higher in the combined intervention groups (41.9% in G1 + G2 vs. 27.8% in G3) at 8 weeks postpartum. • Smoking cessation had declined in both groups (22.8% in G1 + G2 vs. 16.5% in G3, p=0.08) at 6 months postpartum.
Ruger et al., 2008[105] U.S. Pregnant smokers and quitters Poor	**G1:** Motivational interviewing home visits and self-help materials (156, 132 smokers and 24 quitters/131, 110 smokers and 21 quitters) **G2:** Usual care including self-help materials (146, 113 smokers and 33 quitters/128, 100 smokers and 28 quitters)	• No difference in the number of nonsmokers at 6 months postpartum in G1 vs. G2 for current smokers (6% vs. 8%) and recent quitters (43% vs. 18%).
Tappin et al., 2005[132] Scotland Pregnant smokers Poor	**G1:** Home based motivational interviewing (351/351) **G2:** Usual care (411/411)	• Cotinine validated quit proportion at the end of pregnancy was 4.8% in G1 and 4.6% in G2 (RR=1.05; 95% CI: 0.55 to 1.98).
Stotts et al., 2002[108] U.S. Pregnant smokers Poor	**G1:** Two motivational interviewing based telephone counseling calls and personalized letter (134/86) **G2:** Usual care (135/89)	• The proportion of women with urinary cotinine confirmed cotinine cessation at the 34-week prenatal visit was comparable between groups (32% in G1 vs. 34% in G2, p<0.65).

Table 8. Smoking cessation outcomes of counseling interventions for pregnant women (continued)

Author, Year Country Population Quality	Comparison Groups (number randomized/ analyzed)	Key Cessation Outcomes
Panjari et al., 1999[129] AUS Pregnant smokers Poor	**G1:** Counseling sessions provided by midwife (476/339) **G2:** Usual care (537/393)	• No significant difference in the proportion of women who quit in late pregnancy between groups (11.9% in G1 vs. 9.8% in G2, p=0.41).
Secker-Walker et al., 1998[111] U.S. Pregnant quitters Poor	**G1:** Structured physician advice and referral to relapse prevention counselor (62/44) **G2:** Usual care (63/48)	• Carbon monoxide exhalation confirmed cessation was 77% in both groups at the 36-week prenatal visit.
Secker-Walker et al., 1995[114] U.S. Pregnant quitters Poor	**G1:** Individualized smoking relapse prevention counseling (89/68) **G2:** Usual care (86/65)	• In the subset of women with cotinine verified smoking outcomes, 29.5% in G1 and 27.9% in G2 relapsed to smoking by the end of pregnancy.
Secker-Walker et al., 1994[115] U.S. Pregnant smokers Poor	**G1:** Individualized smoking cessation counseling (300/188) **G2:** Usual care (300/226)	• The proportion of women who had urinary cotinine-creatinine ratios ≤80 ng/mg at the 36-week visit was similar in both groups (11.8% in G1 vs. 12.5% in G2).

Abbreviations: AUS = Australia; CI = confidence interval; G = group; MAPS = motivation and problem solving; NS = not significant; OR = odds ratio; RR = risk ratio; U.S. = United States.

Relapse Prevention

Four U.S. studies, all of poor quality, enrolled pregnant women who had quit smoking at the start of the study.[99, 105, 111, 114] One of these studies also enrolled current smokers.[105] The counseling intervention was individualized smoking relapse prevention in two studies,[111, 114] a combination of problem-solving skills and motivational interviewing in one study,[99] and an individually tailored motivational intervention in one study.[105] Counseling was conducted in person in three studies, either at the clinic[111, 114] or in the patient's home,[105] and via telephone in one study.[99]Some of the participants in the study with telephone counseling also received in-person counseling sessions.[99] Two studies used in-person clinic individualized smoking relapse prevention counseling.[111, 114]

None of the studies found statistically significant differences in cessation between the intervention and control groups. The proportions of cessation ranged from 70 percent to 77 percent in the two studies that reported validated measures at the end of pregnancy[111, 114] and 17 percent to 43 percent in the two studies that reported validated measure at 8 weeks[99] and 6 months[99, 105] postpartum. Outcomes of these studies are summarized in Table 8.

Postpartum Women

Relapse Prevention

Two studies, one good and one poor quality, enrolled women during postpartum hospitalization who had quit smoking while they were pregnant.[81, 82]

A good-quality study conducted in five Canadian hospitals randomized 254 women who had quit at least 6 weeks prior to birth to intervention or usual care.[82] Mothers in the intervention arm

received an in-person counseling session from a nurse and up to eight telephone followup phone calls during the first 3 postpartum months, which was compared with usual care. Smoking status was assessed at a home visit six months postpartum and verified by a carbon monoxide exhalation level of less than 10 parts per million (ppm). The majority of women in this study had resumed smoking, but a higher proportion of women who received counseling maintained cessation compared with those who had usual care (37.6% vs. 27.0%; OR=1.63; 95% CI: 0.96 to 2.78). At 12-month followup, cessation had declined to 21.0 percent in the intervention group and to 18.5 percent in the control group.[136] The authors noted that among women who maintained cessation at 6 months, 21 percent had relapsed at one year. However, 16 percent who were smoking at 6 months had stopped smoking at 12 months. The poor-quality study[81] of motivational interviewing telephone counseling sessions enrolled both current smokers and recent quitters (defined as women who had stopped smoking at the beginning of or during pregnancy) but only reported outcomes on the latter, which can be found in Table 9.

Table 9. Smoking cessation outcomes of counseling interventions for postpartum women

Author, Year Country Population Quality	Comparison Groups (number randomized/ analyzed)	Key Cessation Outcomes
Johnson et al., 2000[82] Canada Postpartum quitters Good	**G1:** In-hospital counseling session after birth and telephone followup up to 8 sessions (125/121) **G2:** Usual care (126/120)	• Smoking cessation at the 6-month postpartum visit fell to 38% in G1 and 27% in G2 (OR=1.63; 95% CI: 0.96 to 2.78).
Jimenez-Muro et al., 2012[81] Spain Postpartum smokers and quitters Poor	**G1:** Four telephone calls based on Motivational Interviewing (205, 117 smokers and 88 quitters/88 quitters) **G2:** Control group received two status check calls (207, 117 smokers and 90 quitters/90 quitters)	• No difference in smoking cessation at 3 months postpartum (31% in G1 vs. 23% in G2, p=0.13). • Only half of the women attended the 3-month visit.

Abbreviations: CI = confidence interval; G = group; NS = not significant; OR = odds ratio.

Educational Materials

Key Points

- Ten studies assessed educational materials interventions: three of good quality, three of fair quality, and four of poor quality.
- Five studies primarily focused primarily on print-based interventions, two on video-based interventions, and three on technology-based interventions.
- One study reported that a computer-based 5A's intervention was associated with higher quit rates than usual care. Two additional studies found greater cessation in intervention participants compared with control participants earlier in pregnancy, but the differences had attenuated by the end of pregnancy.
- No specific educational materials were associated with higher cessation than other materials.
- Loss to followup for reasons other than pregnancy loss or changing practitioners was high across studies.

Description of Included Studies

Ten studies reported in 13 publications addressed educational materials interventions for smoking cessation.[94, 97, 113, 116, 117, 119, 123, 125, 126, 134, 137-139] Six studies were conducted in the

United States,[94, 97, 113, 116, 117, 119, 139] three in the United Kingdom,[123, 125, 126, 137, 138] and one in Sweden.[134] All of the studies were conducted during the prenatal period. Most studies (8) enrolled women who were current smokers. One included both current smokers and recent quitters,[126] and one included only recent quitters.[94] These 10 studies included a total of 4,418 participants at randomization (range 60 to 1527) and 2,562 participants at analysis (range 46 to 653). All ten studies report outcomes at the end of pregnancy, and two studies report postpartum outcomes with the latest followup at 8 weeks postpartum. We rated three studies as good quality,[97, 123, 126] three as fair,[94, 117, 119] and four as poor.[113, 116, 125, 134]

Studies assessed print-based, video-based, or technology-based educational materials and often combined modalities. We have organized studies in this section by the modality of the key active component. The materials included quit guides, which provide practical advice for quitting smoking or preventing relapse, and information, which is factual or educational material only. An overview of the good and fair studies is presented in Table 10; outcomes for all of the studies are presented in Table 11.

Table 10. Overview of good and fair quality studies for educational materials

Study, Year Number Randomized Quality	Intervention	Components of Intervention Arm(s)	Time Point for Final Validated Cessation Measure	Population	Effect
Naughton et al., 2012[123] 207 Good	Tailored self-help materials via mail and text message vs. non-tailored self-help materials via mail	Quit guide and personal followup	Pregnancy: 12 weeks post-enrollment Postpartum: NR	Adult smokers <21 weeks pregnant at baseline, median age 26,100% White, 100% National Health Service	No difference
Ondersma et al., 2012[97] 110 Good	Computer-delivered 5A's vs. contingency management vs. computer-delivered 5A's plus contingency management vs. usual care	Information and other vs. feedback and incentives vs. incentives, information, feedback, and other	Pregnancy: 10 weeks post-enrollment Postpartum: NR	Lower income, adult smokers, ≤27 weeks pregnant at baseline, 90% Black	Significantly ($p<0.05$) greater cotinine-validated cessation in computer-based 5A's arm vs. usual care (OR=10.1,[a] 95% CI: 1.4 to 75.0)
Moore et al., 2002[126] 1,527 Good	Quit guides vs. usual care	Quit guide and counseling	Pregnancy: End of second trimester Postpartum: NR	Adult smokers and recent quitters, < 17 weeks pregnant at baseline, 100% National Health Service	No difference

Table 10. Overview of good and fair quality studies for educational materials (continued)

Study, Year Number Randomized Quality	Intervention	Components of Intervention Arm(s)	Time Point for Final Validated Cessation Measure	Population	Effect
Burling et al., 1991[119] 139 Fair	Counseling with and without a personalized letter from the Chief of Service and American Cancer Society pamphlet vs. usual care	Information, counseling, and personal followup	Pregnancy: Last study contact[a] Postpartum: NR	Adult smokers average gestation less than 24 weeks	No difference in the overall cessation, but greater cessation for the intervention group at the second contact, so intervention may be associated with earlier quitting
Ershoff et al., 1989[117] 323 Fair	Quit guides vs. usual care	Quit guide, counseling, and information	Pregnancy: 34 weeks Postpartum: NR	Adult smokers, majority 9 to 13 weeks pregnant at baseline, majority White, 100% HMO	No difference in overall cessation, although investigators suggest that intervention participants quit earlier in pregnancy

Abbreviations: HMO = health maintenance organization; NR = not reported.
[a] Varied, (approximately 34 weeks' gestation)

Detailed Synthesis

Of the 10 studies evaluating educational materials, five focused primarily on print-based interventions,[94, 117, 119, 126, 134] two on video-based interventions,[113, 116] and three on technology-based interventions.[97, 123, 125] The proportion of women with validated smoking cessation ranged from zero to 85 percent at the end of pregnancy and from 4 to 16 percent at 10 days[125] to 8 weeks[134] postpartum. Three studies demonstrated some effectiveness of an educational materials intervention. In one good-quality but small study (n=110), 43.5 percent of women that completed a tailored, single-session, interactive computer program had validated cessation at the end of pregnancy compared with 17.4 percent of women that received usual care (OR=10.2; 95% CI: 1.4 to 75.0).[97] Two studies found a higher proportion of cessation in intervention participants compared with control participants at one time point but no difference at another time point.[119, 134]

Print-Based Interventions

Five studies examined the effects of print-based educational materials.[94, 117, 119, 126, 134] Of these, one was good quality,[126] three fair,[94, 117, 119] and one poor.[134]

The one good-quality cluster RCT was conducted in the United Kingdom and allocated midwives to usual care or usual care plus distribution of five self-help booklets (quit guides) with pregnant women who were currently smoking or who had stopped after learning they were pregnant.[126] No description was provided of what smoking cessation elements may have been a part of usual care. Midwives were instructed to spend about 5 minutes reviewing the first booklet with participants allocated to the self-help intervention; subsequent booklets were mailed. Booklets included motivational and behavioral strategies for cessation and relapse prevention. Women completed a mailed questionnaire at 26 weeks' gestation, and investigators collected a urine sample for cotinine analysis from those indicating smoking cessation for 7 or more days

(n=363/1317 completing the followup questionnaire). Results for current smokers and recent quitters were not reported separately. One hundred thirteen (18.8%) women in the intervention group and 144 (20.7%) women in the usual care group had validated non-smoking status, and there was no significant difference in cessation between the two groups (difference=1.9%; 95% CI: −3.5% to 7.3%; p=NS).

Three fair-quality studies considered the potential for written educational materials to lead to increases in cessation during pregnancy.[94, 117, 119] Two of the studies used the same intervention in different study populations (current smokers and recent quitters).

In one fair-quality study, investigators randomized pregnant smokers, defined by either self-report or exhaled carbon monoxide analysis, to receive either nurse-provided education (counseling) about health behaviors including smoking or the same education plus a personal letter from the chief of the prenatal clinic and an American Cancer Society pamphlet about smoking during pregnancy.[119] The counseling component was a standard part of prenatal care. The letter identified participants as probable smokers based on interviews and carbon monoxide exhalation samples, advised them about the health risks of smoking, and encouraged them to quit.[119] Investigators assessed smoking status via self-report and exhaled carbon monoxide at each clinic visit. The number of study contacts ranged from 2 to 12, and investigators analyzed data from the first, second, and last contacts, which they say roughly corresponded to the 24th, 28th, and 34th weeks of gestation. Cessation was significantly higher in the intervention group compared with the usual care group at the second study contact (11.6% vs. 1.4%, p<0.01) but not at the third contact (13.0% in the intervention group vs. 5.7% in usual care, p<0.10), suggesting that although women in the intervention group may have quit earlier, rates of quitting evened out through pregnancy.[119]

One HMO-based RCT reported in two publications[117, 139] and conducted in the United States included 323 current smokers from varied socioeconomic and ethnic backgrounds. The study assessed the effects of a quit guide that comprised a series of eight self-help booklets focused on cessation motivation and relapse prevention and targeted to pregnant women compared with usual care. All participants received a two-page pamphlet on smoking cessation delivered by a health educator, and the participants randomized to the intervention group also received the first of eight self-help booklets along with a brief overview from a health educator. Investigators mailed the remaining booklets to participants at weekly intervals. Participants completed a telephone interview at 26 weeks followed by analysis of stored urine samples to validate self-reported quitting (quit defined as no cotinine value greater than 29 ng/ml and at least one value less than 10 ng/ml). Investigators also performed a final urinalysis at 34 weeks.

Investigators classified the participants as follows:

- early quitters (quit when less than 20 weeks pregnant)
- middle quitters (quit between 20 and 26 weeks pregnancy)
- late quitters (smoking at 26-week interview but cotinine-demonstrated quit at 34 weeks)
- early relapsers (quit prior to the 26-week interview but had relapsed by 26 weeks)
- late relapsers (quit prior to 26 weeks and were not smoking at the 26-week interview, but cotinine demonstrated smoking at 34 weeks)
- nonquitters (had made no quit attempts and were continuing to smoke at 26 weeks, with cotinine-demonstrated smoking at 34 weeks)

When combining early, middle, and late quitters to calculate overall cessation, 26.2 percent of women in the intervention arm and 17.2 percent of control women quit over the study period. The difference in overall cessation is not significant as calculated by the review team (p=0.09).

The authors report that 22.2 percent of the intervention group were early quitters, while 8.6 percent of the comparison group were early quitters, suggesting that if timing of quitting is the key outcome, there may be an effect of the intervention, despite no overall advantage. The selection of early quitting as an outcome appears to have been a post hoc decision, however, and doing so assigns a smoking status to individuals who were later quitters, more of whom were in the control group, thus inflating the observed effect in terms of overall quit rates. However, this study may demonstrate a benefit in terms of timing of quitting, under the assumption that earlier quitting may be beneficial.

In a separate study, but using the same intervention, study investigators randomized 218 women who reported having stopped smoking since learning of their pregnancy to receive the self-help booklets or usual care in order to assess the program's utility in preventing relapse.[94] More women in the intervention arm were primigravida (32.6% vs. 13.1% of usual care women, $p<0.01$), and more reported they were very confident in their ability to maintain smoking cessation during pregnancy (95.4% vs. 86.9% of usual care women, $p<0.05$). At the 26-week interview, 78.9 percent of women in the intervention group and 84.7 percent of women in the usual care arm had confirmed smoking cessation (proportions adjusted for gravida, length of abstinence, smoking belief, and quitting self-efficacy); the difference between the arms was not significant.[94]

One poor quality RCT[134] compared a basic information sheet to a quit guide and reported no effect at 30 to 34 weeks' gestation but a significant difference at 8 weeks after birth when 15.8% of intervention and 9.1% of control participants had stopped smoking (OR=0.5; 95% CI: 0.3 to 0.9).

Video-Based Interventions

Two studies of video-based interventions were both of poor quality. One reported no difference in cessation when a video focused on potential effects of smoking on the fetus was compared with a quit guide or usual care.[116] The second reports significantly ($p=0.02$) greater cessation with a video, created using principles of social learning, about the personal experiences of four lower-income women as they attempted to quit smoking.[113] Five of the 19 video group participants reported not smoking at 36 weeks and had exhaled carbon monoxide levels in the non-smoking range compared with zero women in the comparison group ($p=0.02$).

Technology-Based Interventions

Three studies, two of good quality and one poor, used technology-based interventions, including text messaging and computer-delivered interventions.

A good-quality trial conducted in the United Kingdom was designed primarily as a feasibility study, but powered to detect a difference in cessation.[123] The study included 207 women randomized to either the MiQuit program, which included a tailored quit guide with advice specific to a participant's smoking history and attitude toward quitting as reported in a baseline questionnaire plus tailored text messages (approximately 80 over 11 weeks, with greater frequency in the first 4 weeks), or a non-tailored self-help pamphlet. Differences in cotinine-validated cessation at a 3-month followup were not significant between groups (12.5% in the MiQuit group vs. 7.8% in the pamphlet-only group, OR=1.68, 95% CI: 0.66 to 4.31).

A second good-quality study conducted at an urban clinic in the United States also primarily evaluated the acceptability of interventions aimed at lower-income smokers,[97] assessing the following four interventions in pregnant smokers:

- Computer-delivered 5A's (Ask, Advise, Assess, Assist, Arrange). Women allocated to this arm completed a single-session interactive computer program tailored to their smoking history and attitudes toward quitting. The program used a video-based "advise" component focused on the benefits of quitting. Women unwilling to set a change goal received a motivational intervention consistent with the 5Rs (Relevance, Risks, Rewards, Roadblocks, Repetition).
- Usual care. Women allocated to this arm received standard cessation advice from their clinic providers. They also completed a computer-based exercise that did not address smoking cessation as a sham technique to maintain blinding of research assistants.
- Lower intensity contingency management. Women in this arm could request urinary cotinine testing at any prenatal visit and were eligible to receive up to five retail gift card reinforcers provided that cotinine levels revealed abstinence from smoking.
- Combined arm. Women allocated to this condition completed the 5A's computer program and could request cotinine testing and be eligible for up to five gift cards if cotinine tests revealed smoking cessation.

At approximately 10 weeks after randomization, four women (17.4%) in the usual care arm, 10 women (43.5%) in the 5A's arm, three women (13.6%) in the contingency management arm, and four women (15.4%) in the combined arm had quit per cotinine validation. Women in the CD-5A's group had 10 times the odds of a cotinine confirmed quit (OR=10.2; 95% CI: 1.4 to 75.0) relative to usual care, but the very small n and thus lack of precision decrease confidence in this result.

A poor-quality cluster-randomized trial[125] reported in three publications[125, 137, 138] and conducted in the United Kingdom allocated prenatal clinics to one of three arms: usual care, stage of change-based quit guides ("Pro-Change Programme for a Healthy Pregnancy"), or a tailored, interactive computer program focused on cessation plus the Pro-Change quit guides. There were no significant differences between arms at 30 weeks' gestation or at 10 days after birth.

Table 11. Smoking cessation outcomes of educational materials

Author, Year Country Population Quality	Comparison Groups (number randomized/analyzed)	Key Cessation Outcomes
Naughton et al., 2012[123] U.K. Pregnant smokers Good	**G1:** Tailored quit guide plus tailored text messages (102/96) **G2:** Non-tailored quit guide (105/102)	• Differences in cotinine-validated cessation 12 weeks after enrollment were not significant (12.5% in G1 vs. 7.8% in G2, OR=1.68, 95% CI: 0.66 to 4.31).
Ondersma et al., 2012[97] U.S. Pregnant smokers Good	**G1:** Computer-delivered 5A's (CD-5A's) brief intervention (26/23) **G2:** Computer-assisted low-intensity contingency management (CM-Lite) (28/22) **G3:** CD-5A's plus CM-Lite (30/26) **G4:** Usual care (26/23)	• At the 10-week followup visit, cotinine validated smoking cessation was 43.5% in G1, 13.6% in G2, and 15.4% in G3 compared with 17.4% in the usual care group (G4). • The difference in outcomes was significant when comparing the CD-5A's group (G1) to the usual care group (G4) only.
Lawrence et al., 2003[125] U.K. Pregnant smokers Poor	**G1:** Stage-quit guides (305/219) **G2:** Stage-based quit guides plus interactive computer program to assess state of change (324/249) **G3:** Controls (standard advice) (289/185)	• No significant differences between groups at 30 weeks pregnancy or at 10 days after birth.

Table 11. Smoking cessation outcomes of educational materials (continued)

Author, Year Country Population Quality	Comparison Groups (number randomized/analyzed)	Key Cessation Outcomes
Moore et al., 2002[126] U.K. Pregnant smokers and quitters Good	**G1:** Quit Guides (724/113) **G2:** Usual care (803/144)	• No difference in the urine cotinine validated smoking cessation (18.8% in G1 vs. 20.7% in G2) at the end of the second trimester of pregnancy.
Secker-Walker et al., 1997[113] U.S. Pregnant smokers Poor	**G1:** Video, advice, and tip sheet (30/19) **G2:** Advice and tip sheet (30/27)	• Five of the 19 video group participants reported not smoking at 36 weeks and had exhaled carbon monoxide levels in the non-smoking range compared with zero women in the comparison group (p=0.02).
Price et al., 1991[116] U.S. Pregnant smokers Poor	**G1:** Educational video (71/46) **G2:** American Lung Association quit guide (52/39) **G3:** Usual care (70/24)	• No significant differences in carbon monoxide exhalation validated smoking cessation between the groups (8.7% in G1, 5.1% in G2, and 4.2% in G3) at birth.
Hjalmarson et al., 1991[134] Sweden Pregnant smokers Poor	**G1:** Quit Guide (Windsor) (492/444) **G2:** Information sheet from physician (231/209)	• No significant differences in cessation at the end of pregnancy (30.4% in G1 vs. 8.6% in G2; OR=0.7; 95% CI: 0.4 to 1.1). • Smoking cessation at 8 weeks postpartum was 15.8% in G1 and 9.1% in G2, a statistically significant difference (OR=0.5; 95% CI: 0.3 to 0.9).
Ershoff et al., 1989[117] U.S. Pregnant smokers Fair	**G1:** Quit Guide (165/126) **G2:** Usual care (158/116)	• No difference in overall cessation, although investigators suggest that intervention participants quit earlier in pregnancy. • Early quit was predicted by intervention status with 22.2% of early quitters in G1 vs. 8.6% in G2.
Burling et al., 1991[119] U.S. Pregnant smokers Fair	**G1:** Counseling plus a personalized letter and American Cancer Society pamphlet (70/70) **G2:** Counseling only (69/69)	• No difference in cessation at the final study visit, but higher cessation at visit 2 (11.6% in G1 vs. 1.4% in G2; p<0.01).
Ershoff et al., 1995[94] U.S. Pregnant quitters Fair	**G1:** Quit Guide to prevent relapse (110/87) **G2:** Usual Care (108/84)	• At the 26-week interview, 78.9% of the 87 women in the intervention group available for followup and 84.7% of 84 women in the usual care arm had confirmed smoking cessation (proportions adjusted for gravida, length of abstinence, smoking belief, and quitting self-efficacy); p=NS.

Abbreviations: CI = confidence interval; G = group; NS = not significant; OR = odds ratio; RR = risk ratio; UK = United Kingdom; U.S. = United States.

NRT

Key Points

- Five studies assessed NRT interventions in pregnant women who were current smokers: two of good quality, one of fair quality, and two of poor quality.
- Three studies used nicotine patches; one used gum; and one allowed participants to choose nicotine patches, gum, or lozenges.

- One good-quality study had inconsistent effectiveness findings with significantly higher cessation in the nicotine patch group than placebo group at some visits and no difference at other visits
- In a poor-quality RCT, a higher proportion of women who chose nicotine patch, gum, or lozenge in addition to CBT quit smoking compared with women who had only CBT.

Description of Included Studies

Five RCTs had NRT interventions as their primary focus. Three of the studies were conducted in the United States,[102, 104, 120] one in England,[122] and one in Australia.[128]

All five studies enrolled pregnant women who were current smokers. These five studies included a total of 1,517 participants at randomization (range 40 to 1050) and 1,438 participants at analysis (range 40 to 1050). All five studies report outcomes at the end of pregnancy, and one study reports postpartum outcomes with the latest followup at 12 weeks postpartum. One study was assessed as good quality,[99, 122] one as fair,[102] and three as poor.[104, 120, 128] Table 12 provides an overview of the good and fair quality studies, and Table 13 reports outcomes for all studies in this section.

Nicotine replacement therapy products provide low doses of nicotine without the toxins found in cigarette smoke. These products can help reduce cravings and symptoms that are experienced with smoking cessation. Five forms of NRT are approved by the U.S. Food and Drug Administration: patch, gum, nasal spray, inhalers, and lozenges.

Table 12. Overview of good and fair quality studies for NRT intervention

Study, Year Number Randomized Quality	Intervention	Components of Intervention Arm(s)	Time point for Final Validated Cessation Measure	Population	Effect
Coleman et al., 2012[122] 1050 Good	NRT (patch) vs. placebo	NRT, counseling, personal followup, quit contract, and quit guide	Pregnancy: Birth Postpartum: NR	Smokers, aged 16 and older, between 12 to 24 weeks' gestation at baseline, 97% White	Higher proportion of women in NRT group quit smoking at one month after quit date, but no difference at birth
Oncken et al., 2008[102] 194 Fair	NRT (gum) + counseling vs. placebo + counseling	NRT, clinic reinforcement, counseling, information, and personal followup	Pregnancy: 32 to 34 weeks Postpartum: 6 to 12 weeks	Smokers, aged 16 and older, ≤ 26 weeks pregnant, 54% Hispanic	No difference at either time point

Abbreviations: CBT = cognitive behavioral therapy; NRT = nicotine replacement therapy: NR = not reported.

Detailed Synthesis

Three studies provided NRT as a patch;[120, 122, 128] one study used nicotine gum;[102] and one study allowed participants to choose nicotine patches, gum, or lozenges.[104] Biologically confirmed cessation at the end of pregnancy ranged from zero to 23 percent. Only one study reported postpartum cessation, and it was decreased from end of pregnancy. One poor-quality study had inconsistent effectiveness findings with significantly higher cessation in the nicotine patch group than placebo group at some visits and no difference at other visits.[120] In a poor-quality RCT, a higher proportion of women who chose nicotine patch, gum, or lozenge in addition to CBT quit smoking compared with women who only had CBT.[104]

In a good-quality study of 1050 pregnant smokers in England, investigators assigned the intervention group to 8 weeks of treatment with nicotine patches (15 mg per 16 hours) and behavioral support while the control group received a placebo patch and behavioral support.[122] At one month after the quit date, cessation with carbon monoxide confirmation was higher in the nicotine patch group than the placebo group (21.3% vs. 11.7%; OR=2.05; 95% CI: 1.46 to 2.88). Cessation at birth was confirmed by exhaled carbon monoxide and salivary cotinine level measurement. Cessation in the nicotine patch group and the placebo group was comparable (9.4% vs. 7.6%; OR=1.26; 95% CI: 0.82 to 1.96).

A fair-quality study in the United States enrolled 194 pregnant smokers.[102] Women in the intervention group received 6 weeks of 2 mg nicotine gum and behavioral counseling while women in the control group received a placebo gum and behavioral counseling. There were no significant differences in cessation between the nicotine gum group and placebo group at 32 to 34 weeks' gestation (18.0% vs. 14.9%) or 6 to 12 weeks postpartum (11.0% vs. 9.6%). The Data and Safety and Monitoring Board recommended that enrollment be stopped early due to lack of efficacy.

A poor-quality study in the United States randomized 52 pregnant smokers to either nicotine patches and CBT or to CBT alone.[120] The study used a 10-week NRT regimen, and one of two dosing options (21 mg-14 mg-7 mg or 14 mg-7 mg) was chosen based on baseline salivary cotinine levels. Participants had six visits, four of which (visits 3 to 6) occurred after the intervention was initiated. The proportion of women with cotinine confirmed cessation was significantly higher in the nicotine patch group compared with the placebo group at visit three (23% vs. zero, p=0.02) and visit six (19% vs. zero, p=0.05), but not at visit four (12% in both groups, p=1.00) or visit five (12% vs. 8%, p=1.00).

In a poor-quality study with 181 pregnant smokers, women in the intervention group received CBT and patient-preference open-label selection of nicotine patch, gum, or lozenge with the dosage adjusted by prior smoking level.[104] Women in the control group received CBT. Another poor-quality study randomized 40 pregnant smokers to counseling to stop smoking and nicotine patches (15 mg over 16 hours) for a maximum of 12 weeks or counseling to stop smoking. Outcomes for these studies can be found in Table 13.[128]

Table 13. Smoking cessation outcomes of NRT

Author, Year Country Population Quality	Comparison Groups (number randomized/ analyzed)	Key Cessation Outcomes
Coleman et al., 2012[122] U.K. Pregnant smokers Good	**G1:** NRT (patch) (521/521) **G2:** Placebo (529/529)	• No difference in cessation at birth between groups (9.4% in G1 vs. 7.6% in G2, OR=1.26; 95% CI: 0.82 to 1.96).
Oncken et al., 2008[102] U.S. Pregnant smokers Fair	**G1:** NRT (gum) (100/100) **G2:** Placebo (94/94)	• No significant differences in cessation between groups at 32 to 34 weeks' gestation (18.0% in G1 vs. 14.9% in G2) or at 6 to 12 weeks postpartum (11.0% in G1 vs. 9.6% in G2).

Table 13. Smoking cessation outcomes of NRT (continued)

Author, Year Country Population Quality	Comparison Groups (number randomized/ analyzed)	Key Cessation Outcomes
El-Mohandes et al., 2012[120] U.S. Pregnant smokers Poor	**G1:** NRT (patch) + CBT (26/26) **G2:** CBT (26/26)	• Cessation was higher in G1 compared with G2 at visit 3 (23% vs. 0%, p=0.02) and visit 6 (19% vs. 0%, p=0.05), but not at visits 4 and 5.
Pollak et al., 2007[104] U.S. Pregnant smokers Poor	**G1:** NRT (patch, gum, or lozenge) + CBT (122/73) **G2:** CBT (59/29)	• Cessation was significantly higher in G1 than G2 at 38 weeks' gestation (18% vs. 7%, p=0.01) but not at 3 months postpartum (20% vs. 14%, p=0.55).
Hotham et al., 2006[128] AUS Pregnant smokers Poor	**G1:** NRT (patch) + counseling (20/20) **G2:** Counseling (20/20)	• At the end of pregnancy 3 women (15%) in G1 and none (0%) in G2 were abstinent (p=NR). • Fourteen women (35%) withdrew from the study.

Abbreviations: AUS = Australia; CBT = cognitive behavioral therapy; NRT = nicotine replacement therapy: NR = not reported; U.K. = United Kingdom; U.S. = United States.

Peer Support

Key Points

- Four studies assessed peer support interventions in pregnant women who were current smokers: two of good quality, one of fair quality, and one of poor quality.
- Two studies used specially-trained, non-smoking peer counselors from the community, and two studies had female friends or family members as peer supporters.
- Compared with family members, friends were more effective supporters, and trends suggested that ex-smokers were the more effective supporters than never or current smokers.
- Adding peer support to office-based counseling programs did not increase cessation.

Description of Included Studies

In this section we describe those studies that were predominantly focused on examining whether improvements in cessation rates could be achieved by proactively involving a peer. We sought studies that included lay women, friends, family members, partners, or other individuals as the peer support person, or that provided group meetings explicitly designed with a peer support and encouragement model, as opposed to a smoking cessation education model.

The approach to peer support varied in each study and is summarized in Table 14. Two of the four studies used specially-trained, non-smoking peer counselors from the community to provide cessation advice and support, in person during visits in one instance,[107] and by telephone referral in the other.[109] In the other studies women identified a candidate peer support person who then either participated with them in smoking cessation sessions[85] or who received special training for those who were peer supporters.[101] In both of these studies the supporters were female friends or family members. We did not identify studies that focused on the partner/spouse or other adult members of the household as the support person.

Table 14. Peer supporters and training strategies used in prenatal smoking cessation interventions

Author, Year, Country, Quality	Characteristics of Peer Supporters	Training for Supporters
Trained Lay Health Advisors		
Solomon et al., 2000[109] U.S. Poor	A female, ex-smoker, peer-support counselor made calls around quit dates, then weekly, and more rarely when "smoking changes stabilized."	Eight hours of training, format not specified. Providers in the study were using Agency for Health Care Policy & Research smoking cessation counseling guidelines.
Malchodi et al., 2003[107] U.S. Good	Smoking cessation counseling from lay community health outreach workers with the same "social-environmental and cultural qualities" as participants. Sessions as convenient for participant by phone, in her home, or at clinic.	Two standardized training sessions: 3-hr Agency for Health Care Policy & Research smoking cessation counseling guidelines and 2-hour strategies for motivational counseling.
Friend or Family Member		
Albrecht et al., 2006[85] U.S. Good	A female peer "buddy" was selected by the teenage smoker receiving prenatal care and the buddy was invited to attend an 8-week cessation program with the teen smoker. The group session were also co-led by a teen.	Other than attendance at the group, no additional training was provided to the supporters.
Hennrikus et al., 2010[101] U.S. Fair	Smokers in prenatal care identified "a woman in her social network" to serve as a supporter: 60% were relatives and 40% were friends.	Supporters had one in-person visit with a cessation counselor and monthly telephone calls. Sessions were used to review efforts and to identify specific activities to support cessation.

Abbreviations: U.S. = United States.

Four RCTs, all conducted in U.S. urban clinics, focused on peer support.[85, 101, 107, 109] Three studies were underpowered for their primary outcomes.[85, 101, 109] All four studies enrolled pregnant women who were current smokers. These four studies included a total of 517 participants (range 82 to 151) at randomization and analysis. All four studies report outcomes at the end of pregnancy, and two studies report postpartum outcomes with the latest followup at one year postpartum. Two studies were good quality,[85, 107] one was fair quality,[101] and one was poor.[109] Table 15 provides an overview of the good and fair quality studies.

Table 15. Overview of good and fair quality studies for peer support interventions

Study, Year Number Randomized Quality	Intervention	Components of Intervention Arm(s)	Time Point for Final Validated Cessation Measure	Population	Effect
Albrecht et al., 2006[85] 142 Good	Teen peer counseling vs. teen peer counseling plus buddy vs. usual care	Group vs. group and peer support	Pregnancy: 8 weeks after intervention Postpartum: 1 year	Teenage smokers, aged 14 to 19, most in second trimester at baseline, 53% White, 42% African-American	No difference in cessation among the groups after 1 year

Table 15. Overview of good and fair quality studies for peer support interventions (continued)

Study, Year Number Randomized Quality	Intervention	Components of Intervention Arm(s)	Time point for Final Validated Cessation Measure	Population	Effect
Malchodi et al., 2003[107] 142 Good	Peer counseling vs. usual care	Clinic reinforcement, counseling, peer support, and quit guide	Pregnancy: 36 weeks Postpartum: NR	Smokers, aged 18 to 41, 63% Hispanic	No difference
Hennrikus et al., 2010[101] 82 Fair	Peer supporters who received monthly counseling vs. no contact with control group supporters	Counseling and peer support	Pregnancy: Just prior to expected due date Postpartum: 3 months	Smokers, median age 24, 67% racial minorities or Hispanic, 71% had other children	No difference at either time point

Abbreviations: NR = not reported.

Detailed Synthesis

The proportion of women with biologically confirmed abstinence at the end of pregnancy ranged from 4 to 24 percent. Only one study reported numerical data for validated postpartum cessation data, ranging from zero to 9 percent. Outcomes of these studies are summarized in Table 16.

Trained Lay Health Advisors

Two RCTs, one of good quality[107] and one of poor quality,[109] engaged lay women as peers in supporting cessation. The good-quality study, which was conducted at a community hospital tertiary care clinic, added peer cessation counselors to a clinic-based brief intervention program designed specifically for pregnant women.[107] In the poor-quality study, participants from a large obstetrics practice were randomized assignment to a clinic-based brief smoking cessation program delivered by obstetricians and midwives compared with the same clinic-based program along with calls from a trained ex-smoker who called participants soon after referral, around quit dates, and thereafter to plan and reinforce steps.[109] Neither study achieved significantly higher cessation among those in the intervention group with additional peer counseling support. Each study noted the difficulty of achieving the target level of exposure, with a median of six contacts (out of goal of eight) in the study with peer counselors and only 53 percent participating in phone counseling in the telephone-based program.

Friends or Family Members as Peer Cessation Supporters

Two studies engaged participants in identifying a specific individual to support them in smoking cessation.[85, 101] A fair-quality study (n=82) was described as a pilot study and noted to be under-powered to detect the anticipated reduction in smoking.[101] The study reported biologically confirmed cessation, using an intention-to-treat approach, of 13.0 percent and 3.6 percent in the peer supported versus usual care group ($p>0.05$). Early in participation both groups of pregnant smokers had one in-person smoking cessation session. In the intervention groups, the identified peer supporters were also invited to an in-person session and had monthly calls with a cessation counselor on the study staff. In the calls, the trained counselor assisted the peer

supporter in developing strategies to help the participant quit smoking. Those with a peer supporter reported greater perceived support for cessation, and trends suggested support was most effective from those who were ex-smokers and for those who selected a friend rather than a family member as their supporter. By 3 months postpartum all but 9.3 percent of the intervention group and the entire usual care group had returned to smoking.

The teen-specific program, Teen FreshStart (TFS), enrolled and randomly assigned 142 pregnant smokers to one of three groups: usual care, TFS—an 8-week group cognitive behavioral program, and TFS plus a peer supporter, called a "buddy."[85] The teens in the peer support arm were encouraged to bring a nonsmoking friend of similar age with them to participate in TFS. Cotinine confirmed cessation rates were comparable between TFS and TFS plus a buddy (p=0.21) and between TFS and usual care (p=0.16). The additional comparison between TFS with a buddy to usual care found that more than three times as many teens in the TFS with buddy group (OR= 3.7; 95% CI: 1.00 to 13.89) were quit after the 8-week program. However, given the lack of significant advantage of TFS with buddy to TFS alone, it would be spurious to conclude that the addition of the buddy is evidence of superiority to TFS alone. By one-year followup cessation among all three arms was comparable.

Table 16. Smoking cessation outcomes of peer support interventions

Author, Year Country Population Quality	Comparison Groups (number randomized/ analyzed)	Key Cessation Outcomes
Albrecht et al., 2006[85] U.S. Pregnant smokers Good	**G1:** Teen peer counseling with peer co-leader, group setting, individual support (47/47) **G2:** Teen peer counseling plus non-smoking buddy (45/45) **G3:** Usual care (50/50)	• After 8 weeks, cotinine confirmed cessation rates were comparable between G1 and G2 (p=0.21) and G1 and G3 (p=0.16). • More teens in G2 quit compared with G3 (p=0.01; OR=3.7; 95% CI: 1.0 to 13.9). • At 1-year followup there were no significant differences in cessation between the groups.
Malchodi et al., 2003[107] U.S. Pregnant smokers Good	**G1:** Peer counseling (67/67) **G2:** Usual care (75/75)	• Cessation was similar in groups G1 and G2 at 36 weeks' gestation (24% vs. 21%, p=0.84).
Hennrikus et al., 2010[101] U.S. Pregnant smokers Fair	**G1:** Support person received monthly contact from counselor (54/54) **G2:** Control- no further contact (28/28)	• No difference in cessation between groups at end of pregnancy (13% in G1 vs. 3.6% in G2, p=NS) or at 3 months postpartum (9.3% in G1 vs. 0% at G2, p=NR).
Solomon et al., 2000[109] U.S. Pregnant smokers Poor	**G1:** Telephone peer support plus cessation advice and printed materials (77/77) **G2:** Brief smoking cessation advice and materials (74/74)	• No significant difference in cessation at 28 to 34 weeks' gestation (18.2% in G1 vs. 14.9% in G2, p=NS).

Abbreviations: NR = not reported; NS = nonsignificant; U.S. = United States.

Other Interventions

Key Points

- Nine studies assessed other interventions: two of good quality, two of fair quality, and five of poor quality.

- Three studies assessed various forms of biologic feedback intended to motivate pregnant smokers to quit. Other studies evaluated facilitation of mother-infant bonding, modified delivery of self-help materials, financial incentives, counseling for depression, and clinic reinforcement.
- In one good-quality study of postpartum women who quit smoking during or prior to pregnancy, a higher proportion of participants who received an intervention to promote maternal-infant bonding remained abstinent at 8 weeks postpartum compared with participants who received usual care.
- A fair-quality study found cessation was higher at the end of pregnancy and 12 weeks postpartum in women who received financial vouchers for retail items contingent on their smoking status compared with women who received vouchers regardless of their smoking status. The different between groups was not sustained at 6 months postpartum. A poor-quality study found higher incidence of smoking abstinence at 12 weeks post-intervention in women who received contingent financial incentives compared with women who received non-contingent incentives or usual care.
- One poor-quality study reported higher cessation in women receiving brief, immediate guidance on self-help materials compared with women offered a 2-hour evening class.

Description of Included Studies

We identified nine studies evaluating various unique strategies to promote smoking cessation or continued abstinence among pregnant or postpartum women.[80, 83, 84, 100, 106, 118, 121, 124, 131] Seven of these studies were conducted in the United States,[80, 83, 84, 100, 106, 118, 121] one in Canada,[131] and one in the United Kingdom.[124] Seven studies focused on pregnant women who were current smokers,[83, 84, 100, 118, 121, 124, 131] while one study also included pregnant women who were recent quitters.[106] One study focused on relapse prevention among postpartum women who had quit smoking during pregnancy.[80] These studies, including eight traditional RCTs[80, 83, 84, 100, 118, 121, 124, 131] and one cluster-randomized trial,[106] had a total of 2056 participants at randomization (range 54 to 609) and participants at analysis (range 49 to 468). For overall quality, we assessed two studies as good,[80, 100] two as fair,[83, 84] and four as poor.[106, 118, 124, 131] Table 17 provides an overview of the good and fair quality studies, and Table 18 reports outcomes for all studies in this section.

Three RCTs explored various forms of biologic feedback intended to motivate pregnant smokers to quit.[83, 118, 124] Two studies examined financial incentives to promote smoking cessation.[84, 121]Four studies evaluated unique interventions for smoking cessation: facilitation of mother-infant bonding,[80] modified delivery of self-help materials,[131] counseling for depression,[100] and clinic reinforcement.[106]

Table 17. Overview of good and fair quality studies for other interventions

Study, Year Number Randomized Quality	Intervention	Components of Intervention Arm(s)	Time Point for Final Validated Cessation Measure	Population	Effect
Phillips et al., 2012[80] 54 Good	Enhanced support for maternal infant bonding vs. usual care	Counseling, information, partner/ household/ social context, personal followup, and other	Pregnancy: NA Postpartum: 8 weeks	Mothers with infants in NICU, not currently smoking; mean age 24, 68% White; majority Medicaid	More women in the intervention group (81%) remained abstinent compared with the women in the control group (46%)
Cinciripini et al., 2010[100] 266 Good	Cognitive behavioral analysis psychotherapy vs. health and wellness education	Counseling and other	Pregnancy: 3 and 6 months post treatment Postpartum: 3 and 6 months	Smokers, 37% DSM-IV criteria major depression, mean age 25,≤ 32 weeks' gestation, 54% African-American	No differences between groups at any time point
Stotts et al., 2009[83] 360 Fair	Ultrasound feedback plus motivational interviewing counseling vs. ultrasound feedback and best practice counseling (AHRQ guidelines) vs. best practice counseling	Counseling, feedback about biologic measures, and information	Pregnancy: 8th month Postpartum: NR	Smokers, age ≥ 16 years, 5th month pregnancy, 55% White, 37% African-American	No differences between groups
Heil et al., 2008[84] 82 Fair	Contingent vouchers vs. non-contingent vouchers	Counseling, incentives, information, and quit contract	Pregnancy: Postpartum: 12 weeks and 6 months	Smokers, mean gestation 9 weeks, > 90% White; 16% private insurance	Cessation higher for contingent vouchers at end of pregnancy and 12 weeks postpartum. (p=0.003) No difference at 6 months postpartum

Abbreviations: AHRQ = Agency for Healthcare Research and Quality; NA = not applicable; NR = not reported.

Detailed Synthesis

Feedback About Biologic Measures

Three RCTs evaluated approaches involving targeted biologic feedback to aid smoking cessation among pregnant smokers. One fair-quality RCT with 360 participants included three arms: a "best practices" standard cessation counseling arm, an arm adding ultrasound imaging with embedded risk counseling during imaging to the standard counseling, and a third arm pairing the ultrasound imaging with embedded risk messages with motivational interviewing.[83] Smoking cessation was comparable in the three groups (10.8% vs. 14.2% vs. 18.3%, respectively) during the eighth month of gestation (p=0.30). Followup analysis did not show any significant effects of group assignment at any time point in the study.

Providing point-of-care urine cotinine testing with visual and quantitative representation of results to pregnant participants was the focus of one poor-quality RCT.[124] Among 192 women followed to birth, 22 percent of women in the intervention group had quit smoking at birth as compared with 6.8 percent in the usual care group (test of statistical significance not reported).

Another poor-quality RCT comprising 170 participants assessed whether providing carbon monoxide testing results and counseling to pregnant smokers led to greater smoking cessation than counseling alone. Carbon monoxide results 6 weeks later among those who had been current smokers at time of intervention indicated that similar proportions of women remained current smokers in each group (76% in intervention arm, 77% in control arm).[118]

Facilitation of Mother-Infant Bonding

A good-quality RCT enrolled 54 postpartum nonsmoking women, with a history of tobacco use during or prior to pregnancy, from a neonatal intensive care unit to evaluate a strategy for prevention of smoking relapse.[80] The study compared continued smoking cessation rates among women randomized to receive educational materials (i.e., DVDs, books, and handouts) about newborn behavior and encouragement of frequent and prolonged skin-to-skin contact with their infants intended to facilitate mother-infant bonding as compared with women receiving usual care. This trial found a significant benefit for the enhanced bonding approach, observing an 81 percent continued cessation rate in the intervention group as compared with 46 percent in the comparison group ($p<0.001$) at 8 weeks postpartum.[80]

Delivery Method for Self-Help Material

A second delivery-focused RCT, assessed as poor quality, compared usual care to an intervention including personalized counseling and use of a quit guide ("Windsor's 7-Day Self-Help Quit Plan"[93]) among 224 pregnant smokers.[131] Women randomized to usual care were offered an evening class providing guidance on the self-help program, which authors described as the routine practice within the clinic. The experimental arm offered women the option of an in-clinic visit, including individual review of the self-help program and a followup call instead of the evening class. While none of the women in the usual care group attended an evening class, 93 percent of the women in the experimental group received the in-clinic intervention by the time of the second followup visit. Followup analysis revealed a significantly increased incidence of cessation in the intervention group as compared with usual care at one month post-intervention (14.9% vs. 5%, $p=0.02$) and at 6 weeks postpartum (13.8% vs. 5.2%, $p=0.04$).

Incentives

One fair-quality RCT explored the utility of financial incentives in improving smoking cessation rates among 82 pregnant smokers.[84] One group received vouchers redeemable for retail items ($15/visit antepartum, $20/visit postpartum) independent of current smoking status, and the other group received vouchers contingent on their current smoking status (starting point $6.25, increasing by $1.25 per consecutive negative test up to a maximum of $45). Biologically confirmed smoking cessation was significantly greater in women receiving the status-contingent vouchers as compared with those receiving noncontingent vouchers at the end of pregnancy (41% vs. 10%, $p=0.003$) and at 12 weeks postpartum (24% vs. 3%, $p=0.006$). However, cessation was similar in the two groups by 24 weeks postpartum.

A second RCT of poor quality compared the efficacy of a contingent incentive intervention with non-contingency management or treatment as usual among pregnant smokers attending a

university-based drug and alcohol treatment clinic for pregnant women.[121] The study included three groups: contingent incentives ($7.50 for meeting first reduction/abstinence target increased by $1.00/day for each consecutive target, up to maximum $41.50); non-contingent incentives (incentives based on previously determined schedule, independent of smoking status): and treatment as usual. At 12 weeks after starting the intervention, 31% of the contingent incentive group achieved the abstinence target (exhaled carbon monoxide <4 ppm) as compared with none of the women in the non-contingent and usual care groups. No test of statistical significance was reported.

Of note, although only two studies focused exclusively on incentives, the use of incentives was explored in other studies and is isolated as an effect in the meta-analysis of components in KQ4.

Treatment of Depression

A good-quality RCT including 266 pregnant smokers explored the utility of a depression-focused cognitive behavioral intervention. Women randomized to the intervention group received ten individualized sessions at a rate of one to two per week until birth, while the control group had a time- and attention-matched health education session.[100] Approximately three-quarters of enrolled women had a lifetime history of major depressive disorder, with about half in full or partial remission at time of study enrollment. Analysis of outcome data revealed no significant main effect of treatment group at any time point (3 and 6 months post treatment, 3 and 6 months postpartum) for any of the study's definitions for abstinence.

Clinic Reinforcement

A cluster-randomized trial assessed as poor quality, including six clinics and 609 patients, evaluated the use of a health-center based intervention as compared with usual care for smoking cessation among pregnant active smokers and pregnant women who had recently quit.[106] The intervention included provider training in delivery of a cessation intervention, an office practice management system which included reminders about screening and education with followup documentation, and a process for sharing documents among prenatal clinics. Analysis of outcome data indicated no significant effect on smoking status by group assignment.

Table 18. Smoking cessation outcomes of other interventions

Author, Year Country Population Quality	Comparison Groups (number randomized/analyzed)	Key Cessation Outcomes
Phillips et al., 2012[80] U.S. Postpartum women who had quit smoking Good	**G1:** Enhanced support for maternal-infant bonding plus weekly encouragement to remain smoke free and breast feeding support (24/21) **G2:** Weekly encouragement to remain smoke free and routine breast feeding support (30/28)	• At 8 weeks postpartum, 81% of women in G1 remained abstinent compared with 46% in G2 (p<0.001).

Table 18. Smoking cessation outcomes of other interventions (continued)

Author, Year Country Population Quality	Comparison Groups (number randomized/analyzed)	Key Cessation Outcomes
Cinciripini et al., 2010[100] U.S. Pregnant smokers Good	**G1:** Cognitive behavioral analysis system of psychotherapy (133/128) **G2:** Health and wellness education (133/129)	• No significant differences in cessation between groups at end of treatment, 3 and 6 months post treatment, and 3 and 6 months postpartum. • Cessation declined over time in both groups and at 6 months postpartum was 7.0% in G1 and 9.3% in G2.
Stotts et al., 2009[83] U.S. Pregnant smokers Fair	**G1:** Ultrasound feedback and motivational interviewing counseling (120/115) **G2:** Ultrasound feedback and best practice counseling per AHRQ guidelines (120/115) **G3:** Best practice counseling (120/114)	• No significant differences in cessation at the end of pregnancy between groups (18.3% in G1 vs. 14.2% in G2 vs. 10.8% in G3, p=0.30).
Heil et al., 2008[84] U.S. Pregnant smokers Fair	**G1:** Contingent vouchers (40/37) **G2:** Non-contingent vouchers (42/40)	• Cessation was higher for women receiving contingent vouchers (41% in G1 vs. 10% in G2, p=0.003) at end of pregnancy and at 12 weeks postpartum (24% in G1 vs. 3% in G2, p=0.006). • The difference was not sustained at 6 months postpartum (G1 8% vs. G2 3%, p=NS).
Pbert et al., 2004[106] U.S. Pregnant smokers and quitters Poor	**G1:** Provider training, office practice management system, coordination of document sharing among clinics (272/214) **G2:** Usual care (278/254)	• No significant effect on smoking status by group assignment.
Cope et al., 2003[124] U.K. Pregnant smokers Poor	**G1:** Feedback from point of care urine test, quit date and leaflet (164/109) **G2:** Usual care including anti-smoking counseling (116/83)	• At 36 weeks' gestation 22% in G1 had quit smoking compared with 6.8% in G2 (p=NR).
O'Connor et al., 1992[131] CAN Pregnant smokers Poor	**G1:** Counseling, quit guide, evening cessation class, individualized counseling session (115/94) **G2:** Usual care (109/96)	• Cessation higher in G1 than in G2 at 1 month post-intervention (14.9% vs. 5.0%, p=0.02) and 6 weeks postpartum (13.8% vs. 5.2%, p=0.04).
Bauman et al., 1983[118] U.S. Pregnant smokers Poor	**G1:** Scripted feedback on exhaled carbon monoxide level (NR/NR) **G2:** Script without exhaled carbon monoxide level provided (NR/NR) **G1+G2:** (226/170)	• No difference in smoking cessation at 6-week followup for subset of participants who were smokers at baseline (24% in G1 vs. 23% in G2).
Tuten et al., 2012[121] U.S. Pregnant smokers Poor	**G1:** Contingent behavioral incentive (42/42) **G2:** Non-contingent behavioral incentive (28/28) **G3:** Treatment as usual (32/32)	• At week 12, 31% in G1 had met the abstinence objective compared to 0% in G2 and G3.

Abbreviations: CAN = Canada; NR = not reported; NS = nonsignificant; U.K. = United Kingdom; U.S. = United States.

Multicomponent

Key Points

- Fourteen studies included multicomponent interventions: three of good quality, five of fair quality, and six of poor quality.
- Thirteen components of interventions (not including usual care) were used in various combinations in these studies. The most common components were counseling, quit guides, clinic reinforcement, peer support, and personal followup.
- Five of 12 studies focused on pregnant smokers reported statistically significant improvements in smoking cessation with a range of 5 to 23 percent difference between the intervention and control groups at the end of pregnancy. Two of these studies also had a significant difference at six to 12 weeks postpartum.
- One of four studies focused on pregnant women who had quit smoking was effective at the end of pregnancy with 65 percent cessation in the intervention participants and 53 percent in the control participants. There was no longer a significant difference at six months postpartum.
- One study focused on postpartum women was not effective for relapse prevention.
- The most common interventions in successful studies were also common in studies that failed to demonstrate effectiveness thus it is not possible to say which interventions are superior.

Description of Included Studies

We classified 14 studies in which a combination of components was implemented as an intervention without a clear primary component as multicomponent studies.[11, 39, 79, 88, 91-93, 98, 103, 110, 112, 127, 130, 133] Ten of these studies were conducted in the United States,[11, 39, 79, 91-93, 98, 103, 110, 112] two in Europe,[88, 133] and two in Australia.[127, 130] Thirteen studies evaluated interventions conducted during pregnancy, and one of these also included an intervention during postpartum hospitalization.[91] One study focused solely on a postpartum intervention.[79] Nine studies only enrolled current smokers,[39, 91-93, 98, 103, 110, 130, 133] two studies only enrolled recent quitters,[79, 112] and three studies enrolled both current smokers and recent quitters.[11, 88, 127] In these 14 studies, a total of 12,139 women were randomized (range 62 to 5572) and 11,868 were analyzed (range 62 to 5572). Smoking cessation outcomes are reported by twelve studies at the end of pregnancy,[11, 39, 88, 91-93, 103, 110, 112, 127, 130, 133] five studies at four to 12 weeks postpartum,[79, 98, 103, 110, 130] and two studies at six months postpartum.[88, 91] Of the 14 multicomponent intervention studies, three were of good quality,[88, 92, 130] five of fair quality,[39, 79, 91, 93, 110] and six of poor quality.[11, 98, 103, 112, 127, 133]

We used the descriptions in Table 4 to classify the components of the interventions in these studies, which are shown in Table 19. This was challenging at times because the level of detail in descriptions of interventions was not consistent across studies. In addition, specific components in individual studies varied. Therefore, the components are defined somewhat broadly to allow a variety of similar studies to be classified together. The most common intervention was counseling, which was included in all 14 studies. Ten studies included information,[11, 39, 79, 91, 93, 98, 112, 127, 130, 133] nine studies included quit guides,[39, 88, 91-93, 98, 103, 110, 130] seven studies included clinic reinforcement,[39, 88, 91, 92, 98, 112, 130] six studies included peer support,[39, 88, 110, 112, 127, 130] and five studies included personal followup.[39, 91, 92, 112, 130] Interventions found in two studies included NRT,[127, 133] incentives,[110, 130] feedback about biologic changes,[88, 92] prescription to quit,[91, 92] and stop smoking contract.[88, 127] One study addressed the smoking status of participants' significant

others,[127] and one study included a group smoking cessation program.[133] The number of interventions per study in the intervention arms ranged from two to seven with a mean of 4.0 interventions.

Table 19. Types of smoking cessation interventions in multicomponent studies

Author, Year Country Quality	Study Arm	Clinic Reinforcement	Counseling	Feedback	Groups	Incentives	Information	NRT	Partner/Household	Peer Support	Personal Followup	Prescription To Quit	Quit Contract	Quit Guide	Usual Care	Total Components
Hajek et al., 2001[88] U.K. Good	Intervention	●	●	●						●			●	●		6
	Control														●	1
Hartmann et al., 1996[92] U.S. Good	Intervention	●	●	●							●	●		●		6
	Control														●	1
Walsh et al., 1997[130] AUS Good	Intervention	●	▲			●	▲			●	●			●		7
	Control		▲				▲									2
Donatelle et al., 2000[110] U.S. Fair	Intervention		●			●	●			●				●		5
	Control		●				●							●		3
Gielen et al., 1997[91] U.S. Fair	Intervention	●	▲				●				●	●		●		6
	Control		▲				●									2
Suplee, 2005[79] U.S. Fair	Intervention		●				●									2
	Control														●	1
Windsor et al., 1993[39] U.S. Fair	Intervention	●	▲				●			●	●			●		6
	Control		▲				●									2
Windsor et al., 1985[93] U.S. Fair	Intervention 1		●				●							▲		3
	Intervention 2		●				●							▲		3
	Control		▲													1

Table 19. Types of smoking cessation interventions in multicomponent studies (continued)

Author, Year Country Quality	Study Arm	Clinic Reinforcement	Counseling	Feedback	Groups	Incentives	Information	NRT	Partner/Household	Peer Support	Personal Followup	Prescription To Quit	Quit Contract	Quit Guide	Usual Care	Total Compone
Bullock et al., 2009[103] U.S. Poor	Intervention 1		●											●		2
	Intervention 2		●													1
	Intervention 3													●		1
	Control						●									1
Eades et al., 2012[127] AUS Poor	Intervention		▲				●	●	●	●			●			6
	Control		▲													1
Hegaard et al., 2003[133] Denmark Poor	Intervention		▲		●		●	●								4
	Control		▲													1
Kendrick et al., 1995[11] U.S. Poor	Intervention		●				●									2
	Control														●	1
Lowe et al., 1997[112] U.S. Poor	Intervention	●	▲				●			●	●					5
	Control		▲													1
Windsor et al., 2011[98] U.S. Poor	Intervention	●	▲				●							●		4
	Control	●	▲													2

Abbreviations: AUS = Australia; U.K. = United Kingdom; U.S. = United States.
Note: Studies organized by quality (good, fair, poor) then alphabetical order.
[a] For interventions, ● indicates the intervention was the same for the different arms, and ▲ indicates the intervention varied for the different arms (e.g., control arm got brief counseling while intervention arm got longer counseling).

Detailed Synthesis

Table 20 provides an overview of the good and fair quality studies, and Table 21 reports outcomes for all studies in this section. The proportion of women with validated smoking cessation ranged from one to 65 percent at the end of pregnancy and from 3 to 37 percent postpartum.

Table 20. Overview of good and fair quality studies for multicomponent interventions

Study, Year Number Randomized Quality	Intervention	Components of Intervention Arm(s)	Time Point for Final Validated Cessation Measure	Population	Effect
Hajek et al., 2001[88c] 1120 Good	Midwife advice with carbon monoxide reading, written material, quit contract, support from another pregnant smoker, reinforcement at visits vs. usual care	Clinic reinforcement, counseling, feedback about biologic measures, peer support, quit contract, and quit guide	Pregnancy: Birth Postpartum: 6 months	Pregnant smokers and recent quitters, mean age 26.9-28.2	No difference for smokers Cessation significantly higher for recent quitters at end of pregnancy but no difference at 6 months postpartum
Walsh et al., 1997[130] 293 Good	Physician advice, videotape, midwife counseling, self-help manual, lottery, social support, and chart reminder vs. prestudy smoking advice	Clinic reinforcement, counseling, incentives, information, peer support, personal followup, and quit guide	Pregnancy: Visit closest to 34th week of gestation Postpartum: 6 to 12 weeks	Pregnant smokers at first prenatal visit	Cessation higher in the intervention group at end of pregnancy and 6 to 12 weeks postpartum (p=0.0353)
Hartmann et al., 1996[92] 207 Good	Counseling, smoking cessation manual, prescription to quit, and followup via mail and telephone vs. usual care	Clinic reinforcement, counseling, feedback about biologic measures, personal followup, prescription to quit, and quit guide	Pregnancy: Last prenatal visit	Pregnant smokers, mean age 24.8, mean of 14.6-14.7 weeks pregnant at first visit, 51% white and 46% black	No effect
Suplee, 2005[79] 62 Fair	Brief counseling session with educational materials vs. usual care	Counseling and information	Postpartum: 4 to 8 weeks	Postpartum women who had quit smoking during pregnancy, mean age 22.6, 81% African American	No effect
Donatelle et al., 2000[110] 220 Fair	Financial incentive vouchers for participant and support person, counseling, information, and quit guide vs. counseling, information, and quit guide	Counseling, incentives, information, peer support, and quit guide	Pregnancy: 8 months Postpartum: 2 months	Pregnant smokers, mean age 23.5 to 24.0, mean gestational age 16.4 to 16.6 weeks, 88% to 90% white, WIC eligible	Cessation higher in the intervention group at the end of pregnancy and 2 months postpartum (p<0.0001)

Table 20. Overview of good and fair quality studies for multicomponent interventions (continued)

Study, Year Number Randomized Quality	Intervention	Components of Intervention Arm(s)	Time Point for Final Validated Cessation Measure	Population	Effect
Gielen et al., 1997[91] 467 Fair	Quit guide, counseling session, education materials, clinic reinforcement including prescription to quit and written letters or encouragement, and routine clinic advice vs. routine clinic advice	Clinic reinforcement, counseling, information, personal followup, prescription to quit, and quit guide	Pregnancy: Third trimester	Pregnant smokers, mean age 23.3 to 24.1, mean gestational age at enrollment 4.1 to 4.2 months, 85% African American	No effect
Windsor et al., 1993[39] 814 Fair	Counseling, quite guide, clinic reinforcement, social support vs. advice and pamphlets	Clinic reinforcement, counseling, information, peer support, personal followup, and quit guide	Pregnancy: After 32nd week of gestation	Pregnant smokers, mean age 24.6, mean gestational age at entry 4.0 months, 52% black	Cessation higher in the intervention group at the end of pregnancy (p=0.01)
Windsor et al., 1985[93] 309 Fair	American Lung Association quit manual, counseling, and education booklet vs. Windsor quit manual, counseling, and education booklet vs. standard cessation advice	Counseling, information, and quit guide	Pregnancy: Last month of gestation or within 48 hours of birth	Pregnant smokers, mean age 23.6, mean gestational age at entry 3.7 months, 57% black	Cessation higher in the intervention (Windsor guide) group at the end of pregnancy compared with the usual care group (RR=0.12, 95% CI: 0.05 to 0.19)

Abbreviations: AUS = Australia; CI = confidence interval; NS = not significant; OR = odds ratio; RR = risk ratio; UK = United Kingdom; U.S. = United States.

Pregnant Women

Smoking Cessation

Twelve multicomponent intervention studies focused on pregnant women who were current smokers: nine only enrolled current smokers,[39, 91-93, 98, 103, 110, 130, 133] and three enrolled both current smokers and recent quitters.[11, 88, 127] All of these studies assessed interventions implemented during pregnancy. One study also included a postpartum intervention in which participants received additional counseling along with a quit or relapse prevention guide (depending on smoking status) during their postpartum hospitalization.[91] Table 19 identifies the specific components of interventions performed in each study. Eleven studies report outcomes at the end of pregnancy (more than 28 weeks' gestation through birth),[11, 39, 88, 91-93, 103, 110, 127, 130, 133] and six studies report postpartum outcomes.[88, 91, 98, 103, 110, 130]

One good-quality RCT enrolled 293 women receiving care at an urban teaching hospital's antenatal clinic in Australia.[130] Women in the experimental group received advice from a physician and counseling from a midwife, watched a smoking cessation videotape, were given a

quit guide, were offered entry into a lottery with a monetary award if they stopped smoking, had the opportunity to identify a support person who was given educational materials to assist with smoking cessation, had a sticker placed in their medical record, and were sent a letter from the midwife they saw at the first visit.[130] Women in the control group received standard stop smoking advice from a physician and midwife and were give a package of anti-smoking materials. Smoking cessation validated by urine cotinine was significantly higher in the experimental group than the control group at the end of pregnancy (13% vs. 7%, p=0.0353) and at 6 to 12 weeks postpartum (10% vs. 1%, p=0.0011). The other two good-quality RCTs did not demonstrate benefit. One was a study of 250 patients at a resident obstetric clinic in North Carolina,[92] and the other included 1120 women receiving care at hospital and community trusts in the United Kingdom where the midwives had been randomized to provide intervention or usual care.[88] There was significant overlap in the interventions across the good-quality studies: all three included clinic reinforcement, counseling, and a quit guide, and two out of three included feedback about biologic measures, peer support, and personal followup.

Three of the four fair-quality RCTs demonstrated effectiveness. Two of these studies were conducted in the same public health clinics in Birmingham, Alabama.[39, 93] The intervention in both studies included similar counseling with a quit guide. In addition, intervention participants in the second study had a reminder form placed in their medical record, received a followup letter and quarterly newsletter, and were given buddy materials (letter, contract, and tip sheet).[39] All of the study participants received informational pamphlets and brief advice about smoking cessation during a group prenatal education class. The first study had 309 participants with two intervention groups that received different quit guides, and one intervention group had 14 percent cessation confirmed with saliva thiocyanate compared with 2 percent in the control group at the end of pregnancy (12% difference, 95% CI: 0.05 to 0.19).[93] Findings for the other intervention group (with a different quit guide) were not significant. The quit guide that was successful in the first study was used in the second study of 994 participants, which had 14.3 percent saliva cotinine confirmed cessation in the intervention group and 8.5 percent in the control group at the end of pregnancy (p=0.01).[39] Interestingly, the addition of clinic reinforcement, personal followup, and peer support interventions in the second study did not lead to higher cessation than was found in the first study which did not include these interventions. Also notable is the fact that two later studies with similar designs, a fair-quality trial with 467 participants conducted in Baltimore, Maryland[91] and a poor-quality trial with 1093 participants across several Alabama counties,[98] did not demonstrate effectiveness. The authors of the Baltimore study[91] propose the lack of effectiveness compared with earlier studies[39, 93] may be due to differences in the populations in Birmingham and Baltimore or the fact that they used a peer counselor while the Birmingham studies used a professional counselor. The authors of the Alabama study[98] believe their results may be explained by exposure of a significant proportion of the control group to the intervention methods.

The third fair-quality study that was effective enrolled 220 women attending WIC clinics in Oregon.[110] All participants received verbal and written information about smoking cessation along with a quit guide. In addition, the intervention group participants identified a social supporter who was preferably a female non-smoker with whom they had regular contact. Both the participant and her social supporter were eligible for financial vouchers for each month of smoking cessation. Cessation confirmed with saliva thiocyanate was higher in the intervention group than the control group at both the end of pregnancy (32% vs. 9%, p<0.0001) and two months postpartum (21% vs. 6%, p<0.0009).

Among the five poor-quality studies focused on current smokers,[11, 98, 103, 127, 133] one trial found a significant difference in cessation between the intervention and control groups (7.0% vs. 2.2% respectively, p=0.004).[133] Interventions in this study of 695 women receiving midwifery care in Denmark included individual and group counseling, written information about the risks of smoking, and NRT.[133]

Relapse Prevention

Four multicomponent intervention studies focused on pregnant women who were recent quitters: one enrolled only pregnant women who had recently quit smoking,[112] and three enrolled both current smokers and recent quitters.[11, 88, 127] (Table 21) identifies the specific categories of interventions performed in each study. Four studies report outcomes at the end of pregnancy (more than 28 weeks' gestation through birth),[11, 88, 112, 127] and two studies report postpartum outcomes.[88, 112]

In the good-quality study, midwives at nine hospital and community trusts in the United Kingdom were randomized to provide intervention or routine care to 1120 women.[88] Participants in the intervention group received midwife counseling that included information about their carbon monoxide reading, a quit guide, a quit contract, pairing with another pregnant smoker for peer support, and clinic reinforcement via notes in their medical charts to encourage cessation at followup visits. At the end of pregnancy, cessation was 65 percent in the intervention group and 53 percent in the control group (p<0.05). There was no longer a significant difference between the groups at six months postpartum. This study also enrolled current smokers, and the findings for those participants were not significant. None of the three poor-quality studies of recent quitters demonstrated effectiveness.

Postpartum Women

Relapse Prevention

One fair-quality, U. S., multicomponent intervention study evaluated a counseling intervention with educational materials conducted during postpartum hospitalization of 62 women.[79] At 4 to 8 weeks postpartum, 37 percent of women in the intervention had biochemically validated cessation compared with 25 percent of the control group (p=0.319).

Table 21. Smoking cessation outcomes of multicomponent interventions

Author, Year Country Population Quality	Comparison Groups (number randomized/analyzed)	Key Cessation Outcomes
Hajek et al., 2001[88] U.K. Good	**G1:** Clinic reinforcement, counseling, feedback about biologic measures, peer support, quit contract, quit guide (431 smokers and 114 quitters/431 and 114) **G2:** Usual care (440 smokers and 135 quitters/440 and 135)	• For current smokers, no significant differences at birth (11% in G1 vs. 10% in G2) or 6 months postpartum (3% in G1 and G2). • For recent quitters, abstinence was 65% in G1 and 53% in G2 at birth (p<0.05) and 23% in G1 and 25% in G2 at 6 months postpartum (p=NS).
Walsh et al., 1997[130] AUS Pregnant smokers Good	**G1:** Clinic reinforcement, counseling, incentives, information, peer support, personal followup, quit guide (148/127) **G2:** Counseling and information that were different than G1 (145/125)	• Cessation higher in G1 than G2 at 34 weeks' gestation (13% vs. 6%, p=0.0353) and 6 to 12 weeks postpartum (10% vs. 1%, p=0.0011).

Table 21. Smoking cessation outcomes of multicomponent interventions (continued)

Author, Year Country Population Quality	Comparison Groups (number randomized/analyzed)	Key Cessation Outcomes
Hartmann et al., 1996[92] U.S. Pregnant smokers Good	**G1:** Clinic reinforcement, counseling, feedback about biologic measures, personal followup, prescription to quit, quit guide (107/107) **G2:** Usual care (100/100)	• No significant difference in cessation at last prenatal visit (20% in G1 vs. 10% in G2, p=0.052, OR=2.20, 95% CI: 0.98 to 4.94).
Suplee, 2005[79] U.S. Fair	**G1:** Counseling, information (30/30) **G2:** Usual care (32/32)	• No significant difference in cessation at 4 to 8 weeks postpartum (37% in G1 vs. 25% in G2, p=0.319).
Donatelle et al., 2000[110] U.S. Fair	**G1:** Counseling, incentives, information, peer support, quit guide (112/105 end of pregnancy/103 postpartum) **G2:** Counseling, information, quit guide (108/102)	• Cessation higher in G1 than G2 at 8 months gestation (32% vs. 9%, p<0.0001) and 2 months postpartum (21% vs. 6%, p<0.0009).
Gielen et al., 1997[91] U.S. Fair	**G1:** Clinic reinforcement, counseling, information, personal followup, prescription to quit, quit guide (232/193) **G2:** Counseling that was different than G1, information (235/198)	• No significant difference in cessation in third trimester (6.2% G1 vs. 5.6% G2).
Windsor et al., 1993[39] U.S. Fair	**G1:** Clinic reinforcement, counseling, information, peer support, personal followup, quit guide (400/400) **G2:** Counseling that was different than G1, information (414/414)	• At end of pregnancy, cessation was higher in G1 than G2 (14.3% vs. 8.5%, p=0.01).
Windsor et al., 1985[93] U.S. Fair	**G1:** Counseling, information, ALA quit guide (103/103) **G2:** Counseling, information, Windsor quit guide (102/102) **G3:** Counseling different than G1 and G2 (104/104)	• At the end of pregnancy, cessation was 6% in G1, 14% in G2, and 2% in G3 (12% difference between G1 and G3, 95% CI: 0.05 to 0.19).
Eades et al., 2012[127] AUS Poor	**G1:** Counseling, information, NRT, partner/household/social context, peer support, quit contract (124 smokers and 24 quitters/124 and 24) **G2:** Counseling that was different than G1 (107 smokers and 8 quitters/107 and 8)	• For current smokers, no significant difference in cessation at end of pregnancy (1% in G1 vs. 2% in G2; p=0.965; RR 1.01; 95% CI: 0.98 to 1.04). • For recent quitters, no significant difference in cessation at end of pregnancy (42% intervention, 25% control (p=0.39[a]).
Windsor et al., 2011[98] U.S. Poor	**G1:** Clinic reinforcement, counseling, information, quit guide (547/547) **G2:** Clinic reinforcement, counseling that was different than G1 (546/546)	• No significant difference in cessation at ≤ 90 days postpartum (12% in G1 vs. 10% in G2, p=0.31).
Bullock et al., 2009[103] U.S. Poor	**G1:** Counseling, quit guide (170/129) **G2:** Counseling (175/132) **G3:** Quit guide (179/141) **G4:** Information (171/128)	• No significant differences in cessation at end of pregnancy (17.0% G1 vs. 22.0% G2 vs. 19.2% G3 vs.17.2% G4, p=0.72) or 6 weeks postpartum (12.4% G1, 11.4% G2, 13.5% G3, 13.3% G4, p=0.71).
Hegaard et al., 2003[133] Denmark Poor	**G1:** Counseling, groups, information, NRT (327/327) **G2:** Counseling that was different than G1 (320/320)	• Cessation in 37th week of gestation was higher in G1 than G2 (7.0% vs. 2.2%, p=0.004).

Table 21. Smoking cessation outcomes of multicomponent interventions (continued)

Author, Year Country Population Quality	Comparison Groups (number randomized/analyzed)	Key Cessation Outcomes
Kendrick et al., 1995[11a] U.S. Poor	**G1:** Counseling, information (3064/888) **G2:** Usual care (2508/1177)	• Results for current smokers and recent quitters reported together. • No significant difference in cessation at end of pregnancy (6.1% in G1, 5.9% in G2, OR=1.0, 95% CI: 0.69 to 1.6).
Lowe et al., 1997[112] U.S. Poor	**G1:** Clinic reinforcement, counseling, information, peer support, personal followup (52/52) **G2:** Counseling that was different than G1 (45/45)	• No significant difference in cessation at end of pregnancy (29% in G1 vs. 44% in G2, p=0.1).

Abbreviations: AUS = Australia; mos. = months; NR = not reported; NS = nonsignificant; U.S. = United States; wks. = weeks**.**

[a] Calculated by the systematic review team using a 2-sided test of proportions.

Key Question 2: Intervention Effects on Infant Outcomes

Key Points

- Only 13 out of the 56 RCTs in our review included infant outcomes, and no studies included child outcomes.
- Thirteen studies reported mean birth weight and had inconsistent findings; three of these studies had results that were statistically significant but not clinically meaningful.
- Seven studies reported gestational age and had inconsistent findings. Only one of these studies had results that were statistically significant with women who received NRT in addition to CBT giving birth an average of one week later than women who received CBT only.
- Seven studies that reported preterm birth found a lower incidence in the intervention group compared to the control group; however, this was not statistically significant in any of these studies. One study did not find any difference in incidence of preterm birth.
- Neonatal deaths were only reported in two studies with no significant difference between intervention and control groups.
- All six studies that reported NICU admissions found a lower incidence in the intervention group compared to the control group; however, this was not statistically significant in any of these studies.

Description of Included Studies

In our pool of included studies, we identified 13 that reported infant outcomes associated with smoking cessation and/or relapse prevention interventions among pregnant women.[84, 102, 104, 105, 117, 120-122, 124, 129, 132-134] Infant outcomes from one of these studies[117] were presented in a separate publication.[139] Eight of these studies were conducted in the United States,[84, 102, 104, 105, 117, 120, 121, 133, 139] three in the United Kingdom,[122, 124, 132] and one study each in Sweden[134] and Australia.[129] The interventions represented include three counseling studies,[105, 129, 132] two assessments of educational materials,[117, 134, 139] four studies of NRT,[102, 104, 120, 122] two studies of incentives,[84, 121] and one study each of a multicomponent intervention,[133] and point-of-care

nicotine testing.[124] One study was good quality,[122] three were of fair quality,[84, 102, 139] and nine of poor quality.[104, 105, 120, 121, 124, 129, 132-134] All studies focused on infant outcomes during the immediate postpartum period; none of the studies included infant outcomes after hospital discharge or further followup of any child-related outcomes.

Detailed Synthesis

Birth Weight

All 13 studies reported mean birth weight outcomes. In a poor-quality Australian study that compared midwife-provided counseling to usual care in pregnant smokers and had outcomes for 728 infants, mean birth weight was higher among infants born to women in the intervention group compared to the control group, (3250 grams vs. 3166 grams, p=0.04) but the difference was reduced to 29 grams (p=0.41) when preterm births were excluded.[129] In a fair-quality multicenter U.S. study that randomized 194 pregnant smokers to receive behavioral counseling plus either nicotine gum or placebo gum, the newborns from the intervention group had a statistically significant higher birth weight than the newborns from the control group (3287 grams vs. 2950 grams, p<0.001).[102] In a poor-quality UK study that assessed the effect of feedback to women about a point-of-care nicotine test, investigators reported a significant difference in birth weight between the intervention and control groups after adjusting for nicotine metabolites (3.26 kg vs. 3.08 kg, p<0.03).[124] While these three studies had statistically significant findings, these differences in birth weight between intervention and control groups are not clinically meaningful. Among the ten studies that did not show a statistically significant between-group difference in birth weight, six reported higher mean birth weight in the intervention group[84, 120, 121, 132, 134, 139] and four reported higher mean birth weight in the control group.[104, 105, 122, 133]

Seven studies reported the proportion of births that were low birth weight (less than 2500 grams).[84, 105, 120, 121, 133, 134, 139] Two were of fair quality,[84, 139] and five of poor quality.[105, 120, 121, 133, 134] None of these studies found statistically significant differences in the incidence of low birth weight between the intervention and control groups.

Gestational Age

Seven studies reported outcomes related to gestational age including one good quality,[122] two of fair quality,[84, 102] and three of poor quality.[104, 120, 121, 132] The primary component of the intervention was counseling in one study,[132] NRT in four studies,[102, 104, 120, 122] and a unique incentive strategy in one study.[84] In a good-quality RCT conducted in the United States that randomized 52 pregnant smokers to either nicotine patches and CBT or to CBT alone, women in the intervention group gave birth at a higher gestational age as compared with their control counterparts (39.4 vs. 38.4 weeks, p=0.02).[120] The other five studies did not show a statistically significant between-group difference in gestational age, which was higher in the intervention group in two studies,[84, 102] higher in the control group in two studies,[104, 132] and equivalent in the intervention and control groups in two studies.[121, 122]

Preterm Birth

Seven studies reported preterm birth outcomes including one of good quality,[122] two of fair quality,[84, 139] and four of poor quality.[120, 129, 132, 134] The primary component of the intervention was counseling in two studies,[129, 132] educational materials in two studies,[134, 139] NRT in two

studies,[120, 122] and a unique incentive strategy in one study.[84] None of the studies had statistically significant findings, but all of the studies found a lower incidence of preterm birth in the intervention group compared to the control group.

Neonatal Death

Two studies[122, 132] reported neonatal death outcomes that were not statistically significant. In a poor-quality RCT that evaluated a counseling intervention, there was one preterm neonatal death in each group (intervention n=351, control n=411).[132] A multicenter UK study of good quality comparing the effectiveness of nicotine patch therapy to placebo for smoking cessation had no neonatal deaths in the intervention group (n=507) and two neonatal deaths in the control group (n=517).[122]

NICU Admission

Six studies reported NICU admission outcomes including one of good quality,[122] two of fair quality,[84, 139] and three of poor quality.[105, 121, 132] The primary component of the intervention was counseling in two studies,[105, 132] educational materials in one study,[139] NRT in one study,[122] and an incentive strategy in two studies.[84, 121] None of the studies had statistically significant findings, but all of the studies found a lower incidence of NICU admissions in the intervention group compared to the control group.

Key Question 3: Intervention Harms for Pregnant and Postpartum Women

Key Points

- Four out of the 56 RCTs in our review reported harms or adverse events associated with smoking cessation interventions. None of the included prospective cohort studies assessed harms of cessation interventions.
- One educational materials study assessed the effect of the cessation intervention on women's stress levels and did not find a difference in mean stress scores between groups.
- Three RCTs did not find adverse events or harms increased with NRT interventions in pregnant smokers. Caution is warranted in interpreting these results, given the low numbers of participants and the low adherence rates.

Description of Included Studies

In our pool of included studies, we identified four RCTs that reported harms or adverse events associated with smoking cessation interventions.[102, 104, 122, 125] Two of these studies were conducted in the United States,[102, 104]and two in the United Kingdom.[122, 125] The interventions included three studies of NRT[102, 104, 122] and one of educational materials.[125] None of the prospective cohort studies included in our review assessed harms of smoking cessation interventions.

Detailed Synthesis

Educational Materials

A poor-quality cluster RCT conducted in the United Kingdom and described in the educational materials interventions addressed KQ3. This study evaluated stage of change-based quit guides and a tailored, interactive computer program focused on cessation.[125] In addition to assessing smoking cessation at 30 weeks' gestation and at 10 days postpartum, investigators assessed the effect of the cessation intervention on women's stress levels using the Perceived Stress Scale.[137] Women completed the questionnaire between 12 and 20 weeks' gestation, between 23 and 25 weeks' gestation, between 28 and 30 weeks' gestation, and at 10 days postpartum. Mean stress scores did not differ between groups at baseline or at 30 weeks' gestation (mean 1.6 ± 0.8 at both time points), but they increased slightly within each group. Mean scores fell slightly in all arms after birth.

NRT

Three RCTs of NRT interventions in pregnant smokers included reporting of adverse events or harms. A good-quality study enrolled 1050 pregnant smokers, between 12 and 24 weeks' gestation, at hospital settings in England.[122] The intervention group was assigned to 8 weeks of treatment with nicotine patches (15 mg per 16 hours) and behavioral support. The control group received a placebo patch and behavioral support. The incidence of adverse pregnancy and birth outcomes was similar in the two groups; raw data were provided without statistics.

A fair-quality U.S. study enrolled 194 pregnant smokers (less than 26 weeks' gestation).[102] Women in the intervention group received 6 weeks of 2 milligram nicotine gum and behavioral counseling, while women in the control group received a placebo gum and behavioral counseling. There was no significant difference between the groups in specific adverse events, nor composite adverse effects (maternal hospitalization, low birth weight, preterm birth, spontaneous abortion, intrauterine fetal death, newborn death, NICU admission).

A poor-quality U.S. study enrolled 181 pregnant smokers (13 to 25 weeks' gestation).[104] Women in the control group received CBT. Women in the intervention group received CBT and patient-preference open-label selection of nicotine patch, nicotine gum, or nicotine lozenge with the dosage adjusted by prior smoking level. This trial was halted for a two-fold difference in serious adverse events between arms, but the Data Safety and Monitoring Board stated they did not believe the difference was related to NRT use. Adverse events, from most to least frequent, included preterm birth (less than 37 weeks), NICU admissions, small-for-gestational age, placental abruption, and fetal demise. Adverse events occurred in 30 percent (34/113) of the women in the intervention arm compared with 17 percent (10/58) of women in the control arm ($p=0.07$). After adjusting for previous preterm birth, the proportion of women with adverse events decreased to 27 percent in the intervention arm and 18 percent in the control arm ($p=0.26$).

Key Question 4: Effectiveness of Intervention Components

Key Points

- In 24 good and fair quality RCTs of smoking cessation interventions, the most common components of the interventions were counseling, information, quit guides, personal followup, and clinic reinforcement.
- A meta-analysis of the study components in 23 smoking cessation RCTs found that the use of incentives was most strongly associated with substantially increased smoking cessation.
- The other components likely to have a positive effect were feedback about biologic measures, NRT, information, personal followup, and quit guides.
- In the six good and fair quality RCTs of relapse prevention interventions, the most common components of the interventions were counseling, quit guides, information, and personal followup. These studies were too heterogeneous to conduct an analysis to assess the effect of the components.
- Data were not available to specifically assess the impact of provider or care site for this Key Question.

Description of Included Studies

Twenty-eight good and fair quality RCTs were available for this Key Question. Three studies targeted postpartum women,[79, 80, 82] and the rest enrolled pregnant women. Twenty-two focused on current smokers,[39, 83-87, 89-93, 97, 100-102, 107, 110, 117, 119, 122, 123, 130] four focused on recent quitters,[79, 80, 82, 94] and two included both smokers and quitters.[88, 126] We did not find any cohort studies that had appropriate information for inclusion in the meta-analysis, which is the basis for this Key Question.

Detailed Synthesis

The included RCTs had multiple components of the intervention itself, and some studies used the same component in both the intervention and control arms. We classified the components of the intervention and control arms for each study in this section according to the descriptions in Table 4. These studies are grouped below by those that focused on smoking cessation versus relapse prevention. Data were not available to specifically assess the impact of provider or care site for this Key Question

Smoking Cessation

Twenty-four studies assessed smoking cessation interventions: 11 of good quality[85, 87, 88, 92, 97, 100, 107, 122, 123, 126, 130] and 13 of fair quality.[39, 83, 84, 86, 89-91, 93, 101, 102, 110, 117, 119] Two of these studies also included recent quitters.[88, 126] All 24 studies evaluated prenatal interventions, and one study also included an intervention during postpartum hospitalization.[91]

Table 22 presents an overview of the components used in these studies. The components were counseling in 21 studies;[39, 83, 84, 86-93, 100-102, 107, 110, 117, 119, 122, 126, 130] quit guides in 14 studies;[39, 84, 88-93, 107, 110, 117, 122, #18, 126, 130] information in 13 studies;[39, 83, 84, 86, 87, 91, 93, 97, 102, 110, 117, 119, 130] personal followup in 12 studies;[39, 83, 86, 87, 89, 91, 92, 102, 119, 122, 123, 130] clinic reinforcement in 10 studies;[39, 83, 86-88, 90-92, 102, 107, 130] peer support in seven studies;[39, 85, 88, 101, 107, 110, 130] feedback about biologic measures in five studies;[83, 88, 90, 92, 97] incentives in four studies;[84, 97, 110, 130] NRT in

two studies;[84, 102, 122] quit contracts in three studies;[84, 88, 122] other unique interventions, including counseling for depression,[100] a computerized interactive telephone support system,[89] and an interactive computer delivered intervention,[97] in three studies; prescriptions to quit in two studies;[91, 92] and groups in one study.[85] No studies included a partner/household/social context component.

Table 22. Smoking cessation intervention components from studies of current smokers[a]

Author, Year Quality	Study Arm	Clinic Reinforcement	Counseling	Feedback	Groups	Incentives	Information	NRT	Partner/Household	Peer Support	Personal Followup	Prescription To Quit	Quit Contract	Quit Guide	Usual Care	Other	Total Components	Description of Other
Coleman et al., 2012[122] Good	Intervention		●					●			●		●	●			5	
	Control		●								●		●	●			4	
Naughton et al., 2012[123] Good	Intervention										●			▲			2	
	Control													▲			1	
Ondersma et al., 2012[97] Good	Intervention 1						●									●	2	Interactive computer-delivered smoking cessation intervention
	Intervention 2			●		●											2	
	Intervention 3			●		●	●									●	4	Interactive computer-delivered smoking cessation intervention
	Control														●	▲	1	Interactive computer program (not smoking related)
Cinciripini et al., 2010[100] Good	Intervention		●													▲	2	Cognitive behavioral analysis system of psychotherapy
	Control		●													▲	2	Health and wellness education
Albrecht et al., 2006[85] Good	Intervention 1				●												1	
	Intervention 2				●					●							2	
	Control		●				●										2	
Rigotti et al., 2006[87] Good	Intervention	●	▲				▲				●						4	
	Control	●	▲				▲										3	

Author, Year Quality	Study Arm	Clinic Reinforcement	Counseling	Feedback	Groups	Incentives	Information	NRT	Partner/Household	Peer Support	Personal Followup	Prescription To Quit	Quit Contract	Quit Guide	Usual Care	Other	Total Components	Description of Other
Malchodi et al., 2003[107] Good	Intervention	●	●							●				●			4	
	Control	●	●											●			3	
Moore et al., 2002[126b] Good	Intervention		●											●			2	
	Control														●		1	

Table 22. Smoking cessation intervention components from studies of current smokers[a] (continued)

Author, Year Quality	Study Arm	Clinic Reinforcement	Counseling	Feedback	Groups	Incentives	Information	NRT	Partner/Household	Peer Support	Personal Followup	Prescription To Quit	Quit Contract	Quit Guide	Usual Care	Other	Total Components	Description of Other
Hajek et al., 2001[88b] Good	Intervention	●	●	●						●			●	●			6	
	Control														●		1	
Walsh et al., 1997[130] Good	Intervention	●	▲			●	▲			●	●			●			7	
	Control		▲				▲										2	
Hartmann et al., 1996[92] Good	Intervention	●	●	●							●	●		●			6	
	Control														●		1	
Hennrikus et al., 2010[101] Fair	Intervention		●							●							2	
	Control		●														1	
Stotts et al., 2009[83] Fair	Intervention 1		●	●			●										3	
	Intervention 2		▲	●							●						3	
	Control		●				●										2	
Heil et al., 2008[84] Fair	Intervention		●			●	●						●				4	
	Control		●				●						●				3	
Oncken et al., 2008[102] Fair	Intervention	●	●				●	●			●						5	
	Control	●	●				●				●						4	
Dornelas et al., 2006[86] Fair	Intervention	●	▲				●				●						4	
	Control	●	▲				●										3	
Donatelle et al., 2000[110] Fair	Intervention		●			●	●			●				●			5	
	Control		●				●							●			3	
Ershoff et al., 1999[89] Fair	Intervention 1													●		●	2	Computerized interactive telephone support system
	Intervention 2		●								●			●			3	
	Control													●			1	
Secker-Walker et al., 1998[90] Fair	Intervention	●	▲	●													3	
	Control		▲				●							●			3	

Table 22. Smoking cessation intervention components from studies of current smokers[a] (continued)

Author, Year Quality	Study Arm	Clinic Reinforcement	Counseling	Feedback	Groups	Incentives	Information	NRT	Partner/Household	Peer Support	Personal Followup	Prescription To Quit	Quit Contract	Quit Guide	Usual Care	Other	Total Components	Description of Other
Gielen et al., 1997[91] Fair	Intervention	●	▲				●				●	●		●			6	
	Control		▲				●										2	
Windsor et al., 1993[39] Fair	Intervention	●	▲				●			●	●			●			6	
	Control		▲				●										2	
Burling et al., 1991[119] Fair	Intervention		●				●				●						3	
	Control		●														1	
Ershoff et al., 1989[117] Fair	Intervention		●				●							●			3	
	Control		●				●										1	
Windsor et al., 1985[93] Fair	Intervention 1		●				●							▲			3	
	Intervention 2		●				●							▲			3	
	Control		▲														1	

[a] Includes good and fair quality studies only; ● indicates the intervention was the same for the different arms; ▲ indicates the intervention varied for the different arms (e.g., control arm got brief counseling while intervention arm got longer counseling); studies organized by quality then chronologically, then alphabetically by first author.
[b] Study also enrolled recent quitters.

We were able to combine 23 of these studies into a robust random effects meta-analysis to quantify the relative impact of components of the interventions on smoking cessation. One study[126] was excluded because outcomes for smoking cessation and relapse prevention were reported together and could not be calculated separately. Nine components were evaluated individually: clinic reinforcement, feedback, incentives, information, NRT, peer support, personal followup, prescription to quit, quit guides and other, which combined relatively rarer components, such as groups and quit contracts. Counseling was ubiquitous in both intervention and control arms of the studies; thus it could not be assessed as a driver of effect. Rather, counseling studies are described qualitatively in the report. The model used was a logistic mixed effects model that estimated quit rates across studies. Table 23 presents the findings of the model.

Table 23. Relative impact of intervention components on smoking cessation

Component	OR	SD	Lower Bound	Upper Bound	Posterior Probability OR >Null
Incentives	3.23	0.69	1.98	4.59	100%
Feedback	1.43	0.30	0.88	2.03	95%
Information	1.32	0.24	0.88	1.79	93%
Personal Followup	1.25	0.16	0.94	1.57	95%
NRT	1.24	0.22	0.84	1.68	87%
Quit Guide	1.18	0.19	0.82	1.56	83%
Prescription to Quit	1.13	0.42	0.46	1.95	57%
Peer Support	1.07	0.20	0.70	1.46	60%
Clinic Reinforcement	1.05	0.22	0.65	1.49	55%

Abbreviations: OR = odds ratio; NRT = nicotine replacement therapy; SD = standard deviation.

Relapse Prevention

Six studies assessed interventions to prevent relapse in women who had recently quit smoking: four of good quality[80, 82, 88, 126] and two of fair quality.[79, 94] Two of these studies also included current smokers.[88, 126] Three studies evaluated prenatal interventions,[88, 94, 126] and three studies evaluated postpartum interventions.[79, 80, 82]

Table 24 presents an overview of the components in these studies. The components were counseling in all six studies, quit guides in four studies,[82, 88, 94, 126] information in three studies,[79, 80, 94] and personal followup in two studies.[80, 82] Clinic reinforcement,[88] feedback about biologic measures,[88] information,[79] partner/household/social context,[80] peer support,[88] a quit contract,[88] and a unique mother-infant bonding intervention[80] were each used in one study. No studies included group, incentive, NRT, or prescription to quit components. These studies were too heterogeneous to conduct an analysis to assess the effect of the components; there was not a sufficient number of studies with the same components.

Table 24. Relapse prevention intervention components from studies of recent quitters[a]

Author, Year Quality	Study Arm	Clinic Reinforcement	Counseling	Feedback	Groups	Incentives	Information	NRT	Partner/Household	Peer Support	Personal Followup	Prescription to Quit	Quit Contract	Quit Guide	Usual Care	Other	Total Interventions	Other Description
Phillips et al., 2012[80] Good	Intervention		●				●		●		●					●	5	Enhanced support in bonding with newborn
	Control		●				●		●		●						4	
Moore et al., 2002[126b] Good	Intervention		●											●			2	
	Control														●		1	
Hajek et al., 2001[88b] Good	Intervention	●	●	●						●			●	●			6	
	Control														●		1	
Johnson et al., 2000[82] Good	Intervention		●								●			●			2	
	Control														●		1	
Suplee, 2005[79] Fair	Intervention		●				●										2	
	Control														●		1	
Ershoff et al., 1995[94] Fair	Intervention		▲				●							●			3	
	Control		▲				●										2	

[a] Includes good and fair quality studies only; ● indicates the intervention was the same for the different arms; ▲ indicates the intervention varied for the different arms (e.g., control arm got brief counseling while intervention arm got longer counseling); studies organized by quality then chronologically and then by alphabetical order of first author.
[b] Study also enrolled current smokers.

Key Question 5: Effect of Patient Characteristics on Effectiveness

Key Points

- In this literature with biochemical validation of non-smoking status, few studies explicitly examined the influence of participant characteristics on probability of response to intervention or probability of successful cessation.
- No RCTs that demonstrated that the intervention being studied was superior to the comparison group outcomes provided analyses of effect modification by participant characteristics.
- Across good and fair quality trials, consistent and inter-related baseline predictors of achieving and maintaining cessation included lower levels of tobacco dependence as measured by biomarkers, questions gauging dependence, and cigarettes per day.
- Data were sparse to document the influence of maternal age, parity, other smokers in the home, a non-smoking partner, and smoke free policies in the home.
- Data were less consistent for the effects of education, prior experience with cessation, readiness to change, and self-reported motivation to quit.

Description of Included Studies

We sought to obtain two types of evidence to inform this Key Question. The strongest, and therefore optimal form of information, is formal analysis of effect modification, also called interaction. The interaction of interest is that of the intervention received with characteristics of the participants. Ideally intention to take this approach is described in the statistical methods section of the publication as an a priori part of the data analysis plan. An example would be a study that specifically hypothesizes that women in their first pregnancy participating in the intervention arm of the trial will achieve higher cessation rates than women who smoke and already have children, and that then tests this hypothesis with an interaction term in a multivariate model that incorporates trial arm and parity. This approach investigates whether the characteristic of the participant in the smoking intervention program modifies the level of success of an intervention that is shown to be effective.

A second type of information comes from analyses of predictors of cessation within both the included clinical trials and large pre-post type cohort studies of smoking cessation and abstinence support programs. These analyses may at times be specified in advance but were most often post hoc and most common within studies that did not demonstrate efficacy of the intervention being studied. The approach may be used to explain the challenges of the population recruited to the study and to dissect why an intervention did not deliver the expected results. In other cases, the analysis of predictors was conducted as secondary activity for a subsequent publication. In other cases included in this grouping of the papers, investigators did formally examine effect modification but within the entire study population irrespective of intervention group. Data from analyses of these types help describe what factors may influence likelihood of cessation but do not provide information about which women will benefit from which types of intervention.

The information summarized here extends similar components of prior reviews because our entire review was restricted to publications that used biochemical validation of smoking status and thus overcomes the bias introduced by misclassification of outcomes as a result of deception.

Detailed Synthesis

Factors That Modify Success of Intervention

Among the eight randomized trials that demonstrated efficacy or effectiveness of an intervention,[39, 84, 86, 93, 97, 110, 117, 130] none had hypotheses or methods sections that indicated an a priori intention to assess effect modification. Likewise, none of the identified cohorts could address whether individual characteristics modified response to an effective intervention.[38, 95, 96] A single study of counseling and phone followup among 105, predominantly low income Hispanic women, provided data stratified by initial smoking status, indicating that the intervention was significantly effective both among those who smoked fewer than 10 cigarettes per day at baseline and heavier smokers, suggesting no effect modification by level of nicotine dependence (baseline smoking intensity) but not providing data for the statistical test of interaction.[86]

An intervention designed specifically to test for an interaction between depression scores and effectiveness of an intervention based on cognitive behavioral analysis system of psychotherapy (CBAP), did not find evidence of benefit of the intervention in their biomarker validated outcome.[100] This report with 257 participants notes significant interaction of higher depression scores and participation in the CBAP arm leading to improved cessation probability at 6 months after the end of treatment. They also report this effect was not present 3 months after end of treatment with CBAP, nor at 3 or 6 months postpartum.

Factors Related to Probability of Cessation

The analyses described here did not test for effect modification and thus did not directly address the type of intervention and the participant characteristic simultaneously to determine what intervention approaches might be projected to be most successful among specific groups of smokers. Therefore we have grouped studies in nested groups to organize the presentation of data about participant characteristics that were associated with likelihood of cessation (Table 25). First we restricted to the 28 fair or good quality trials identified in the overall literature review[39, 79, 80, 82-94, 97, 100-102, 107, 110, 117, 119, 122, 123, 126, 130] and three cohort studies that also included biomarkers of cessation.[38, 95, 96]

We evaluated only those analyses using cessation endpoints for which there were biologically validated measures of cessation available, for instance if cessation was assessed at 3, 6, 9, and 12 months but cotinine was only measured at 6 and 12, we include only 6 and 12 month data. We present information by timing of the intervention (during pregnancy and postpartum), and within those time periods, we begin with data from trials that demonstrated efficacy of the intervention and conclude each subsection with data from studies that did not document a significant impact of intervention. We further group the type of characteristic associated with cessation in the same manner as Table 25:

- Maternal age
- Education
- Parity (first baby or not)
- Presence of other smokers in home
- Partner smoking status
- Smoke free home
- Level of tobacco dependence
- Prior success with cessation

- Baseline desire or motivation for cessation
- Other predictors of cessation

In total, studies from 18 populations provide information about how participant characteristics related to success in quitting smoking. This includes 14 randomized trials[39, 82-94] of which four are from studies with interventions proven effective[84, 86, 93, 140] and three cohort studies.[38, 95, 96]

Cessation During Pregnancy

Across intervention types, there were commonalities. Younger maternal age, which is correlated with fewer years of smoking, was reported to be associated with improved chance of cessation. A successful trial of in-person counseling and telephone followup reported that women ages 18 to 24 were most likely to quit and that this effect was retained in models that adjusted for number of children and number of prior pregnancies.[86] A trial of telephone counseling also reported that women younger than 25 had higher odds of cessation (OR=2.41; 95% CI: 1.20 to 4.82).[87] In contrast, in a large quasi-experimental analysis of 777 women in the Baby & Me Tobacco Free program implemented among postpartum women, authors report increasing maternal age was associated with improved odds of cessation (OR=1.07; 95% CI: 1.02 to 1.12).[95]

No studies of interventions found to be effective addressed the influence of maternal education. One trial of brief midwifery intervention in the United Kingdom found education did not predict cessation but was strongly associated with relapse among those who entered the intervention in a maintenance phase and needed to sustain cessation.[88] Another study conducted in the United States reported that maternal education entered their multivariate model of predictors but did not report the effect size or statistical significance.[89] The Baby & Me Tobacco Free cohort did not find years of school completed was associated with cessation in multivariable adjusted models.[95]

No studies of interventions found to be effective addressed the influence of parity. A single study reported from adjusted logistic models that women with fewer children were more likely to quit ($p<0.01$).[92] Another trial, also using multivariate logistic models, found women having their first child may be much more likely to achieve cessation; however, the estimate was imprecise (OR=8.50; 95% CI: 1.03 to 70.21).[94] A Danish cohort (n=3,156) of intervention during pregnancy as part of midwifery care reports women having their first child were more likely to quit but did not include the effect size estimate.[96]

How smoking is handled in the home can be captured in a number of ways that include whether others who live in the home are smokers, whether the partner smokes, and whether or not anyone is allowed to smoke inside the home as opposed to going outside to smoke. Though these characteristics are often considered predictors in the health behavior literature and in cohort analyses, only three trials comment on the influence with two addressing cessation during pregnancy. Neither study showed the intervention in the trial was effective. Both were conducted in the United States, and both reported an influence on cessation but did not provide direct statistical support. One group reported that a non-smoking policy in the home was a predictor in multivariate models but no odds ratios or confidence intervals were provided;[87] the other noted exposure to passive smoke [in the home] was included in models but also did not provide data.[89] A single intervention initiated in the postpartum period, for which the intervention itself was not superior to usual care, reported that those who had partners who smoked had higher odds of

smoking (OR=1.81; 95% CI: 1.02 to 3.20),[82] while the Baby & Me Smoke Free program found partner/spouse smoking status was not an independent predictor in multivariate models.[95]

Smoking habits at the time of enrollment were evaluated in several studies. Biomarkers and quantity of smoking were found to play a role in predicting cessation in a successful trial of a multicomponent intervention that centered around a pregnancy-specific quit guide.[39, 93] There was a significant association of baseline cotinine levels with cessation such that those with higher cigarette use were less likely to quit.[39] This research team also reported similar findings without providing statistical significance testing or estimates of the effect size, noting that "most quitters were light smokers" in a subsequent trial.[93]

Five other trials for which the intervention was not demonstrated to be more effective than the comparison group, reported similar findings: lower cigarette use at baseline improved chances of cessation,[83] smoking fewer than 10 cigarettes per day was associated with nearly three-fold higher odds of cessation (OR=2.94; 95% CI: 1.37 to 6.29) as were women who smoked less than five compared to more in another study,[87, 89] greater nicotine dependence as assessed by smoking first cigarette of the day within 30 minutes of awakening reduced chance of quitting[88] as did higher breath carbon monoxide levels as a measure of intensity of smoking.[90] A single study that initiated intervention postpartum evaluated baseline smoking and found a continuous decrease in chance of quitting for each cigarette smoked per day at baseline.[82] Results in the Baby & Me cohort also support the role of baseline carbon monoxide and cigarettes per day in predicting cessation, including risk of dropping out of intervention.[95]

Self-reported readiness or motivation to quit as well as confidence in one's own ability to do so, were evaluated in multiple studies as markers of being able to successfully quit. The only trial with an effective intervention reported that baseline self-efficacy did not predict who would be able to quit. Other trials that pooled trial participants across arms found higher intention to quit predicted more than two-fold higher odds of cessation,[90] self-reported desire to quit was associated with cessation,[92] high levels of confidence in ability to remain abstinent multiple cessation by more than five-fold,[94] and in a postpartum intervention, poor self-efficacy for cessation was associated with less ability to remain quit.[82]

Candidate predictors of cessation explored in single studies, indicated as "Other" in Table 25, included three results from trials for which the intervention was superior to the comparison:

- Smoking status in the first two weeks of treatment was a predictor of cessation status at the end of pregnancy.[141]
- The intervention was most effective when initiated early in gestation (<17 weeks).[86]
- Black women in one Alabama trial (n=814) were more likely to quit, but were also lighter smokers.[39]
- While in a cohort of 265 low-income women in Alabama, race was not found to be an independent predictor in models.[38]

Other characteristics reported to be modest predictors in studies without proven effectiveness of the intervention included these factors that were statistically meaningfully associated with cessation:

- Adolescents who quit had greater knowledge of harmful effects of smoking.[142]
- Helpful family and friends were more commonly reported among quitters.[91, 92]
- Perceived greater risks to the baby.[92]

Maintaining Cessation Achieved Before Study Participation

Some studies enrolled women who had already achieved cessation in order to assist them in remaining smoke free during and after their pregnancies. None of these achieved effectiveness for supporting maintenance using the intervention being studied compared to a usual care group. Only two studies,[82, 88] with three publications,[82, 88, 136] report on any predictors of continued abstinence among women who had quit.

A single study of midwife-delivered brief intervention in the United Kingdom[88] found minimal educational attainment was associated with poor maintenance of cessation which was reduced by more than half compared to those with greater education at the time of birth. This association was no longer observed at last followup (i.e., 6 months after birth) when overall relapse rates were higher.[88] They also reported that employment outside the home in a non-manual occupation and being married were linked with an 80 to 90 percent higher odds of remaining smoke-free.[88] Other factors reported to be linked to maintaining cessation included: continuing to breastfeed for 12 months and having good mental health scores; whereas, having a partner who smoked was linked to relapse.[82, 136]

Table 25. Individual characteristics in relation to achieving or maintaining cessation

Author, Year Timing of Intervention	Younger Maternal Age	Higher Education Level	First Baby	No Smokers in Home	Partner Does Not Smoke	Smoke Free Home	Less Tobacco Dependent	Prior Cessation Success	Motivation for Cessation	Other (See text)
Achieving Cessation[a,b]										
Cinciripini PM et al., 2010[100]										NS
Stotts AL et al., 2009[83]							↑		NS	
Heil SH et al., 2008[84, 141, 143]										↑
Albrecht SA et al., 2006[85, 142, 144, 145]										↑
Dornelas EA et al., 2006[86]	↑								NS	↑
Rigotti NA et al., 2006[87, 146, 147]	↑					NR	↑			NR
Hajek P et al., 2001[88c]		NS					↑		↑	
Ershoff DH et al., 1999[89]		NR				NR	↑		NR	NR
Secker-Walker RH et al., 1998[90]							↑		↑	
Gielen AC et al., 1997[91]										↑
Hartmann KE et al., 1996[92]			↑				↑		↑	↑

Table 25. Individual characteristics in relation to achieving or maintaining cessation (continued)

Author, Year Timing of Intervention	Younger Maternal Age	Higher Education Level	First Baby	No Smokers in Home	Partner Does Not Smoke	Smoke Free Home	Less Tobacco Dependent	Prior Cessation Success	Motivation for Cessation	Other (See text)
Windsor, RA et al., 1993[39, 140]							↑			↑
Maintaining Cessation[α,e]										
Hajek P et al., 2001[88f]		↑					↑			↑
Ershoff, DH et al., 1995[94]			↑					↑	↑	↑
Johnson JL et al., 2000[82, 136]Postpartum					↑		↑			↑

Abbreviations: NS = not significant; NR = p-value not reported but they reported the data in the context of other data with statistical backup.

Notes: Table limited to good and fair quality studies that evaluated a participant characteristic, biochemically validated cessation outcome, and presented statistical significance testing with the data.

[a]Reported in a total of 20 papers (12 unique studies plus eight related papers)

[b]Interventions targeted current smokers during pregnancy (25 studies); no studies of good or fair quality targeted interventions for current smokers in the postpartum period

[c]Study enrolled smokers and quitters; characteristics of quitters reported in "Maintaining Cessation" section

[d]Reported in a total of four papers (3 unique studies plus one related paper)

[e]Interventions targeted recent quitters during pregnancy in two studies[88, 94] and in postpartum in one study[82]

[f]Study enrolled smokers and quitters; characteristics of smokers reported in "Achieving Cessation" section

Discussion

Key Findings

State of the Literature

We included 72 publications from 59 unique studies in this review, including 56 RCTs and three prospective controlled cohort studies. Most studies (42) were conducted in the United States with six from the United Kingdom, four from Australia, two from Canada, two from Denmark, and one study each in Scotland, Sweden, and Spain. The majority of the studies recruited pregnant women (55) and only four studies recruited women in the postpartum period. Studies enrolled women who were current smokers (42 studies), recent quitters (8 studies), or both (9 studies). There were 13 studies of good quality, 15 of fair quality, and 28 of poor quality.

Key Question 1 (KQ1)

Fifty-six RCTs examined the effectiveness of interventions intended to achieve or maintain smoking cessation in women who are pregnant or postpartum. We categorized these studies broadly by primary intervention as counseling (14 studies), educational materials (10 studies), NRT (5 studies), peer support (4 studies), other interventions, consisting of various unique studies (9 studies); and multicomponent (14 studies) interventions. Studies within each category were heterogeneous. We only included studies that provided biochemical validation methods because discrepancies between self-reported smoking status and biochemically validated smoking status are common and sometimes considerable. The duration of followup in the studies included in this review was generally short with most studies that delivered an intervention during pregnancy limiting followup to the prenatal period. No study reported validated cessation outcomes beyond 12 months postpartum.

Eight of 24 studies of good or fair quality demonstrated effectiveness for cessation with a difference in cessation between intervention and control groups ranging from 5.8 percent to 31.0 percent, as shown in Table 26. Four of these studies used multicomponent interventions.[39, 93, 110, 130] Counseling,[86] educational materials,[97] peer support,[85] and voucher incentives[84] were each the primary intervention in one positive study. This qualitative synthesis suggests that, generally speaking, multicomponent approaches were most effective, but does not provide evidence to drive selection of specific components to form those interventions. The most common interventions in successful multicomponent studies were also common in studies that failed to demonstrate effectiveness. For each study with a primary intervention that demonstrated effectiveness, there were other studies of this intervention that did not demonstrate effectiveness.

Table 26. Studies demonstrating a significant difference in smoking cessation/relapse prevention

Author, Year Country (Number Randomized)	Quality	Intervention (number analyzed)	Cessation, %	Cessation, %Δ	Significance (association)
Smoking Cessation					
Heil et al., 2008[84] U.S. (82)	Fair	Contingent vouchers (37) Control (40)	41.0 10.0	31.0	(p=0.003)
Ondersma et al., 2012[97] U.S. (110)	Good	Educational materials (CD-5A's) (23) Usual care (23)	43.5 17.4	26.1	(p<0.05) (OR=10.1,[a] 95% CI: 1.4 to 75.0)
Donatelle et al., 2000[110] U.S. (220)	Fair	Multicomponent (105) Usual care (102)	32.0 9.0	23.0	(p<0.0001)
Dornelas et al., 2006[86] U.S. (105)	Fair	Counseling (53) Usual care (52)	28.3 9.6	18.7	(p=0.02)
Windsor et al., 1985[93] U.S. (309)	Fair	Multicomponent (102) Usual care (104)	14.0 2.0	12.0	(RR=0.12, 95% CI: 0.05 to 0.19)
Walsh et al., 1997[130] U.S. (293)	Good	Multicomponent (127) Control (125)	13.0 6.0	7.0	(p=0.0353)
Windsor et al., 1993[39] U.S. (994)	Fair	Multicomponent (400) Usual care (414)	14.3 8.5	5.8	(p=0.01)
Albrecht et al., 2006[85] U.S. (142)	Good	Peer Support (TFS-B) (45) Usual care (50)	NR	NR	(p=0.01) (OR=3.73, 99% CI: 1.00 to 13.89)
Relapse Prevention					
Phillips et al., 2012[80] U.S. (54)	Good	Mother-infant bonding (21) Usual care (28)	81.0[b] 46.0	35.0	(p<0.001)

Abbreviations: CBT = cognitive behavioral therapy; CI = confidence interval; CD-5A's = computer delivered 5A's; NRT = nicotine replacement therapy; OR = odds ratio; RR = relative risk; TFS-B = Teen FreshStart plus buddy; U.S. = United States.
Notes: Includes good and fair quality studies that demonstrated a statistically significant difference in biochemically confirmed smoking cessation or relapse prevention outcomes; rows ordered by studies in current smokers followed by studies in recent quitters and then by difference in cessation.
[a] Odds ratio adjusted for minority status and baseline smoking status; unadjusted OR=3.7 (95% CI: 0.94 to 14.2) p=NS
[b] 8 weeks postpartum

One of five studies of good or fair quality demonstrated effectiveness for relapse prevention with a 35 percent higher cessation in the intervention group than the control group, as shown in Table 26. This study evaluated a unique intervention to promote mother- infant bonding. Additional studies are needed to confirm the effectiveness of this intervention, as this study included only 54 participants and cessation outcomes were not reported beyond 8 weeks postpartum.

Key Question 2 (KQ2)

Infant and child outcomes associated with smoking cessation and relapse prevention interventions targeted at pregnant and postpartum women have not been well-explored. Only 13 of 56 RCTs identified in this review assessed infant outcomes, and these were limited to data collected at the time of birth. No studies addressed longer-term or child outcomes. In addition,

given the prevalence of adverse birth outcomes, all studies were likely underpowered to detect meaningful differences in infant outcomes in terms of both benefit and harms.

Findings regarding mean birth weight were inconsistent, and no clinically meaningful differences were identified. Only one of the seven studies that reported gestational age had statistically significant results with women who received NRT in addition to CBT giving birth an average of one week later than women who received CBT only. No studies found statistically significant differences in the incidence of preterm birth, neonatal deaths, or NICU admissions between the intervention and control groups.

Key Question 3 (KQ3)

Only 4 out of the 56 RCTs in our review reported harms associated with smoking cessation interventions; three of these were studies in which NRT was the primary intervention. None of the studies reported a higher incidence of adverse events in women receiving interventions compared to the control groups. As noted in recent systematic reviews and reflected in the regulatory guidance from the FDA, the safety of NRT and other pharmacologic smoking cessation aids in pregnancy is uncertain. Data from the studies included in this review add little to the current understanding of NRT risks in pregnancy. The NRT trials that assessed harms had low numbers of participants and low adherence rates. A review including a much larger sample would be required to comprehensively assess the effect of this therapy on infrequent adverse birth outcomes. Caution is warranted in interpreting the lack of harms identified with NRT, particularly given risks to the fetus articulated in the FDA guidance about use of the nicotine transdermal patch in pregnancy. None of the studies that evaluated relapse prevention interventions reported harms data.

Key Question 4 (KQ4)

Twenty-nine good or fair quality studies were available to separate out the effect of components of the smoking cessation intervention itself on cessation of smoking or durability of cessation. The most common components of the interventions were counseling, information, quit guides, personal followup, and clinic reinforcement. In a Bayesian random effects meta-analysis of the 23 studies that could be combined, the use of incentives was most clearly associated with substantially increased smoking cessation. The odds of quitting with the use of incentives were three times the odds of quitting in the absence of incentives holding all other interventions constant (OR 3.23; 95% BCI, 1.98 to 4.59). Additional intervention components that may have some positive effect, as demonstrated by 80 percent or greater probability that the odds are higher than the null for the intervention increasing smoking cessation, include feedback about biologic measures, information, personal followup, NRT, and quit guides. Clinic reinforcement, peer support, and prescriptions to quit were ineffective in these studies. Because counseling was ubiquitous and heterogeneous, it could not be appropriately measured in the meta-analysis. Therefore, we need to look at those studies that purport to be primarily focused on counseling interventions. None of those studies demonstrated effectiveness of counseling or relatively better results for any type of counseling.

The most common components of relapse prevention interventions were counseling, quit guides, information, and personal followup. These studies were too heterogeneous to conduct an analysis to assess the effect of the components. Data were not available to specifically address the impact of who delivered the intervention or where the intervention was delivered.

Key Question 5 (KQ5)

In this literature with biochemical validation of non-smoking status, few studies explicitly examined the influence of participant characteristics on probability of response to intervention or probability of successful cessation. No randomized clinical trials that demonstrated that the intervention being studied was superior to the comparison group outcomes provided analyses of effect modification by participant characteristics. Across good and fair quality trials, consistent and inter-related baseline predictors of achieving and maintaining cessation included lower levels of tobacco dependence as measured by biomarkers, questions gauging dependence, and cigarettes per day. Data were sparse to document the influence of maternal age, parity, other smokers in the home, a non-smoking partner, and smoke free policies in the home. Data were less consistent for the effects of education, prior experience with cessation, readiness to change, and self-reported motivation to quit.

Findings in Relationship to What Is Already Known

To put this review into context of what is currently known, we sought available systematic reviews. Fifteen systematic reviews published since 2008 were considered to be relevant. Most of the reviews looked at smoking cessation interventions overall, rather than at specific interventions.

A 2012 Cochrane review[51] of pharmacologic agents for cessation included six trials of NRT agents and reported insufficient evidence to permit conclusions about benefits and harms. A 2012 meta-analysis by Myung and colleagues included six trials of NRT and one of bupropion.[52] In contrast to the Cochrane review,[51] Myung et al.[52] found a higher rate of abstinence in pregnant smokers receiving pharmacotherapy than in women serving as controls, with no significant differences between groups in mean birth weight, rate of low birth weight, mean gestational age, and preterm birth rate. The Myung et al. analysis,[52] however, included a large study that was excluded from the Cochrane review because it was judged to have high risk of bias and it is likely that this poor quality study had a significant effect on the conclusions.[51]

A 2011 review conducted by the British Columbia Centre for Excellence in Women's Health,[54] reviewed 97 studies including observational studies and clinical trials, and reported positive effects from 14 interventions including counseling, self-help materials, and incentives; the report described weak evidence for 56 interventions and noted that 27 "showed promise."[54] A 2009 Cochrane review of randomized and quasi-randomized trials conducted between 1975 and 2008 concluded that smoking cessation interventions in pregnancy reduce the proportion of women who continue to smoke in late pregnancy.[53] The treatment group in this review had a reduction in low birth weight and preterm birth as well as an increase in mean birth weight. A 2007 review of randomized controlled trials (RCTs) found no evidence that providing advice, materials, and counseling affected postpartum smoking cessation.[50] Incentive-based interventions were found to be the most likely to be effective. However, the 2007 review did not attempt to identify the content of the intervention or if there were subgroups of women that were better suited to benefit from it. The review was also focused on interventions delivered during pregnancy but not in the postpartum period.[50]

Overall, the findings from existing systematic reviews suggest that NRT, behavioral and educational cessation strategies, and multicomponent interventions may be beneficial to women who smoke in pregnancy or the postpartum period. Despite these previous systematic review efforts, however, the efficacy of specific components and the impact of these various strategies

on smoking and infant outcomes in pregnant and postpartum women remain unclear. Findings regarding birth outcomes, including birth weight and preterm birth, are inconsistent across reviews. These differences may reflect the fact that reviews differed in inclusion and exclusion criteria and thus the studies that were included.

Thus our analysis is consistent with and extends prior reviews in demonstrating mixed effects overall for pregnancy focused smoking interventions. Our review adds two important elements to the literature. First, we focus on biochemically validated outcomes, so the outcomes in our review are likely to be most accurate. Second, the use of the meta-analysis enables us to quantify the relative benefit of specific components of what are almost always multicomponent interventions in practice. This addition to the literature provides data that end users can apply in selecting interventions for their practice settings.

Applicability

Applicability for this literature is largely dependent on the target population and the feasibility of the interventions in the clinical setting. The target populations are defined by whether women were pregnant or postpartum, whether they were current smokers or recent quitters, and whether they were selected from sociodemographically at-risk populations. Interventions could be resource intensive across axes of time, money and personnel. Thus, to ascertain the applicability of any given intervention, the potential end user must consider whether research on the intervention has been conducted in their target population, and whether the intervention is appropriate and feasible in terms of resource allocation.

The majority of studies (55 studies) included in this review recruited pregnant women; four studies were conducted in the postpartum period. Most studies (42) were conducted in the United States and thus should be applicable to the U.S. health system. Studies enrolled women who were current smokers (42 studies), recent quitters (8 studies) or both (9 studies). The duration of followup in the studies included in this review was generally short, and thus little is known about durability of effects. Most studies that delivered an intervention during pregnancy limited followup to the prenatal period. Only 15 studies reported biochemically validated cessation after birth. For studies evaluating an intervention delivered in the postpartum period, one study reported cessation at 6 weeks postpartum,[79] one at 8 weeks postpartum,[80] one at 3 months postpartum,[81] and one at 6 months postpartum.[82]

It would be particularly helpful to end users to know whether certain interventions were effective in high-risk populations. One study enrolled adolescents only,[85] six studies targeted income-specific groups,[11, 101, 103, 106, 107, 110] and one study specifically selected participants from the Medicaid population.[98] Of these, only one demonstrated a positive effect[110]; this study evaluated a multicomponent intervention in WIC clinics in Oregon. One study[120] included only African American pregnant smokers and one study[127] targeted indigenous Australian women.

Interventions were generally more effective among participants with lower levels of tobacco dependence, so even the more effective approaches may be less applicable in populations with extremely high levels of nicotine dependence. Younger maternal age, which is correlated with fewer years of smoking, was reported to be associated with improved chance of cessation.

In terms of interventions, smoking cessation and relapse prevention interventions, both prenatal and postpartum, were overwhelmingly multifaceted. Studies deployed multiple components in the intervention being compared with usual care or an alternative level of standard cessation services. As described earlier, incentives had the highest independent effect, but given that statistical model underlying the meta-analysis was additive and that the likelihood

of positive effects was high for a number of intervention components, it would be reasonable for providers to select a set of components that might have greatest applicability in their setting and develop those into a multicomponent intervention. To that end, we have made relative assessments of the resources and considerations that end users might have around implementation of the components assessed in this report (Table 27).

Table 27. Resource considerations for applicability

Component	Definition	Resource Considerations
Clinic Reinforcement	Identifying participants at followup visits (usually by flagging patient charts) to remind staff to address smoking (e.g., assessment of smoking status, encouragement to achieve or maintain cessation).	Clinic reinforcement can be easily integrated into standard clinical care and conducted during usual processes such as weight and blood pressure measurements. It is low intensity in terms of human and cost resources.
Counseling	Any form of individual counseling, however brief, delivered by a range of practitioners (e.g., obstetrician, peers).	Counseling ranges in intensity. At its most intense, it can be costly in terms of provider time and can require provider training in approaches. On average, we consider it to be medium intensity in human and financial resources.
Feedback about Biologic Measures	Ultrasound images, stress tests, biochemical tests for smoking (e.g., carbon monoxide, cotinine), or other biologic data delivered to the pregnant woman.	Feedback is low in intensity by the clinical provider, but may require substantial resources to obtain biologic data, particularly if materials must be sent to an external laboratory.
Groups	Support groups or group counseling to promote and/or sustain smoking cessation.	Support groups require a trained facilitator, which may entail upfront costs, but are able to reach multiple patients simultaneously. We therefore consider them to be of moderate intensity. This would depend substantially, however, on the personnel and space availability at a given clinical site.
Incentives	Both financial and symbolic rewards (baby gifts, t-shirts, mugs, awards) contingent upon smoking reduction or cessation. This does not include gifts given at study enrollment or incentives for study visits.	Incentives are of variable resource intensity in terms of financial costs, depending on the size and type of incentives, but are easy to distribute and require little sustained effort by staff. As the intervention component found to be most effective, their relative human resource low intensity could make them an attractive option.
Information	Education about pregnancy and smoking in the form of pamphlet, video, or other educational material. This includes factual or educational material only as distinguished from a Quit Guide, which contains practical information and/or directions that the patient can use.	Providing information in the form of existing pamphlets or other educational material is a very low-intensity intervention, provided that the materials exist and are available. Producing, printing, and purchasing materials could be challenging from a resource perspective.
NRT	Pharmacological nicotine replacement therapy (e.g., patches, gum).	For the provider, this is a low-cost, low-intensity intervention. For the pregnant woman or her third-party payer, this may be viewed as costly. For the pregnant woman, the cost of NRT may be offset by savings of tobacco not purchased.
Partner/ household/ social context	Identification of the smoking patterns of the partner, friends, and family as key aspects of the assessment process. This may include household members.	Identification of smoking patterns in the household can be done in the context of regular history-taking in clinic visits and thus requires little additional effort on the part of the provider or the patient.

Table 27. Resource considerations for applicability (continued)

Component	Definition	Resource Considerations
Peer support	Encouraging the identification and involvement of a peer or "buddy" for the pregnant woman as ongoing social support during the cessation process. This includes buddy contracts and lay health advisors.	Peer support requires that an individual outside of the patient-clinical dyad commit resources and potentially training time to be prepared to support the patient in quitting. It may also require clinical care sites to implement training programs and develop contracts for peers.
Personal Followup	Followup with the purpose of sustaining the impact of the other components and offering encouragement (e.g., calls, postcards, congratulations letters).	The ability to personally follow up with patients outside of the typical clinical encounter likely varies by clinical care site and should be a consideration for implementation. This effort requires both a tracking system of some sort and the personnel effort to make contacts, and is thus resource intense.
Prescription to quit	A written "prescription" from care provider typically including a target quit date.	Prescriptions to quit require little additional effort beyond the standard clinical encounter and are thus a very low-resource-intensive intervention.
Quit contract	Contract or formalized commitment to a specific quit date.	Once a contract template is developed, there is additional effort required in the clinical environment to discuss and have a fully informed commitment to the quit contract.
Quit guide	A take-home, patient-focused guide to quitting, usually incorporating some skill building, tips on reduction and cessation, and practical advice. This includes practical information and/or directions that the patient can use or do as distinguished from Information which provides factual or educational material only.	Quit guides are currently available and thus could be made available to patients fairly easily. Deciding to develop or modify existing quit guides would add to the resources needed for implementation, but this may be a consideration for clinical sites wishing to target a particular population. The resources expended for quit guides are primarily on the side of the patient in terms of time and effort.

Summary of Strength of Evidence and Findings

Overall the evidence to answer KQs about smoking cessation and relapse prevention interventions for pregnant and postpartum women did not reach standards for high strength of evidence. The strength of evidence tables (Tables 28-30) summarize the total number of studies and within those studies the number of participants randomized. The tables also provide the assessment of the risk of bias, consistency of findings across trials, directness of the evidence, and precision of the estimate provided by the literature. For effectiveness, we assessed strength of evidence based on the good and fair quality included studies because there were enough of these studies to form a "best evidence" set that would not be obscured by biased and poorly conducted studies. To support this decision, we assessed the likelihood that inclusion of the poor quality studies would change the strength of evidence and determined that inclusion of those studies would not have modified our assessment. For infant outcomes (KQ2) and harms of interventions (KQ3), we included poor-quality studies in the strength-of-evidence assessment. These Key Questions warrant a more expansive assessment of the literature because they focus on outcomes that are rarely reported.

We assessed the strength of evidence for the effectiveness of intervention components using the meta-analysis for all components other than counseling, which was ubiquitous across studies. Strength of evidence was moderate for the effectiveness of incentives and low for all other intervention components (Table 28).

Table 28. Strength of evidence for effectiveness of intervention components for smoking cessation among current smokers in pregnancy

Number of Studies (participants randomized) Intervention Component	Risk of Bias	Consistency	Directness	Precision	OR (BCI) Posterior Probability[a] Strength of Evidence[b]
Incentives	Medium	Consistent	Direct	Precise	3.23 (1.98 to 4.59) 100% Moderate for effect
Feedback	Medium	Inconsistent	Direct	Precise	1.43 (0.88 to 2.03) 95% Low for effect
Information	Medium	Inconsistent	Direct	Precise	1.32 (0.88 to 1.79) 93% Low for effect
Personal followup	Medium	Inconsistent	Direct	Precise	1.25 (0.94 to 1.57) 95% Low for effect
NRT	Medium	Inconsistent	Direct	Precise	1.24 (0.84 to 1.68) 87% Low for effect
Quit guide	Medium	Inconsistent	Direct	Precise	1.18 (0.82 to 1.56) 83% Low for effect
Prescription to quit	Medium	Inconsistent	Direct	Precise	1.13 (0.46 to 1.95) 57% Low for no effect
Peer support	Medium	Inconsistent	Direct	Precise	1.07 (0.7 to 1.46) 60% Low for no effect
Clinic reinforcement	Medium	Inconsistent	Direct	Precise	1.05 (0.65 to 1.49) 55% Low for no effect

Note: Table data from 8, 086 participants randomized in 23 RCTs[39, 83-93, 97, 100-102, 107, 110, 117, 119, 122, 123, 130] BCI = Bayesian credible interval; OR = odds ratio.
[a]Probability that the OR is greater than the null
[b]The effect is positive if the posterior probability is 80% or greater

There is insufficient strength of evidence to determine the effect of smoking cessation interventions on birth weight, gestational age, and neonatal deaths (Table 29). There is low strength of evidence for no significant effect on preterm birth and NICU admission (Table 29). There is also insufficient strength of evidence to determine the harms of smoking cessation interventions (Table 30).

Table 29. Strength of evidence for infant outcomes associated with smoking cessation interventions in pregnancy and the postpartum period compared with usual care or other interventions

Outcome	Number of Studies (participants randomized)	Risk of Bias	Consistency	Directness	Precision	Magnitude of Effect Strength of Evidence
Birth weight	13 RCTs[84, 102, 104, 105, 117, 120-122, 124, 129, 132-134] (5759)	Medium	Inconsistent	Direct	Imprecise	Insufficient to determine effect
Gestational age	7 RCTs[84, 102, 104, 120-122, 132] (2423)	Medium	Inconsistent	Direct	Imprecise	Insufficient to determine effect
Neonatal death	2 RCTs[122, 132] (1812)	Medium	Consistent	Direct	Imprecise	Insufficient to determine effect
Preterm birth	7 RCTs[84, 117, 120, 122, 129, 132, 134] (4005)	Medium	Consistent	Direct	Imprecise	No significant difference Low for lack of effect
NICU admission	6 RCTs[84, 105, 117, 121, 122, 132] (2621)	Medium	Consistent	Direct	Imprecise	No significant difference Low for lack of effect

Table 30. Strength of evidence for harms of interventions for smoking cessation in pregnancy and the postpartum period

Outcome Intervention	Number of Studies (participants randomized)	Risk of Bias	Consistency	Directness	Precision	Magnitude of Effect Strength of Evidence
Maternal and fetal-neonatal adverse effects NRT plus counseling vs. counseling	3 RCTs[102, 104, 122] (1425)	Medium	Inconsistent	Indirect	Imprecise	Insufficient to determine effect
Stress levels Quit guides vs. quit guides and interaction computer program vs. standard advice	1 RCT[125] (918)	High	NA	Indirect	Imprecise	Insufficient to determine effect

Implications for Clinical and Policy Decisionmaking

As clinicians and policymakers consider implementing smoking cessation interventions, their primary consideration is choosing those approaches that are most likely to be effective and feasible. Qualitatively, this review suggests approaches that combine multiple components will have the best likelihood of success. Selecting which components to include is more complex and should be based on the particular considerations of the interventions and clinical setting.

Efficacy is foremost in choosing the combination of interventions in a multicomponent strategy. The meta-analysis presented in this review allowed us to calculate the posterior probability that specific intervention components contributed to success of smoking cessation. Multiple components had a greater than 80 percent probability of having a positive effect with

incentives demonstrating the strongest effect. While incentives require a financial investment, they are not time intensive. In addition, prior research in other fields, such as weight loss,[148, 149], vaccination,[150], and medication adherence[151] suggests that modest incentives can be adequate to change behavior. However, use of financial incentives remains controversial. The other components with high probability of success were feedback about biologic measures, information, personal followup, NRT, and quit guides. Our meta-analysis results suggested that clinic reinforcement, peer support, and prescriptions to quit contributed little in multicomponent interventions.

Resource allocation is another important consideration in selecting which smoking cessation interventions to implement. Financial and human resources needed for development and implementation vary by intervention (Table 27). In addition to resources, the logistics of the clinical setting and how a specific intervention can be integrated into current processes or added needs to be assessed.

Harms must also be evaluated in selecting which interventions to implement. With the exception of medications, for which limited harms data are available, smoking cessation interventions lack adverse effects. The safety of these interventions makes it reasonable to include a number of interventions in a multicomponent approach.

Understanding whether specific populations of patients are more amenable to behavior change could be useful in intervention development and implementation. Although few data are available to guide targeting of services, the research reviewed in this report suggests that women who are less tobacco dependent, younger, and of lower parity may have a greater chance of successfully quitting. More intensive interventions are worth considering for other populations of women (e.g., heavier smokers, older, higher parity) who are less likely to successfully quit smoking.

Limitations of This Review

Studies of effectiveness in this review were limited to RCTs which are known at times to have limited applicability and to be suboptimal for assessing harms and long-term outcomes. Nonetheless, they provide the greatest evidence for effectiveness, and we had adequate numbers of RCTs to evaluate these interventions. Limiting trials to those with biochemical validation improves the accuracy of outcomes but decreases the number of studies that are available to provide information. We required cessation, rather than reduction, as the outcome because this is the optimal outcome for maternal and infant health.

Limitations of the Evidence Base

Nearly half of the studies (n=28) were of poor quality, and the most common reason for high risk of bias was incomplete outcome data. Losses to followup varied by intervention, but the reasons for this variation and its impact on the results are unclear. Studies were most commonly rated fair quality (n=15) due to unclear risk of bias associated with allocation concealment and random sequence generation.

The interventions are almost always multicomponent as is the care to which they are being compared. Because the interventions are often poorly characterized, it can be difficult to clearly identify the components of the intervention and what is having the effect. In addition, poor characterization of interventions reduces the potential that they can be replicated both in practice and in research. None of the studies adequately assessed intervention fidelity, which is likely to be particularly challenging with behavioral interventions and has implications for biasing the

estimate of effect and the applicability of the results. The field is not consistent in selecting a specific gestational age as the optimal time point to measure cessation, which makes comparing studies very difficult. For example, outcomes reported as the end of pregnancy spanned the entire third trimester. More precision around ideal end points would help future research. Ideally these should be linked to fetal development and likelihood of being able to maintain cessation. Few studies assess cessation beyond birth, which is important in light of the high rate of relapse and need to know which interventions are most durable.

Future Research Needs

Future research needs around smoking cessation in pregnancy are both substantive and methodologic. There are several interventions that warrant additional research and replication, including better assessments. Priorities for future research about interventions include—

- Conducting additional studies of incentives, including the amount needed and under what circumstances they are effective.
- Replicating the evaluation of the mother-infant bonding intervention that was found to be effective in the relapse prevention study.
- Developing much more rigorous studies that isolate counseling and its components. Counseling was ubiquitous, and studies were heterogeneous in their approach.
- Studying intervention components, either in isolation or in multicomponent studies with very high rigor, identified in the meta-analysis as having a high probability of being effective so that the effect of individual components, or specific combinations of components, can be measured.

Methodologic and study design considerations for future research include—

- Clear characterization of the components of both the intervention and comparator.
- A plan for assessment and reporting of fidelity of intervention implementation and the potential for crossover of the intervention into the comparator group.
- Use of biochemically validated outcomes. Self-report is known to underestimate smoking prevalence. A sustained measure of smoking abstinence, as opposed to a point prevalence measure, would be ideal.
- Assessment of the degree to which timing matters in successfully achieving cessation Intervention timing varies substantially across studies, including early and late in pregnancy, and some studies suggest interventions may have potential for getting women to stop earlier even when overall differences are not significant.
- Adequate sample sizes with long-term followup. Current studies are short term and have no ability to assess effectiveness over time including long-term health implications. This is in part due to need for large numbers at study inception in order to maintain adequate power over time. Larger sample sizes are needed to assess comprehensively infant and longer term child outcomes as well as events and harms.
- Identification of the underlying study purpose. There is a lack of clarity overall in this body of research about whether encouraging women to stop smoking in pregnancy is for the purpose of optimizing fetal growth or creating a smoke free home by the end of pregnancy. While both goals are important, identifying the specific underlying rationale for a study can help in intervention development in a way that is targeted and potentially more effective.

Conclusions

Across interventions, data are sparse to evaluate sustained cessation among pregnant and postpartum women. This review suggests approaches that combine multiple components will have the best likelihood of success. Selecting which components to include is more complex and should be based on the particular considerations of the clinical setting including patient characteristics and resource allocation, but incentives demonstrated the greatest effect among components studied. Infant outcomes are limited to data collected at time of birth; no studies assessed longer-term or child outcomes. Harms data were rarely reported.

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Abbreviations and Acronyms

5A's Model	Ask, Advise, Assess, Assist, and Arrange
ACOG	American College of Obstetricians
AHRQ	Agency for Healthcare Research and Quality
BCI	Bayesian credible interval
CBT	Cognitive Behavior Therapy
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CO	Carbon Monoxide
g	Gram
G	Group
HMO	Health Maintenance Organization
kg	Kilogram
KQ	Key Question
LBW	Low Birth Weight
MeSH	Medical Subject Heading
mg	milligram
ml	milliliter
N	Number
ng	nanogram
NICU	Neonatal Intensive Care Unit
NRT	Nicotine Replacement Therapy
NS	Non-significant
OR	Odds ratio
PICOTS	Population, Interventions, Comparators, Outcomes, Timing, Settings
ppm	Parts Per Million
RCT	Randomized Controlled Trials
RR	Relative Risk
SCRIPT	Smoking Cessation or Reduction in Pregnancy Treatment Program
SOE	Strength of Evidence
TEP	Technical Expert Panel
U.S.	United States
VLBW	Very Low Birth Weight
WIC	Women, Infants, and Children
wks.	weeks

Appendix A. Literature Search Strategies

Last updated: May 15, 2013

Table A1. Search strategy and results from PubMed (PubMed.gov interface)

Search terms		Search results
#1	smoking/th[mh] OR tobacco use cessation[mh] OR tobacco use disorder/th[mh] OR tobacco use cessation products[mh] OR "smoking cessation"[tiab] OR (smoking[tiab] AND (quit[tiab] OR cessation[tiab] OR quitting[tiab] OR stop[tiab] OR stopping[tiab] OR stopped[tiab])) OR "smoking abstinence"[tiab] OR "tobacco abstinence"[tiab]	39310
#2	pregnancy[mh] OR pregnant women[mh] OR postpartum period[mh] OR postnatal care[mh] OR pregnancy[tiab] OR pregnant[tiab] OR postpartum[tiab] OR post-partum[tiab] OR postnatal[tiab] OR post-natal[tiab] OR prenatal[tiab] OR pre-natal[tiab]	841048
#3	#1 AND #2 NOT (comment[pt] OR letter[pt] OR review[pt] OR guideline[pt] OR case reports[pt] OR editorial[pt] OR news[pt] OR patient education handout[pt] OR legal cases[pt] OR meta-analysis[pt] OR newspaper article[pt] OR news[pt] OR historical article[pt] OR jsubsetk)	1804
#4	#3 AND English[la] AND humans[mh]	1458

Key: [tiab] title or abstract word; [th] therapy; [la] language; [mh] medical subject heading; [pt] publication type; "jsubsetk" consumer health journal subset

Table A2. Search strategy and results from CINAHL (EBSCO Host interface)

Search Terms		Search results
#1	MH "Smoking/DT/DH/TH/PC" OR (MH "Smoking Cessation") OR (MH "Smoking Cessation Programs") OR (smoking AND (cessation OR quit OR quitting OR stop OR stopping OR stopped))	15319
#2	(MH "reproduction+") OR (MH "obstetric care+") OR (MH "attitude to pregnancy") OR pregnancy OR pregnant OR prenatal OR pre-natal OR postnatal OR postpartum OR post-natal OR post-partum	129706
#3	#1 AND #2	1161
#4	#3 AND limiters: English Language; Peer Reviewed; Research Article; Exclude MEDLINE records	84

Key: MH CINAHL medical subject heading; + explode term; DT/DH/TH/PC: therapy subheadings

Table A3. Search strategy and results from PsycINFO (ProQuest interface)

Search terms		Search results
#1	SU.EXACT.EXPLODE("Smoking Cessation") OR SU.EXACT.EXPLODE("Tobacco Smoking") OR "smoking cessation" OR (smoking AND (quit OR cessation OR quitting OR stop OR stopping OR stopped)) OR "smoking abstinence" OR "tobacco abstinence"	24899
#2	SU.EXACT.EXPLODE("Pregnancy") OR SU.EXACT.EXPLODE("Adolescent Pregnancy") OR pregnancy OR pregnant OR prenatal OR pre-natal OR postnatal OR postpartum OR post-natal OR post-partum	54089
#3	#1 AND #2, limited to human, English language, peer-reviewed scholarly journals	1309

Key: SU.EXACT.EXPLODE explode subject term to include more specific related concepts

Appendix B. Screening Forms

Smoking Cessation Interventions in Pregnancy and Postnatal Care
Systematic Evidence Review
Abstract Review Form

	Primary Inclusion/Exclusion Criteria			
X-1	**1.** Study reports results from a clinically-oriented smoking cessation intervention/a cessation intervention that intersects with clinical care and is aimed at pregnant women or postpartum (</= 6 months post-birth) women	Yes	No	Unclear
	If answer to question 1 is "No", this form is complete. Submit the form to move to the next reference.			
X-2	**2.** Study is original research (includes systematic reviews and meta-analyses).	Yes	No	Unclear
X-3	**3.** Study includes at least 20 pregnant or postpartum women PER GROUP. If "no", indicate total number of participants in study: _____	Yes	No	Unclear
X-4	**4.** Study is an RCT, prospective cohort study (includes an intervention and a control group), systematic review, or meta-analysis.	Yes	No	Unclear
	If the study is excluded, retain for review of references? Comments:			

Smoking Cessation Interventions in Pregnancy and Postpartum Care
Systematic Evidence Review
Full Text Review Form

	Primary Inclusion/Exclusion Criteria		
X-2	**5.** Reports original research (i.e., not a review, editorial, commentary, letter to editor, etc.)	Yes	No
X-5	**6.** Reports outcomes/results for smoking cessation intervention(s) If "no", indicate reason: □ Evaluates smoking prevention □ Other: _____	Yes	No
X-4	**7.** Eligible study design If "yes", indicate study design: □ RCT □ Prospective cohort with intervention and control group (KQ4 or KQ5 only)	Yes	No
X-6	**8.** Eligible study population If "yes", indicate study population: □ Pregnant women who smoke or who smoked and quit in the index pregnancy □ Postpartum (up to 6 months after birth) women who smoke or who smoked and quit in the index pregnancy	Yes	No
X-3	**9.** Includes 20 or more participants in each group If "no", indicate total number of participants in study: _____	Yes	No
X-7	**10.** Biochemical validation of abstinence outcomes	Yes	No

If excluded, retain for:

□ Background □ Review of references □ Other_____

COMMENTS: _____

Other:

□ Describes methods or protocol for potentially eligible study □ Family □ Unavailable (X-8) □ Duplicate (X-9)

Appendix C. Cochrane Risk of Bias Tool

The Cochrane Collaboration tool is used to assess risk of bias for randomized controlled trials. Bias is assessed as a judgment (high, low, or unclear) for individual elements from five domains (selection, performance, attrition, reporting, and other).

Table C1. Risk of bias assessment form

Domain	Description	High Risk of Bias	Low Risk of Bias	Unclear Risk of Bias	Reviewer Assessment	Reviewer Comments
Selection bias ***Random sequence generation***	Described the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence	Random sequence generation method should produce comparable groups	Not described in sufficient detail	**High** **Low** **Unclear**	
Selection bias ***Allocation concealment***	Described the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrollment	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment	Intervention allocations likely could not have been foreseen in before or during enrollment	Not described in sufficient detail	**High** **Low** **Unclear**	
Reporting bias ***Selective reporting***	Stated how the possibility of selective outcome reporting was examined by the authors and what was found	Reporting bias due to selective outcome reporting	Selective outcome reporting bias not detected	Insufficient information to permit judgment†	**High** **Low** **Unclear**	
Other bias ***Other sources of bias***	Any important concerns about bias not addressed above*	Bias due to problems not covered elsewhere in the table	No other bias detected	There may be a risk of bias, but there is either insufficient information to assess whether an important risk of bias exists or insufficient rationale or evidence that an identified problem will introduce bias	**High** **Low** **Unclear**	

* If particular questions/entries were pre-specified in the study's protocol, responses should be provided for each question/entry.
† It is likely that the majority of studies will fall into this category.
Assess each main or class of outcomes for each of the following. Indicate the specific outcome.

Risk of Bias Assessment (Reference ID #)

Outcome:

Domain	Description	High Risk of Bias	Low Risk of Bias	Unclear Risk of Bias	Reviewer Assessment	Reviewer Comments
Performance bias ***Blinding (participants and personnel)***	Described all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.	Blinding was likely effective.	Not described in sufficient detail	**High** **Low** **Unclear**	
Detection bias ***Blinding (outcome assessment)***	Described all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective.	Detection bias due to knowledge of the allocated interventions by outcome assessors.	Blinding was likely effective.	Not described in sufficient detail	**High** **Low** **Unclear**	
Attrition bias ***Incomplete outcome data***	Described the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. Stated whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported.	Attrition bias due to amount, nature or handling of incomplete outcome data.	Handling of incomplete outcome data was complete and unlikely to have produced bias	Insufficient reporting of attrition/exclusions to permit judgment (e.g., number randomized not stated, no reasons for missing data provided)	**High** **Low** **Unclear**	

Appendix D. Cochrane Risk of Bias Criteria

Table D1. Criteria for judging risk of bias using the Cochrane Collaboration Risk of Bias Tool[a]

Bias	Judgment	Criteria
RANDOM SEQUENCE GENERATION Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.	'Low risk' of bias.	The investigators describe a random component in the sequence generation process such as: • Referring to a random number table; • Using a computer random number generator; • Coin tossing; • Shuffling cards or envelopes; • Throwing dice; • Drawing of lots; • Minimization*. *Minimization may be implemented without a random element, and this is considered to be equivalent to being random.
	'High risk' of bias.	The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; • Sequence generated by some rule based on hospital or clinic record number. Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example: • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; • Allocation by availability of the intervention.
	'Unclear risk' of bias.	Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk'.
ALLOCATION CONCEALMENT Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.	'Low risk' of bias.	Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: • Central allocation (including telephone, web-based and pharmacy-controlled randomization); • Sequentially numbered drug containers of identical appearance; • Sequentially numbered, opaque, sealed envelopes.
	'High risk' of bias.	Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: • Using an open random allocation schedule (e.g. a list of random numbers); • Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); • Alternation or rotation; • Date of birth; • Case record number; • Any other explicitly unconcealed procedure.
	'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

Bias	Judgment	Criteria
SELECTIVE REPORTING Reporting bias due to selective outcome reporting.	‘Low risk’ of bias.	Any of the following: • The study protocol is available and all of the study’s pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; • The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
	‘High risk’ of bias.	Any one of the following: • Not all of the study’s pre-specified primary outcomes have been reported; • One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; • One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); • One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; • The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
	‘Unclear risk’ of bias.	Insufficient information to permit judgement of ‘Low risk’ or ‘High risk’. It is likely that the majority of studies will fall into this category.
OTHER BIAS Bias due to problems not covered elsewhere in the table.	‘Low risk’ of bias.	The study appears to be free of other sources of bias.
	‘High risk’ of bias.	There is at least one important risk of bias. For example, the study: • Had a potential source of bias related to the specific study design used; or • Has been claimed to have been fraudulent; or • Had some other problem.
	‘Unclear risk’ of bias.	There may be a risk of bias, but there is either: • Insufficient information to assess whether an important risk of bias exists; or • Insufficient rationale or evidence that an identified problem will introduce bias.
BLINDING OF PARTICIPANTS AND PERSONNEL Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.	‘Low risk’ of bias.	Any one of the following: • No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; • Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
	‘High risk’ of bias.	Any one of the following: • No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; • Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
	‘Unclear risk’ of bias.	Any one of the following: • Insufficient information to permit judgment of ‘Low risk’ or ‘High risk’; • The study did not address this outcome.
BLINDING OF OUTCOME ASSESSMENT Detection bias due to knowledge of the allocated interventions by outcome assessors.	‘Low risk’ of bias.	Any one of the following: • No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; • Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
	‘High risk’ of bias.	Any one of the following: • No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; • Blinding of outcome assessment, but likely that the blinding could have been broken and the outcome measurement is likely to be influenced by lack of blinding.
	‘Unclear risk’ of bias.	Any one of the following: • Insufficient information to permit judgment of ‘Low risk’ or ‘High risk’; • The study did not address this outcome.

Bias	Judgment	Criteria
INCOMPLETE OUTCOME DATA Attrition bias due to amount, nature or handling of incomplete outcome data.	'Low risk' of bias.	Any one of the following: • No missing outcome data; • Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); • Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; • Missing data have been imputed using appropriate methods.
	'High risk' of bias.	Any one of the following: • Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; • 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization; • Potentially inappropriate application of simple imputation.
	'Unclear risk' of bias.	Any one of the following: • Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided); • The study did not address this outcome.

[a]Adapted from the Cochrane Collaboration Risk of Bias Tool. See Higgins JP, Altman DG, Sterne JA. Chapter 8: Assessing the risk of bias in included studies. In: Higgins JP, Green S, eds. Cochrane handbook for systematic reviews of interventions. The Cochrane Collaboration; 2011.

Appendix E. Newcastle-Ottawa Quality Assessment Scale

Selection (tick one box in each section)	
1. Representativeness of the intervention cohort	
a) truly representative	☐
b) somewhat representative	☐
c) selected group of patients	☐
d) no description of the derivation of the cohort	☐
2. Selection of the non-intervention cohort	
a) drawn from the same community as the intervention cohort	☐
b) drawn from a different source	☐
c) no description of the derivation of the non-intervention cohort	☐
3. Ascertainment of intervention	
a) secure record	☐
b) structured interview	☐
c) written self-report	☐
d) other / no description	☐
4. Demonstration that outcome of interest was not present at start of study	
a) yes	☐
b) no	☐
Comparability (tick one or both boxes, as appropriate)	
1. Comparability of cohorts on the basis of the design or analysis	
a) study controls for age, sex, marital status	☐
b) study controls for any additional factors (e.g. socio-economic status, education)	☐
Outcome (tick one box in each section)	
1. Assessment of outcome	
a) independent blind assessment	☐
b) record linkage	☐
c) self-report	☐
d) other / no description	☐
2. Was follow up long enough for outcomes to occur	
a) yes, if median duration of follow-up >= 6 month	☐
b) no, if median duration of follow-up < 6 months	☐
3. Adequacy of follow up of cohorts	
a) complete follow up: all subjects accounted for	☐
b) subjects lost to follow up unlikely to introduce bias: number lost <= 20%, or description of those lost suggesting no different from those followed	☐
c) followup rate < 80% and no description of those lost	☐
d) no statement	☐

NOS – CODING MANUAL FOR COHORT STUDIES

SELECTION

1) Representativeness of the Exposed Cohort (NB exposure = intervention)

Item is assessing the representativeness of exposed individuals in the community, not the representativeness of the study sample from some general population. For example, subjects derived from groups likely to contain exposed people are likely to be representative of exposed individuals, while they are not representative of all people the community.

Allocation of points as per rating sheet

2) Selection of the Non-Exposed Cohort

Allocation of points as per rating sheet

3) Ascertainment of Exposure

Allocation of points as per rating sheet

4) Demonstration That Outcome of Interest Was Not Present at Start of Study

In the case of mortality studies, outcome of interest is still the presence of a disease/ incident, rather than death. That is to say that a statement of no history of disease or incident earns a point.

COMPARABILITY

1) Comparability of Cohorts on the Basis of the Design or Analysis

Either exposed and non-exposed individuals must be matched in the design and/or confounders must be adjusted for in the analysis. Statements of no differences between groups or that differences were not statistically significant are not sufficient for establishing comparability. Note: If the relative risk for the exposure of interest is adjusted for the confounders listed, then the groups will be considered to be comparable on each variable used in the adjustment.

A maximum of 2 points can be allotted in this category.

OUTCOME

2) Assessment of Outcome

For some outcomes, reference to the medical record is sufficient to satisfy the requirement for confirmation. This may not be adequate for other outcomes where reference to specific tests or measures would be required.

a) Independent or blind assessment stated in the paper, or confirmation of the outcome by reference to secure records (health records, etc.)
b) Record linkage (e.g. identified through ICD codes on database records)
c) Self-report (i.e. no reference to original health records or documented source to confirm the outcome)
d) No description.

3) Was Follow-Up Long Enough for Outcomes to Occur

An acceptable length of time should be decided before quality assessment begins.

4) Adequacy of Follow Up of Cohorts

This item assesses the follow-up of the exposed and non-exposed cohorts to ensure that losses are not related to either the exposure or the outcome.

Allocation of points as per rating sheet

Appendix F. Thresholds for Quality Assessment

A. Quality Assessment Thresholds for Cochrane Risk of Bias (RoB) Tool

There are three categories for describing the quality of studies: "Good", "Fair", and "Poor". To categorize studies, we used the Cochrane Collaboration interpretation of risk of bias within a study to establish the threshold between good and fair quality studies and between fair and poor quality studies. We assessed study quality using the following criteria:

- Good quality: low risk of bias for all domains.
- Fair quality: unclear risk of bias for one or more domains and no known important limitation that could invalidate its results.
- Poor quality: high risk of bias for one or more domains.

Table F1. Threshold for study quality

Risk of bias	Interpretation	Within a study	Across studies
Low	Plausible bias unlikely to seriously alter the results.	Low risk of bias for all key domains.	Most information is from studies at low risk of bias.
Unclear	Plausible bias that raises some doubt about the results.	Unclear risk of bias for one or more key domains.	Most information is from studies at low or unclear risk of bias.
High	Plausible bias that seriously weakens confidence in the results.	High risk of bias for one or more key domains.	The proportion of information from studies at high risk of bias is sufficient to affect the interpretation of results.

Adapted from the Cochrane Handbook Chapter 8

B. Quality Assessment Thresholds for the Newcastle-Ottawa Scale

The Newcastle-Ottawa Scale includes 3 categories, with a maximum of 9 points, based on:

Selection ***(maximum of 4 points)***

1) Representativeness of the exposed cohort (one point)
2) Selection of the non-exposed cohort (one point)
3) Ascertainment of exposure (one point)
4) Demonstration that outcome of interest was not present at start of study (one point)

Comparability ***(maximum of 2 points)***

1) Comparability of cohorts on the basis of the design or analysis
    a) Study controls for age (one point)
    b) Study controls for any additional factor (one point)

Outcome ***(maximum of 3 points)***

1) Assessment of outcome (one point)
2) Was follow-up long enough for outcomes to occur (one point)
3) Adequacy of follow up of cohorts (one point)

Table F2. Scoring algorithm for risk of bias assessment

Quality rating	Selection Domain	Comparability Domain	Outcome Domain
Good	≥3	≥2	≥2
Fair	2	≥1	≥2
Poor	0-1	0	0-1

Appendix G. Reasons for Exclusion

Exclusion Code	Exclusion Reason	Count
X-1	Does not report results from a clinically-oriented smoking cessation intervention/a cessation intervention that intersects with clinical care and is aimed at pregnant women or postpartum women.	2015
X-2	Does not report original research.	90
X-3	Does not include 20 or more participants in each group.	159
X-4	Not an eligible study design.	245
X-5	Does not report outcomes/results for smoking cessation intervention(s).	184
X-6	Not an eligible study population.	120
X-7	Does not report biochemical validation of abstinence outcomes.	57
X-8	Unavailable.	3
X-9	Duplicate.	3
N/A	Related to an included study but does not address a Key Question	8

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Appendix H. Evidence Tables

Table H1. Evidence table (Reference ID# 2)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Eades et al., 2012 **Country:** Australia **Enrollment period:** June 2005 to December 2008 **Setting:** Aboriginal community-controlled health services prenatal clinics **Funding:** Grant (National Health and Medical Research Council) **Author industry relationship disclosures:** None **Study Design:** RCT **Blinding:** None Randomization was by week of clinic attendance	**Intervention:** Tailored advice and support at first antenatal visit; asked to bring partner/support at second visit; nicotine replacement therapy offered if still smoking 7 to 10 days after initial visit. **Intervention provider:** Initial visit: Physician; Followup: Aboriginal health workers and midwives **Intervention setting:** Prenatal clinics **Comparator:** *Usual care:* Advice to quit smoking and support/ advice from provider at scheduled antenatal visits. **Followup:** 36 weeks gestation **Groups:** **G1:** Intervention **G2:** Usual care	**Inclusion criteria:** • Aboriginal or Torres Strait Islanders attending first prenatal apt at one of the Aboriginal community controlled health services • ≤ 20 weeks gestation • Age 16 or older • Self-reported current smokers or recent quitters (quit when they knew of pregnancy) • Residents of local area **Exclusion criteria:** • Mental illness • Receiving treatment for chemical dependencies other than tobacco or alcohol **Enrollment, n:** **G1:** 148 **G2:** 115 **Followup, n (%):** **G1:** 98 (66.2) **G2:** 78 (67.8) **Age, mean years ± SD:** NR **Education:** NR **Gestation, median weeks (interquartile range):**	**Maternal smoking status** Quit since becoming pregnant, n (%): **G1:** 24 (18) **G2:** 8 (8) Number of cigarettes per day, median (interquartile range): **G1:** 10 (5 to15) **G2:** 10 (4 to 15)	**Maternal smoking status** Smoking at end of pregnancy, n (%): **G1:** 137 (93) **G2:** 111 (97) **G1 vs. G2:** OR=0.95 (95% CI: 0.90 to 1.01) Relapse: NR **Child/infant outcomes:** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: High Allocation concealment: High Selective reporting: Low Blinding patients/personnel: High Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G1: 12 (8 to 17) **G2:** 12 (8 to 19) **Insurance status:** NR **Parity, n (%):** No previous births **G1:** 41 (30) **G2:** 28 (30) One previous birth **G1:** 30 (22) **G2:** 22 (23) 2 or more previous births **G1:** 66 (48) **G2:** 44 (47) **Partner status:** **G1:** 118 (88) **G2:** 86 (92) **Partner smoking status:** NR **Race/ethnicity:** Aboriginal, % **G1 + G2:** 100 **Socioeconomic status:** NR **Smoking history:** Regular smoker, n (%): **G1:** 92 (67) **G2:** 73 (77) Occasional smoker, n (%): **G1:** 21 (15) **G2:** 14 (15)			

Table H2. Evidence table (Reference ID# 11)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Coleman et al., 2012 **Country:** England **Enrollment period:** May 2007 to February 2010 **Setting:** 7 Hospital prenatal clinics **Funding:** Grant **Author industry relationship disclosures:** 0/7 **Study Design:** RCT **Blinding:** Double blind (provider and patient)	**Intervention:** Behavioral support and nicotine replacement therapy **Intervention provider:** Research midwives **Intervention setting:** Clinic **Comparator:** Placebo **Groups:** **G1:** Intervention **G2:** Placebo **Followup:** 1 month after quit date and end of pregnancy (at delivery)	**Inclusion criteria:** • Pregnant 12 to 24 weeks gestation and agreed to set a quit date • Age 16 to 50 years • Smoked 10 or more cigarettes daily before pregnancy • Currently smoked 5 or more cigarettes per day • Exhaled carbon monoxide concentration of 8 ppm or greater **Exclusion criteria:** • Known major fetal abnormalities • Inability to provide informed consent • Chemical or alcohol dependence • Contraindications to nicotine replacement therapy (recent cerebral vascular accident or transient ischemic attack, chronic generalized skin disorders, sensitivity to nicotine patch) **Enrollment, n:** **G1:** 521 **G2:** 529 **Followup, n (%):** **G1:** 485 (93.1) **G2:** 496 (93.8) **Age, mean years ± SD:** **G1:** 26.4 ± 6.2 **G2:** 26.2 ± 6.1	**Maternal smoking status** Number of cigarettes per day, median (IQR): **G1:** 13 (10 to 20) **G2:** 15 (10 to 20) Cotinine level, median (IQR): **G1:** 123.1 (80.1 to 179.8) **G2:** 121.2 (77.2 to 175.9)	**Maternal smoking status** Abstinence from quit date to delivery[1], n (%): **G1:** 49 (9.4) **G2:** 40 (7.6) **G1 vs. G2:** OR=1.26 (95% CI: 0.82 to 1.96) Abstinent for 1 month after quit date[2], n (%): **G1:** 111 (21.3) **G2:** 62 (11.7) **G1 vs. G2:** OR=2.05 (95% CI: 1.46 to 2.88) Abstinence from quit date to delivery[3], n (%): **G1:** 42 (8.1) **G2:** 32 (6.0) **G1 vs. G2:** OR=1.36 (95% CI: 0.84 to 2.19) Abstinence at delivery[b], n (%) **G1:** 63 (12.1) **G2:** 53 (10.0) **G1 vs. G2:** OR=1.23 (95% CI: 0.84 to1.82) Relapse: NR **Child/infant outcomes** Miscarriage, n (%): **G1:** 3 (0.6) **G2:** 2 (0.4) Stillbirth, n (%): **G1:** 5/512 (1.0) **G2:** 2/519 (0.4)	**Overall quality:** Good **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

[1] Biochemically verified by salivary cotinine
[2] Biochemically verified by exhaled carbon monoxide
[3] Biochemically verified at 1 month after quit date and at delivery

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Education: Age leaving full-time education, mean ± SD **G1:** 16.2 ± 1.4 **G2:** 16.3 ± 1.7 **Gestation, mean weeks ± SD:** **G1:** 16.2 ± 3.6 **G2:** 16.3 ± 3.5 **Insurance status:** NR **Parity, n (%):** 0 to 1 previous births **G1:** 356 (68.3) **G2:** 356 (68.3) 2 to 3 previous births **G1:** 129 (24.8) **G2:** 129 (24.8) 4 or more previous births **G1:** 36 (6.9) **G2:** 36 (6.9) **Partner status:** NR **Partner smoking status:** Partner smokes, n (%) **G1:** 356 (74.0) **G2:** 360 (74.7) **Race/Ethnicity, n (%):** White **G1:** 503 (96.5) **G2:** 515 (97.4) Other **G1:** 18 (3.5) **G2:** 14 (2.6) **Socioeconomic status:** NR **Smoking history:** Cigarettes per day before pregnancy, median number (IQR): **G1:** 20 (15 to 20) **G2:** 20 (15 to 20)		Neonatal death, n: **G1:** 0/507 **G2:** 2/517 Post-neonatal death, n: **G1:** 1/507 **G2:** 0/517 Gestational age, mean weeks ± SD: **G1:** 39.5 ± 2.1 **G2:** 39.5 ± 2.1 **G1 vs. G2:** p=NS Birthweight, mean kg ± SD: **G1:** 3.18 ± 0.61 **G2:** 3.20 ± 0.59 **G1 vs. G2:** p=NS Low birthweight (less than 2.5 kg), n (%): **G1:** 56/507 (11.0) **G2:** 43/517 (8.3) **G1 vs. G2:** 1.38 (0.90 to 2.09) NICU admission, n (%): **G1:** 33/507 (6.5) **G2:** 35/517 (6.8) **G1 vs. G2:** OR=0.96 (95% CI: 0.58 to 1.57) Asthma exacerbation : NR Asthma hospitalization : NR Upper respiratory infection: NR **Adverse**	

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
				Events: See manuscript table 4 on page 816.	

Table H3. Evidence table (Reference ID# 18)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Naughton et al., 2012 **Country:** United Kingdom **Enrollment period:** December 2008 to October 2009 **Setting:** 7 national health service trusts **Funding:** Grant (Cancer Research UK) **Author industry relationship disclosures:** None **Study Design:** RCT **Blinding:** Allocation sequence was concealed; Researcher collecting data was blinded.	**Intervention:** Self-help intervention (MIQuit), tailored text messages, and leaflet **Intervention provider:** Midwives **Intervention setting:** Home **Comparator:** *Control:* non-tailored self-help leaflet and assessment text messages only **Followup:** 3 months **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • < 21 weeks pregnant • Age 16 years or older • Smoked 7 or more cigarettes per week • Owned or had regular use of mobile phone • Understand written English **Enrollment, n:** **G1:** 102 **G2:** 105 **Followup, n (%):** **G1:** 96 (94) **G2:** 102 (97) **G1 + G2:** 174/198 (88) **Age, mean years ± SD:** **G1:** 27.2 ± 6.4 **G2:** 26.6 ± 6.2 **Education, n (%):** None **G1:** 16 (16) **G2:** 16 (15) GCSEs or similar **G1:** 49 (49) **G2:** 54 (51) A-levels **G1:** 17 (17) **G2:** 12 (11) Degree or similar **G1:** 8 (8) **G2:** 3 (3) Other **G1:** 11 (11) **G2:** 20 (19) **Gestation, mean weeks ± SD:** **G1**: 12.7 ± 3.3 **G2**: 12.8 ± 3.2 **Insurance status, %:** UK National Health Service **G1 + G2:** 100	**Maternal smoking status** Number of cigarettes per day, n (%): 1 to 3 **G1:** 13 (13) **G2:** 18 (17) 4 to 5 **G1:** 19 (19) **G2:** 12 (11) 6 to 10 **G1:** 37 (36) **G2:** 43 (41) 11 to 15 **G1:** 15 (15) **G2:** 20 (19) 16 to 20 **G1:** 14 (14) **G2:** 12 (11) 21 or more **G1:** 4 (4) **G2:** 0 (0) Nicotine dependency category (determined by cigarettes per day and time to first cigarette after waking) Low **G1:** 27 (27) **G2:** 37 (35) Medium **G1:** 49 (48) **G2:** 40 (38) High **G1:** 26 (26) **G2:** 28 (27)	**Maternal smoking status** Abstinence at 12 weeks, n (%) **G1:** 12 (12.5) **G2:** 8 (7.8) **G1 vs. G2:** OR=1.68 (95% CI: 0.66 to 4.31) Relapse: NR **Child/infant outcomes:** NR **Adverse events:** NR	**Overall quality:** Good **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Parity, n (%): No previous births **G1:** 50 (50) **G2:** 41 (39) One previous birth **G1:** 27 (27) **G2:** 36 (34) Two or more previous births **G1:** 24 (24) **G2:** 28 (27) **Partner status, n (%):** No partner **G1:** 13 (13) **G2:** 9 (9) **Partner smoking status, n (%):** Smokes **G1:** 68 (67) **G2:** 72 (69) Does not smoke **G1:** 21 (21) **G2:** 24 (23) **Race/ethnicity, n (%):** White **G1:** 101 (100) **G2:** 104 (100) **Socioeconomic status:** NR **Smoking history:** Cigarettes per day before pregnancy, n (%) None **G1:** 1 (1) **G2:** 1 (1) 1 to 3 **G1:** 1 (1) **G2:** 0 (0) 4 to 5 **G1:** 2 (2) **G2:** 4 (4) 6 to 10 **G1:** 13 (13) **G2:** 18 (17) 11 to 15 **G1:** 23 (23) **G2:** 18 (17) 16 to 20			

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G1: 41 (40) **G2:** 43 (41) 21 or more **G1:** 21 (21) **G2:** 21 (20) Smoked in prior pregnancy, n (%) **G1:** 45 (44) **G2:** 61 (59) Did not smoke in prior pregnancy, n (%) **G1:** 11 (11) **G2:** 11 (11)			

Table H4. Evidence table (Reference ID# 31)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Ondersma et al., 2012 **Country:** USA **Enrollment period** NR **Setting:** 4 urban prenatal clinics **Funding:** Grant (Federal) **Author industry relationship disclosures:** 1/6 **Study Design :** RCT **Blinding:** Research staff blinded to brief intervention status	**Intervention:** A computer-delivered 5As brief intervention (CD-5As) Computer assisted, simplified low intensity contingency management (CM-Lite) **Intervention provider:** Research assistants **Intervention setting:** Prenatal clinic **Comparator:** Treatment as usual from prenatal care providers and non-smoking intervention computer videos. **Followup:** 10 weeks **Groups:** **G1:** Combined (CD-5As + CM-Lite) **G2:** CD-5As **G3:** CM-Lite **G4:** Usual care	**Inclusion criteria:** • Age 18 or older • No further than 27 weeks gestation • Reported smoking in the past week while pregnant **Exclusion criteria:** • Unable to understand spoken English **Enrollment, %:** **G1:** 30 **G2:** 26 **G3:** 28 **G4:** 26 **Followup, %:** **G1:** 26 **G2:** 23 **G3:** 22 **G4:** 23 **Age, mean years ± SD:** **G1:** 27.7 ± 6.1 **G2:** 25.8 ± 4.8 **G3:** 29.3 ± 6.7 **G4:** 28.5 ± 7.5 **Education:** NR **Gestation, weeks >20, n (%):** **G1:** 8 (26.7) **G2:** 7 (26.9) **G3:** 14 (50.0) **G4:** 7 (26.9) **Insurance status:** NR **Parity:** NR **Partner status:** NR **Partner smoking status:**	**Maternal smoking status** Number of cigarettes per day in past week, mean ± SD: **G1:** 8.3 ± 9.6 **G2:** 7.6 ± 7.4 **G3:** 8.3 ± 5.8 **G4:** 7.6 ± 9.6 Exhaled carbon monoxide ≥4 ppm, n (%): **G1:** 15 (50.0) **G2:** 15 (57.7) **G3:** 17 (60.7) **G4:** 17 (65.4) Fagerstrom test for nicotine dependence score ≥4, n (%): **G1:** 20 (66.7) **G2:** 11 (42.3) **G3:** 14 (50.0) **G4:** 13 (50.0)	**Maternal smoking status** Abstinence at 10 weeks post-randomization (7-day point prevalence plus carbon monoxide validation), n (%) **G1:** 5 (19.2) **G2:** 7 (30.4) **G3:** 2 (9.1) **G4:** 2 (8.7) **G1 vs. G4:** OR=2.5 (95% CI: 0.4 to 14.4) **G2 vs. G4:** OR=4.6 (95% CI: 0.84 to 25.2) **G3 vs. G4:** OR=1.1 (95% CI: 0.1 to 8.2) Abstinence at 10 weeks post-randomization (30-day abstinence plus carbon monoxide validation), n (%) **G1:** 5 (19.2) **G2:** 6 (26.1) **G3:** 2 (9.1) **G4:** 1 (4.3) Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Good **Risk of bias:** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Lives with a smoker **G1:** 21 (70.0) **G2:** 15 (57.7) **G3:** 15 (53.6) **G4:** 19 (73.1) **Race/ethnicity, n (%):** Black **G1:** 27 (90.0) **G2:** 24 (92.3) **G3:** 21 (75.0) **G4:** 18 (69.2) **Socioeconomic status:** NR **Smoking history:** NR			

Table H5. Evidence table (Reference ID# 58)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Phillips et al., 2012 **Country:** USA **Enrollment period:** May 2009 to February 2010 **Setting:** Academic hospital neonatal intensive care unit **Funding:** Grant (AAP Richmond Center, Flight Attendant Medical Research Institute, and March of Dimes) **Author industry relationship disclosures:** None (0/6) **Study Design:** RCT **Blinding:** Salivary cotinine levels assessed by blinded investigator	**Intervention:** Enhanced support of mother-infant bonding with materials (videos, pamphlets, books and DVDs) during newborn hospitalization plus weekly encouragement to remain smoke-free and breastfeeding support, handouts on danger of secondhand smoke **Intervention provider:** Neonatologist **Intervention setting:** NICU **Comparator:** Weekly encouragement to remain smoke free and routine breast feeding support, handouts on danger of secondhand smoke **Groups:** **G1:** Intervention **G2:** Control **Followup:** 8 weeks postpartum	**Inclusion criteria:** • Mothers of infants admitted to NICU who used tobacco during or within 1 year before pregnancy • Not currently smoking **Exclusion criteria:** • Mothers of infants admitted at greater than 1 week of age or with an expected length of stay less than 1 week • Mothers who had never smoked or who smoked at time of delivery • Used illicit drugs • Unavailable (incarceration, adoption or surrogacy) • Non English speakers **Enrollment, n:** **G1:** 24 **G2:** 30 **Followup, n (%):** **G1:** 21 (87.5) **G2:** 28 (93.3) **Age, mean years ± SD:** **G1:** 24 ± 5 **G2:** 24 ± 5 **Education, %:** High school/vocational **G1:** 81 **G2:** 86 College graduate **G1:** 19 **G2:** 14 **Gestation, weeks:**	**Maternal smoking status** Number of cigarettes per day: NA Quit smoking, %: Before pregnancy **G1:** 33 **G2:** 35 First trimester **G1:** 52 **G2:** 57 Second trimester **G1:** 5 **G2:** 4746 Third trimester **G1:** 10 **G2:** 4	**Maternal smoking status** Relapse prevention at 8 weeks postpartum, %: **G1:** 81 **G2:** 46 **G1 vs. G2:** p<0.001 **Child/infant outcomes:** NR **Adverse events:** NR	**Overall quality:** Good **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		NA **Insurance status, %:** Medicaid **G1:** 52 **G2:** 82 Private **G1:** 48 **G2:** 18 **Parity:** NR **Partner status, %:** Has partner **G1:** 81 **G2:** 82 **Partner smoking status:** Smoker in home, % **G1:** 48 **G2:** 32 **Race/ethnicity, %:** Caucasian **G1:** 67 **G2:** 68 Hispanic **G1:** 19 **G2:** 14 African-American **G1:** 9 **G2:** 18 Other **G1:** 5 **G2:** 0 **Smoking history:** Smoked, mean years ± SD **G1:** 5 ± 4 **G2:** 7 ± 5			

Table H6. Evidence table (Reference ID# 72)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Windsor et al., 2011 **Country:** USA **Enrollment period:** NR **Setting:** 10 prenatal clinics **Funding:** Grant (NIH) **Author industry relationship disclosures:** None 0/4 **Study Design:** RCT **Blinding:** NR	**Intervention:** Assist procedures from the 5A's: "Commit to Quit Smoking During and After Pregnancy" video, Windsor guide "A Pregnant Woman's Guide to Quit Smoking", and ≤ 10 minute counseling session Both groups received Ask-Advise-Assess-Arrange procedures from the 5A's. **Intervention provider:** Clinic staff (n=28) **Intervention setting:** Prenatal clinic **Comparator:** Usual care **Followup:** Saliva collected at baseline, ≥ 60 days and ≤90 days postpartum **Groups:** **G1a:** Intervention **G1b:** Intervention-lost to followup **G2a:** Control **G2b:** Control- lost to followup	**Inclusion criteria[a]:** • Pregnant smokers attending one of the selected clinics (see footnote) • Smoker defined as patient who reported ≥ 1 cigarettes (even a puff) in last 7 days or had cotinine ≥ 20ng/mL. • Medicaid **Enrollment, n:** **G1a:** 452 **G1b:** 95 **G2a:** 449 **G2b:** 97 **Followup, n:** NR **Age, mean years:** **G1a:** 22.2 **G1b:** 23.0 **G2a:** 22.4 **G2b:** 24.0 **Education:** NR **Gestation, mean weeks:** **G1a:** 9.2 **G1b:** 9.6 **G2a:** 10.0 **G2b:** 9.2 **Insurance status:** Medicaid, % **G1:** 100 **G2:** 100 **Parity:** NR **Partner status:** NR **Partner smoking status:**	**Maternal smoking status:** Cigarettes per day, mean: **G1a:** 10.4 **G1b:** 12.0 **G2a:** 9.8 **G2b:** 10.3 Cotinine, mean ng/mL: **G1a:** 181 **G1b:** 178 **G2a:** 163 **G2b:** 181	**Maternal smoking status** Abstinence, n (%)[b] **G1a + G1b:** 65/544 (12.0) **G2a + G2b:** 55/549 (10.0) Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Random sequence generation: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: High Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Unclear

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Living with smoker, % **G1a:** 73.7 **G1b:** 66.0 **G2a:** 69.8 **G2b:** 75.3 **Race/ethnicity:** Black, % **G1:** 15.4 **G2:** 14.7 **G1:** 15.7 **G1:** 19.6 **Socioeconomic status:** NR **Smoking history:** NR			

Notes: [a] Site selection: Eight matched dyads (16 counties) created based on number of smokers and percent black and white. One county per dyad was randomly selected included 10 prenatal care clinics and 28 regular staff members. [b] Baseline data presented for G1: 452 + 95= 547 and G2: 449+97= 546; These numbers do not match the N's reported in Table 2G1: 544 and G2: 549

Table H7. Evidence table (Reference ID# 171)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Reitzel et al., 2010 **Country:** USA **Enrollment period:** October 2004 to April 2008 **Setting:** Recruited from Houston metropolitan area **Funding:** Federal grants **Author industry relationship disclosures:** None 0/12 **Study Design:** RCT **Blinding:** None	**Intervention:** • Motivation and Problem Solving (MAPS) • MAPS+ **Intervention provider:** Trained counselor **Intervention setting:** Prenatal clinic and home **Comparator:** Usual Care **Groups**[4] **G1a:** MAPS **G1b:** MAPS+ **G2:** Usual care **Followup:** 26 weeks	**Inclusion criteria:** • English speaking pregnant age 18 or older • Stopped smoking during pregnancy (prior to 30th week) or within 2 months prior to becoming pregnant • 30th to 33rd week of pregnancy **Exclusion criteria:** • High-risk pregnancy **Enrollment, n:** **G1a:** 68 **G1b:** 68 **G2:** 115 **Followup, n (%):** 26 weeks **G1a:** 46 (67.6) **G1b:** 52 (76.5) **G2:** 88 (76.5) **Age, mean years ± SD:** **G1:** 24.6 ± 5.2 **G2:** 24.6 ± 5.5 **Education, %:** Less than high school/ GED **G1:** 22.1 **G2:** 14.8 More than high school/ GED **G1:** 77.9 **G2:** 85.2 **Gestation:** NR **Insurance status:** NR	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 9.7 ± 7.1 **G2:** 10.7 ± 8.2	**Maternal smoking status** Abstinence at week 8, mean %: **G1:** 41.9 **G2:** 27.8 **G1 vs. G2:** p=NR Abstinence at week 26, mean %: **G1:** 22.8 **G2:** 16.5 **G1 vs. G2:** p=0.08 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: High Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

[4] Comment: Groups were randomized to MAPS or MAPS + but results presented for both groups combined.

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Parity: NR **Partner status, %:** Partner **G1:** 61.0 **G2:** 65.2 No partner **G1:** 39.0 **G2:** 34.8 **Partner smoking status:** NR **Race/ethnicity, %:** White **G1:** 36.0 **G2:** 34.8 Black **G1:** 32.4 **G2:** 32.2 Latino **G1:** 30.1 **G2:** 30.4 Other **G1:** 1.5 **G2:** 2.6 **Socioeconomic status:** Household income less than $30,000/year, % **G1:** 55.2 **G2:** 54.7 Household income $30,000 or more/year, % **G1:** 44.8 **G2:** 45.3 **Smoking history:** Quit within 4 weeks of pregnancy, % ± SD **G1+G2:** 7.6 ± 2.05 Quit smoking about 8 weeks after pregnancy, % ± SD **G1+G2:** 92.4 ± 5.70			

Table H8. Evidence table (Reference ID# 176)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Cinciripini et al., 2010 **Country:** USA **Enrollment period:** January 2005 to January 2008 **Setting:** Clinic **Funding:** Grant (Federal) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Cognitive Behavioral Analysis System of Psychotherapy **Intervention provider:** Intervention: 5 PhD level postdocs in clinical psychology Control: Delivered by same as above plus 2 masters level counselors **Intervention setting:** In-person counseling sessions **Comparator:** Time and contact control focused on health and wellness **Followup:** Assessments at 2, 4, and 6 weeks post-treatment and 3 and 6 months postpartum **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Women ≤ 32 weeks pregnant, aged 16 or older who smoked at least a puff or more during past 7 days • Have a telephone • Express willingness to quit smoking during the study (women with goal of reducing cigarette consumption only not eligible) **Exclusion criteria:** • Currently participating in psychotherapy or other smoking cessation treatment • Unstable medical conditions or psychological instability **Enrollment, n:** **G1:** 133 **G2:** 133 **Followup, n (%):** **G1:** 128 (96.2) **G2:** 129 (97.0) **Age, mean years ± SD:** **G1:** 24.4 ± 6.5 **G2:** 25.5 ± 5.3 **Education, n (%):** Less than high school **G1:** 38 (29.7) **G2:** 44 (34.1) High school/GED **G1:** 45 (35.2) **G2:** 45 (34.9)	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 9.8 ± 7.1 **G2:** 9.7 ± 6.7 Motivation to quit smoking (0-50) **G1:** 40.8 ± 7.6 **G2:** 41.3 ± 6.1 Fagerstrom Test for Nicotine Dependence, mean score ± SD: **G1:** 3.2 ± 2.1 **G2:** 3.5 ± 2.0	**Maternal smoking status** Abstinence at end of treatment, n (%): **G1:** 58 (45.3) **G2:** 51 (39.2) **G1 vs. G2:** OR=1.2 (95% CI: 0.7 to 2.0) Abstinence at 3 months post-treatment, n (%): **G1:** 47 (36.7) **G2:** 40 (31.0) **G1 vs. G2:** OR=1.3 (95% CI: 0.8 to 2.2) Abstinence at 6 months post-treatment, n (%): **G1:** 23 (18.0) **G2:** 21 (16.3) **G1 vs. G2:** OR=1.1 (95% CI: 0.6 to 2.2) Abstinence at 3 months postpartum, n (%): **G1:** 24 (18.8) **G2**: 23 (17.8) **G1 vs. G2:** OR=1.1 (95% CI: 0.5 to 2.4) Abstinence at 6 months postpartum, n (%): **G1:** 9 (9) **G2:** 12 (12) **G1 vs. G2:** OR=0.8 (95% CI: 0.3 to 1.8) Relapse: NR	**Overall quality:** Good **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Vocational school some college or greater **G1:** 45 (35.2) **G2:** 40 (31.1) **Gestation, weeks mean ± SD** **G1:** 19.5 ± 8.5 **G2:** 19.6 ± 8.5 **Insurance status:** Medicaid or county health care, n (%) **G1:** 79 (61.7) **G2:** 83 (64.3) **Parity:** NR **Partner status** Married and living with partner **G1:** 24 (18.8) **G2:** 25 (19.4) Not married and living with partner **G1:** 27 (21.1) **G2:** 31 (24.0) Never married and not living w/partner **G1:** 64 (50) **G2:** 61 (47.3) Widowed, divorced or separated **G1:** 13 (10.2) **G2:** 12 (9.3) **Partner smoking status:** NR **Race/ethnicity, n (%):** African American **G1:** 71 (55.5) **G2:** 68 (52.7) White **G1**: 41 (32.0) **G2:** 45 (34.9) Hispanic **G1:** 13 (10.2) **G2:** 11 (8.5) Other **G1**: 3 (2.3) **G2:** 5 (3.9) **Socioeconomic**		**Child/infant outcomes** NR **Adverse events:** NR	

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		status: Less than $10,000 **G1:** 48 (37.5) **G2:** 40 (31.0) $10,000 to $19,999 **G1:** 19 (14.8) **G2:** 17 (13.2) $20,000 to $29,999 **G1:** 5 (3.9) **G2:** 6 (4.7) More than $30,000 **G1:** 25 (19.5) **G2:** 28 (21.7) Prefer not to say **G1:** 31 (24.2) **G2:** 38 (29.7) **Smoking history:** Age started smoking, mean year ± SD **G1:** 15.4 ± 3.2 **G2:** 15.9 ± 3.9 Number of cigarettes per day before finding out pregnant, mean ± SD **G1:** 16.8 ± 8.7 **G2:** 15.8 ± 9.1			

Table H9. Evidence table (Reference ID# 178)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Gadomski et al., 2011 **Country:** United States **Enrollment period:** NR **Setting:** 22 WIC offices and prenatal clinics, New York **Funding:** Grant (Tobacco Use Prevention and Control Program) **Author industry relationship disclosures:** NR **Study Design:** Prospective cohort **Blinding:** None	**Intervention:** Implementation models of combined prenatal and postpartum counseling and incentive-based intervention (BABY & ME—Tobacco Free program) *Model 1*: On-site BABY & ME—Tobacco free counselors at sites where the program was first implemented *Model 2:* Social workers and counselors in a public health department *Model 3*: Itinerant tobacco cessation specialists; longer visits. **Intervention provider:** Counselors, social workers, tobacco cessation specialists **Intervention setting:** WIC sites; prenatal clinics **Comparator:** Standard care and/or referral to telephonic cessation counseling **Groups:** **G1:** Model 1 **G2:** Model 2 **G3:** Model 3 **G4:** Standard care **Followup:** 12 months postpartum	**Inclusion criteria:** Pregnant smokers (regular or occasional) or women who quit 1 month before or during pregnancy **Enrollment, n:** **G1:** 378 **G2:** 22 **G3:** 152 **G4:** 66 **Followup, n:** 4th prenatal counseling session **G1 + G2 + G3:** 707 3 months postpartum **G1 + G2 + G3:** 425 **Age, mean years:** **G1:** 23.0 **G2:** 23.1 **G3:** 23.6 **G4:** 24.9 **Education:** Years of school, mean: **G1:** 12.1 **G2:** 11.6 **G3:** 12.0 **G4:** 12.3 **Gestation, weeks:** NR **Insurance status:** Medicaid, % **G1:** 62 **G2:** 73 **G3:** 70 **G4:** 38 **Parity:** Number of children, mean **G1:** 0.70 **G2:** 0.50 **G3:** 0.68 **G4:** 1.01 **Partner status:**	**Maternal smoking status:** Number of cigarettes per day, mean: **G1:** 13.3 **G2:** 9.7 **G3:** 15.5 **G4:** 11.6	**Maternal smoking status:** Abstinence at the 4th prenatal counseling session, %: **G1:** 61.0 **G2:** 50.0 **G3:** 60.5 **G4:** NR Abstinence at 3 months postpartum, %: **G1:** 52.0 **G2:** 37.5 **G3:** 77.0 **G4:** NR Relapse: NR **Child/infant outcomes:** NR **Adverse events:** NR	**Overall quality:**

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		NR **Partner smoking status:** Spouse/partner smokes, % **G1:** 61 **G2:** 73 **G3:** 64 **G4:** 54 **Race/ethnicity, %:** Caucasian **G1:** 90 **G2:** 91 **G3:** 89 **G4:** 95 **Socioeconomic status:** NR **Smoking history:** Years smoking, mean **G1:** 7.4 **G2:** 6.9 **G3:** 8.2 **G4:** 8.6 Number of prior quit attempts, mean **G1:** 3.3 **G2:** 4.6 **G3:** 3.2 **G4:** 3.0		

Table H10. Evidence table (Reference ID# 181)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Hennrikus et al., 2010 **Country:** USA **Enrollment period:** 2005 **Setting:** WIC clinic and urban university outpatient clinic **Funding:** Grant (Robert Wood Johnson) **Author industry relationship disclosures:** 0/6 **Study Design:** RCT **Blinding:** None	**Intervention:** Subjects identified woman in their social network to help them quit smoking. Supporters of subject in intervention group received monthly contact from counselor about providing effective support. Supporters of control subjects not contacted. All subjects received one in-person counseling session designed to increase motivation to quit and provide info about community resources. Intervention group **Intervention provider:** Counselor **Intervention setting:** Clinic/home **Comparator:** No further contact **Followup:** 3 months postpartum **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • First or second trimester of pregnancy • Current smoker • Age 18 or older **Enrollment, n:** **G1:** 54 dyads **G2:** 28 dyads **Followup, n (%):** **G1:** 44 subjects/43 confidants **G2:** 19 subjects/19 confidants **Age, median years (range):** **G1 + G2:** 24 (18 to 39) **Education:** Less than high school, % **G1 + G2:** 65 **Gestation:** NR **Insurance status:** NR **Parity:** Had other children, % **G1 + G2:** 71 **Partner status:** Married or living in marriage-like relationship, % **G1 + G2:** 48 **Partner smoking status:** NR **Race/ethnicity:** Racial minority including Hispanic, % **G1 + G2:** 67 **Socioeconomic status:**	**Maternal smoking status** Number of cigarettes per day, median (range): **G1+ G2:** 5 (1 to 25)	**Maternal smoking status** Abstinence at end of pregnancy, %: **G1:** 13.0 **G2:** 3.6 **G1 vs. G2:** p=NS Abstinence at 3 months post-partum, %: **G1:** 9.3 **G2:** 0 **G1 vs. G2:** p=NR Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Fair **Risk of bias** Randomization: Low Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Unclear Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		NR **Smoking history:** NR			

Table H11. Evidence table (Reference ID# 231)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Stotts et al., 2009 **Country:** USA **Enrollment period:** NR **Setting:** Clinic **Funding:** Grant (Federal and Robert Wood Johnson) **Author industry relationship disclosures:** 0/7 **Study Design:** RCT **Blinding:** None	**Intervention:** • Personalized feedback on nicotine effects on developing fetus during ultrasound (US) and subsequent motivation interviewing (MI)-based counseling sessions • Best practice (BP) (counseling as per AHRQ 5 A's strategy) plus ultrasound (US) feedback **Intervention provider:** MI**:** delivered by masters level trained counselors US**:** sonographers **Intervention setting:** NR **Comparator:** Best practice (BP) only **Followup:** End of pregnancy (8th month gestation) **Groups:** **G1:** MI + US **G2:** BP + US **G3:** BP only	**Inclusion criteria:** • Current smoking, report of having smoked a cigarette in past 7 days • Age 16 and older • Gestational age between 16 to 26 weeks • English speaking **Enrollment, n:** **G1:** 120 **G2:** 120 **G3:** 120 **Followup, n:** Completed study **G1:** 115 **G2:** 115 **G3:** 114 **Age, mean years ± SD:** **G1:** 25.21 ± 6.01 **G2:** 25.45 ± 6.45 **G3:** 24.65 ± 5.69 **Education, mean years ± SD:** **G1:** 11.63 ± 1.72 **G2:** 11.37 ± 2.28 **G3:** 11.40 ± 1.99 **Gestation, mean weeks ± SD** **G1:** 21.12 ± 3.40 **G2:** 22.48 ± 3.64 **G3:** 23.63 ± 3.50 **Insurance status:** NR **Parity:** Number of births, mean ± SD **G1:** 1.5 ± 1.5 **G2:** 1.2 ± 1.4 **G3:** 1.3 ± 1.4 **Partner status, n (%):** Married, living with partner **G1:** 32 (26.67) **G2:** 18 (15.00) **G3:** 26 (21.67) Not married, living with partner **G1:** 45 (37.50) **G2:** 52 (43.33)	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 11.03 ± 8.14 **G2:** 11.78 ± 9.47 **G3:** 11.72 ± 8.73 Cotinine, median ng/ml: **G1:** 131.0 **G2:** 116.0 **G3:** 117.0	**Maternal smoking status** Abstinence at end of pregnancy, %: **G1:** 18.3 **G2:** 14.2 **G3:** 10.8 **G1 vs. G2 vs. G3:** p=0.30 **(G1 + G2) vs. G2:** p=0.17 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Fair **Risk of bias** Randomization: Low Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G3: 39 (32.50) Widowed/divorced/separated **G1:** 17 (14.17) **G2:** 11 (9.17) **G3:** 17 (14.17) Never married, not living with a partner **G1:** 26 (21.67) **G2:** 39 (32.50) **G3:** 38 (31.67) **Partner smoking status:** NR **Race/ethnicity, n (%):** African American **G1:** 52 (44.44) **G2:** 46 (40.35) **G3:** 36 (31.30) Caucasian **G1:** 58 (49.57) **G2:** 65 (57.02) **G3:** 75 (65.22) Other **G1:** 7 (5.98) **G2:** 3 (2.63) **G3:** 4 (3.48) Hispanic **G1:** 18 (28.57) **G2:** 25 (20.83) **G3:** 20 (16.67) **Socioeconomic status, n (%):** Income less than $15,000/year **G1:** 68 (56.67) **G2:** 67 (55.83) **G3:** 59 (49.58) Income $15,000 to $24,999 **G1:** 33 (27.50) **G2:** 28 (23.33) **G3:** 34 (28.57) Income $25,000 to $34,999 **G1:** 7 (5.83) **G2:** 15 (12.50) **G3:** 14 (11.76) Income $35,000 to $40,000 **G1:** 12 (10.00) **G2:** 10 (8.33) **G3:** 12 (10.08) **Smoking history:** Age smoking regularly, mean years ± SD **G1:** 16.19 ± 4.35 **G2:** 16.02 ± 3.72 **G3:** 15.78 ± 3.15			

Table H12. Evidence table (Reference ID# 291)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Oncken et al., 2008 **Country:** USA **Enrollment period:** July 2003 to September 2006 **Setting:** 3 hospital prenatal clinics, private practice **Funding:** Grant (Federal) Nicotine gum provided by Glaxo-Smith Kline **Author industry relationship disclosures:** 2/7 **Study Design:** RCT **Blinding:** Double blind	**Intervention:** Nicotine gum (2 mg) plus individualized behavioral counseling **Intervention Provider:** Study nurse **Intervention setting:** Clinic **Comparator:** Placebo gum plus individualized behavioral counseling **Followup:** Visit 4 (6 weeks post-treatment), visit 5 (32 to 34 weeks gestation), and visit 6 (6 to 12 weeks postpartum) **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Currently smoking at least 1 cigarette/day • ≤ 26 weeks gestation • Age 16 or older • Able to speak English or Spanish • Intending to carry pregnancy to term • Living in stable residence • High risk pregnancies included if they were medically stable (e.g. HIV or diabetes) **Exclusion criteria:** • Evidence of current illicit drug or alcohol disorder within preceding month (women taking methadone maintenance included if reported not currently using illicit drugs • Twins or other multiple gestation • Unstable psychiatric problem, unstable medical problem , or medical problem that would interfere with study participation	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 9.99 ± 6.1 **G2:** 8.84 ± 5.7 Expired carbon monoxide, mean ppm ± SD: **G1:** 9.43 ± 6.3 (n=100) **G2:** 8.69 ± 7.3 (n=94) Cotinine level, mean ng/ml ± SD: **G1:** 672 ± 438 (n=98) **G2:** 633 ± 559 (n=93)	**Maternal smoking status** Abstinence[5] at visit 4 (6 weeks post-treatment), mean %[6]: **G1:** 13.0 **G2:** 9.6 **G1 vs. G2:** p=0.NS Abstinence[d] at visit 5 (32 to 34 weeks gestation), mean %[e]: **G1:** 18.0 **G2:** 14.9 **G1 vs. G2:** p=0.56 Abstinence[d] at 6 to 12 weeks postpartum, mean %[e]: **G1:** 11.0 **G2:** 9.6 **G1 vs. G2:** p=NS Relapse: NR **Child/infant outcomes** Gestational age, mean weeks ± SD: **G1:** 38.9 ± 1.7 **G2:** 38.0 ± 3.3 **G1 vs. G2:** p=0.014 Birthweight, mean grams ± SD: **G1:** 3287 ± 566 **G2:** 2950 ± 653 **G1 vs. G2:** p<0.001 NICU admission,	**Overall quality:** Fair **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Unclear Other: Low

[5] Carbon monoxide exhalation value less than 8 ppm
[6] Standard errors shown in figures only

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Enrollment, n: **G1:** 100 **G2:** 94 **Followup, n (%):** Perinatal outcomes **G1:** 97 (97) **G2:** 89 (95) Visit 6 to 12 weeks postpartum, n (%) **G1:** 65 (65) **G2:** 47 (50) **Age, mean years ± SD:** **G1:** 25.5 ± 6.8 **G2:** 24.7 ± 5.4 **Education, n (%):** Less than high school **G1:** 53 (53) **G2:** 44 (47) High school **G1:** 28 (28) **G2:** 36 (39) More than high school **G1:** 19 (19) **G2:** 13 (14) **Gestation, mean weeks ± SD:** **G1:** 17.1 ± 5.6 **G2:** 17.1 ± 5.5 **Insurance status, n (%):** Public **G1:** 81 (81) **G2:** 80 (85) Private **G1:** 19 (19) **G2:** 14 (15) **Parity:** Number of previous pregnancies, median (interquartile range) **G1:** 3 (2, 4) **G2:** 3 (2, 4) First pregnancy, n (%) **G1:** 16 (16)		n (%): **G1:** 7 (7) **G2:** 11 (13) **G1 vs. G2:** p=0.20 Asthma exacerbation: NR Asthma hospitalization: NR Upper respiratory infection: NR **Adverse events:** Maternal hospitalization, n (%): **G1:** 9 (9) **G2:** 8 (9) **G1 vs. G2:** p=0.90 Low birthweight (less than 2500 g), n (%): **G1:** 2 (2) **G2:** 16 (18) **G1 vs. G2:** p<0.001 Very low birthweight (less than 1500 g), n (%): **G1:** 1 (1) **G2:** 4 (5) **G1 vs. G2:** p=0.19 Preterm delivery (less than 37 weeks gestation), n (%): **G1:** 7 (7.2) **G2:** 16 (18.0) **G1 vs. G2:** p=0.027 Spontaneous abortion, n (%): **G1:** 2 (2) **G2:** 0 (0)	

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G2: 16 (17) History preterm delivery, n (%) **G1:** 13 (13) **G2:** 16 (17) **Partner status:** Married or partnered, n (%) **G1:** 30 (30) **G2:** 28 (30) **Partner smoking status:** NR **Race/ethnicity, n (%):** Hispanic **G1:** 53 (53) **G2:** 52 (55) Non-Hispanic white **G1:** 38 (38) **G2:** 30 (32) Non-Hispanic African-American **G1:** 8 (8) **G2:** 7 (7) Other **G1:** 1 (1) **G2:** 5 (5) **Socioeconomic status:** NR **Smoking history:** Cigarettes per day before pregnancy, mean ± SD **G1:** 17.5 ± 9.6 **G2:** 17.8 ± 9.3 Cigarettes per day previous 7 days, mean ± SD **G1:** 10.2 ± 6.6 **G2:** 8.7 ± 5.7 Previous quit attempts, mean ± SD **G1:** 3.03 ± 5.69 **G2:** 2.55 ± 5.66 Fagerstrom score, mean ± SD **G1:** 3.83 ± 1.91 **G2:** 3.55 ± 1.95		**G1 vs. G2:** p=0.50 Intrauterine fetal death, n (%): **G1:** 2 (2) **G2:** 1 (1) **G1 vs. G2:** p=0.54 Second trimester pregnancy loss, n (%): **G1:** 0 (0) **G2:** 1 (1) **G1 vs. G2:** p=0.47 Newborn death, n (%): **G1:** 1 (1) **G2**: 2 (2) **G1 vs. G2:** p=0.60 Any serious adverse event, n (%): **G1:** 24 (24.7) **G2:** 33 (37.9) **G1 vs. G2:** p=0.06	

Two outcome p-values for comparison between groups presented 1) with substitution of missing data with last available data or 2) analysis of change scores for participants with follow-up data (completer analysis)

Table H13. Evidence table (Reference ID #336)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Bullock et al., 2009 **Country:** USA **Enrollment period:** January 2002 to October 2005 **Setting:** Recruitment from WIC clinics **Funding:** Grant (Federal) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** *Social support:* Baby BEEP- scheduled weekly phone call and 24 hour access to nurse for additional social support *Booklets:* Eight booklets "Stop Smoking"- first distributed at recruitment and others mailed weekly **Intervention provider:** Nurses **Intervention setting:** Home **Comparator:** Control **Followup:** 6 weeks post delivery **Groups:** **G1:** Social support plus booklets **G2:** Social support only **G3:** Booklets only **G4:** Control	**Inclusion criteria:** • Reported smoking at least 1 cigarette per day • Spoke English • Age ≥18 years • < 24 weeks gestation **Exclusion criteria:** • Spontaneous abortion prior to home visit **Enrollment, n:** **G1:** 170 **G2:** 175 **G3:** 179 **G4:** 171 **Followup, n:** **G1:** 129 **G2:** 132 **G3:** 141 **G4:** 128 **Age, mean years ± SD:** **G1:** 23.1 ± 4.3 **G2:** 24.0 ± 4.7 **G3:** 23.6 ± 4.8 **G4:** 23.9 ± 4.8 **Education, n (%):** High school diploma/ GED **G1:** 112 (66) **G2:** 100 (57) **G3:** 109 (61) **G4:** 116 (68) **Gestation:** NR **Insurance status:** NR **Parity, mean ± SD:** **G1:** 0.92 ± 1.1 **G2:** 0.97 ± 1.1 **G3:** 0.89 ± 1.2 **G4:** 1.1 ± 1.2 **Partner status:**	**Maternal smoking status** Number of cigarettes per day: NR	**Maternal smoking status** Abstinence in late pregnancy, n (%): **G1:** 22 (17) **G2:** 29 (22) **G3:** 27 (19.2) **G4:** 22 (17.2) Abstinence in postpartum, n (%:) **G1:** 16 (12.4) **G2:** 15 (11.4) **G3:** 19 (13.5) **G4:** 17 (13.3) Relapse: NR **Child/infant outcomes:** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Living in married like relationship, n (%) **G1:** 108 (64) **G2:** 138 (79) **G3:** 114 (64) **G4:** 123 (72) **Partner smoking status** NR **Race/ethnicity, n (%):** White **G1:** 151 (89) **G2:** 161 (92) **G3:** 161 (90) **G4:** 161 (90) African-American **G1:** 6 (3.5) **G2:** 4 (2.3) **G3:** 6 (3.4) **G4:** 8 (4.7) Hispanic **G1:** 3 (1.8) **G2:** 3 (1.7) **G3:** 6 (3.4) **G4:** 0 Asian **G1:** 0 **G2:** 0 **G3:** 0 **G4:** 2 (1.2) Native American **G1:** 5 (2.9) **G2:** 4 (2.3) **G3:** 0 **G4:** 1 (0.6) Other **G1:** 5 (2.9) **G2:** 3 (1.7) **G3:** 6 (3.4) **G4:** 3 (1.8) **Socioeconomic status:** Participants recruited from WIC clinics **Smoking history:** 1 or more quit attempts in pregnancy, % **G1:** 65 **G2:** 66 **G3:** 73			

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G4: 68 Fagerstrom score before pregnancy, mean **G1:** 4.7 **G2:** 4.9 **G3:** 5.0 **G4:** 4.8 Fagerstrom score after pregnancy was known, mean **G1:** 2.7 **G2:** 2.8 **G3:** 2.5 **G4:** 2.8			

Table H14. Evidence table (Reference ID# 337)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Heil et al., 2008 **Country:** USA **Enrollment period:** NR **Setting:** University based research clinic **Funding:** Grant **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Contingent vouchers redeemable for retail items earned contingent on breath CO specimen ≤ 6 ppm during initial 5 days, then based on urine cotinine ≤80 ng/ml thereafter (starting amount $6.25 increased by $1.25 for each consecutive negative specimen up to maximum $45) **Intervention provider:** Study staff **Intervention setting:** NR **Comparator:** Non-contingent voucher ($15/visit antepartum, $20/visit postpartum regardless of smoking status) **Followup:** 24 weeks postpartum **Groups:** **G1:** Contingent voucher **G2:** Non-contingent voucher	**Inclusion criteria:** • Self-reported smoking at a prenatal visit • Gestational age ≤ 20 weeks • Reside within county where study clinic located and plans to remain in area for 6 months post delivery • English speaking **Exclusion criteria:** • Incarceration • Previous participation in study or resides with previous study participant **Enrollment, n:** **G1:** 40 **G2:** 42 **Followup, n:** **G1:** 37 **G2:** 40 **Age, mean years ± SD:** **G1:** 25.3 ± 6.1 **G2:** 23.4 ± 4.1 **Education, mean years ± SD:** **G1:** 11.9 ± 2.6 **G2:** 11.8 ± 1.9 **Gestation, mean weeks ± SD:** **G1:** 8.9 ± 2.7 **G2:** 9.5 ± 3.6 **Insurance status, %:** Private **G1:** 19 **G2:** 13	**Maternal smoking status** Number of cigarettes per day in past 7 days, mean ± SD: **G1:** 7.9 ± 5.6 **G2:** 9.5 ± 5.9 Expired carbon monoxide, mean ppm ± SD: **G1:** 10.1 ± 5.6 **G2:** 11.9 ± 6.6 Urinary cotinine, mean ng/ml ± SD: **G1:** 943.4 ± 562.3 **G2:** 1000.5 ± 590.4	**Maternal smoking status** Abstinence at end of pregnancy, % **G1:** 41 **G2:** 10 **G1 vs. G2:** p=0.003 Abstinence at 12 weeks postpartum, % **G1:** 24 **G2:** 3 **G1 vs. G2:** p=0.006 Abstinence at 24 weeks postpartum, %: **G1:** 8 **G2:** 3 **G1 vs. G2:** p=NS Relapse: NR **Child/infant outcomes** **G1:** n=34 **G2:** n=39 Gestational age at delivery, mean weeks ± SD: **G1:** 39.1 ± 0.4 **G2:** 38.5 ± 0.3 **G1 vs. G2:** p=0.27 Preterm birth, % **G1:** 9 **G2:** 23 **G1 vs. G2:** p=0.10 Birthweight, mean grams ± SD: **G1:** 3355 ± 96 **G2:** 3102 ± 89	**Overall quality:** Fair **Risk of bias** Randomization: Low Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Parity, %: First pregnancy **G1:** 54 **G2:** 45 **Partner status, %:** Married **G1:** 14 **G2:** 23 **Partner smoking status, %:** Living with smoker **G1:** 73 **G2:** 85 **Race/ethnicity, %:** Caucasian **G1:** 89 **G2:** 98 **Socioeconomic status:** NR **Smoking history:** Pre-pregnancy cigarettes per day, mean number ± SD **G1:** 18.7 ± 8.9 **G2:** 18.4 ± 6.5 Started smoking, mean age ± SD **G1:** 13.9 ± 2.4 **G2:** 14.0 ± 2.8		**G1 vs. G2:** p=0.06 Low birthweight, %: **G1:** 9 **G2:** 21 **G1 vs. G2:** p=0.16 NICU admission, %: **G1:** 12 **G2:** 15 **G1 vs. G2:** p=0.74 **Adverse events:** NR	

Table H15. Evidence table (Reference ID# 395)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Pollak et al., 2007 **Country:** USA **Enrollment period:** May 2003 to August 2005 **Setting:** 14 clinics **Funding:** Grant (Federal) **Author industry relationship disclosures:** 0/11 **Study Design:** RCT **Blinding:** None	**Intervention:** Cognitive behavior therapy (CBT) plus nicotine replacement therapy (NRT) **Intervention provider:** Trained support specialists **Intervention setting:** Clinic **Comparator:** CBT only **Followup:** Telephone surveys at 7 weeks post randomization, 38 weeks gestation, and 3 months postpartum. **Groups:** **G1:** CBT+ NRT **G2:** CBT	**Inclusion criteria:** • Between 13 to 25 weeks pregnant • Smoked ≥100 cigarettes in their lifetime • Currently smoked ≥ 5 cigarettes per day • Planning to continue prenatal care in a participating clinic • ≥ 18 years old • Spoke English **Exclusion criteria:** • Evidence of cognitive or mental health problems, drug or alcohol addiction • History of placental abruption, poorly controlled hypertension, cardiac arrhythmia, MI within past 6 months, previous pregnancy with congenital anomaly, or family history congenital anomalies **Enrollment, n:** **G1:** 122 **G2:** 59 **Followup, n (%)** 38 weeks gestation **G1:** 73 (59.8)	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 11 ± 5 **G2:** 12 ± 5	**Maternal smoking status** Abstinence at 7 weeks post randomization (unadjusted), %: **G1:** 18.0 **G2:** 3.0 **G1 vs. G2:** p=0.006 Abstinence at 7 weeks post randomization (adjusted)[7], %: **G1:** 24.0 **G2:** 8.0 **G1 vs. G2:** p=0.02 Abstinence at 38 weeks pregnancy (unadjusted), %: **G1:** 14.0 **G2:** 2.0 **G1 vs. G2:** p=0.01 Abstinence at 38 weeks pregnancy (adjusted)[f], %: **G1:** 18.0 **G2:** 7.0 **G1 vs. G2:** p=0.04 Relapse: NR **Child/infant outcomes** Perinatal outcome data available, n **G1:** 113 **G2:** 58 Gestational age, mean weeks ± SD:	**Overall quality:** Poor **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: High Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

[7] Adjusted analysis controlled for number of completed counseling sessions

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G2: 29 (50.9) 3 months postpartum **G1:** 76 (62.3) **G2:** 39 (66.1) **Age, mean years ± SD:** **G1:** 27 ± 6 **G2:** 26 ± 5 **Education** Less than high school, % **G1:** 27 **G2:** 31 High school/GED, % **G1:** 31 **G2:** 33 Vocational school, % **G1:** 6 **G2:** 10 Some college, % **G1:** 33 **G2:** 17 College graduate or higher, % **G1:** 3 **G2:** 9 **Gestation, mean weeks ± SD:** **G1:** 17 ± 3 **G2:** 18 ± 4 **Insurance status:** NR **Parity:** First pregnancy, % **G1:** 18 **G2:** 12 Number of prior pregnancies, median (interquartile range): **G1:** 2 (1, 4) **G2:** 2 (1, 3) **Partner status, %:** Has partner **G1:** 66 **G2:** 69 **Partner smoking**		**G1:** 37.9 ± 3.1 **G2:** 38.6 ± 2.7 **G1 vs. G2:** p=0.14 Birthweight, mean grams ± SD: **G1:** 3061 ± 661 **G2:** 3132 ± 688 **G1 vs. G2:** p=0.51 NICU admission, n: **G1:** 13 **G2:** 4 Asthma exacerbation: NR Asthma hospitalization: NR Upper respiratory infection: NR **Adverse Events:** At least one serious adverse event, n (%): **G1:** 34/113 (30) **G2:** 10/58 (17) **Risk difference:** 0.13 (95% CI: 0.00 to 0.26), p=0.07 At least one serious adverse event adjusted for previous history of preterm birth, %: **G1:** 27.0 **G2:** 18.0 **Risk difference:** 0.09 (95% CI: 0.05 to 0.2), p=0.26	

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		status: NR **Race/ethnicity, %:** White **G1:** 67 **G2:** 73 Black **G1:** 26 **G2:** 19 Other **G1:** 7 **G2:** 8 **Socioeconomic status, %:** Employed full time **G1:** 30 **G2:** 31 Employed part time **G1:** 21 **G2:** 9 Not employed **G1:** 49 **G2:** 60 **Smoking history:** Cigarettes smoked daily 30 days before pregnancy, mean ± SD **G1:** 19 ± 9 **G2:** 20 ± 8 24-hour quit attempt, % **G1**: 57 **G2:** 61 24-hour quit attempts, mean number ± SD **G1:** 3 ± 3 **G2:** 2 ± 2 Longest quit, mean days ± SD **G1:** 100 ± 171 **G2:** 79 ± 133 24-hour quit attempt in previous pregnancy, % **G1:** 50 **G2:** 62 Longest quit in previous pregnancy, mean days ± SD **G1:** 102 ± 111			

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G2: 63 ± 90			

Table H16. Evidence table (Reference ID# 396)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Ruger et al., 2008 **Country:** USA **Enrollment period:** NR **Setting:** Community-based health care practices and health care centers **Funding:** Grant (NIH) **Author industry relationship disclosures:** 0/4 **Study Design:** RCT **Blinding:** None	**Intervention:** Motivational interviewing and self-help smoking cessation manuals **Intervention provider:** Public health nurse **Intervention setting:** Home **Comparator:** *Usual care:* Up to 5 minute intervention outlining harmful effects of smoking during and after pregnancy and self-help materials. **Followup:** 1 month after intervention and 6 months postpartum **Groups:** **G1:** Intervention **G2:** Usual care **Ga:** Smoker **Gb:** Quitter	**Inclusion criteria:** • < 28 weeks pregnant • Speak English or Spanish • Current smoker or recent quitter (quit during previous 3 months) **Exclusion criteria:** • In drug addiction treatment **Enrollment, n:** **G1:** 156 **G1a:** 132 **G1b:** 24 **G2:** 146 **G2a:** 113 **G2b:** 33 **Followup, n:** **G1:** 131 **G2:** 128 **Age, mean years (range):** **G1:** 25.6 (24.5 to 26.5) **G2:** 25.7 (24.6 to 26.8) **Education, n (%):** Less than high school **G1:** 54 (34.6) **G2:** 44 (30.1) Completed high school **G1:** 57 (36.5) **G2:** 67 (45.9) Post secondary **G1:** 45 (28.9) **G2:** 34 (23.3) **Gestation, weeks:** NR **Insurance status, n (%):** Major medical **G1:** 39 (25.3)	**Maternal smoking status** Number of cigarettes per day: NR	**Maternal smoking status** Abstinence at 6 months postpartum, n (%): **G1:** 7/110 (6.4) **G2:** 8/100 (8.0) **G1 vs. G2:** p=NS Relapse prevention, n (%): **G1:** 9/21 (42.9) **G2:** 5/28 (17.9) **G1 vs. G2:** p=0.056 **Child/infant outcomes** Gestational age: NR Birthweight, mean grams ± SD: **G1:** 3241.2 ± 586.0 **G2:** 3321.3 ± 612.1 **G1 vs. G2:** p=0.186 Low birthweight (less than 2500 g), n: **G1:** 16 **G2:** 11 NICU admission, n (%): **G1:** 14 (10.1) **G2:** 23 (17.6) Respiratory problems at birth, n (%): **G1:** 21 (15.1) **G2:** 23 (17.8) Asthma exacerbation: NR	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Unclear Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G2: 41 (28.3) Medicaid **G1:** 10 (6.5) **G2:** 7 (4.8) Mass health **G1:** 110 (71.4) **G2:** 103 (71.0) Other **G1:** 1 (0.7) **G2:** 2 (1.4) **Parity:** NR **Partner status:** Married, n (%) **G1:** 34 (21.8) **G2:** 27 (18.5) **Partner smoking status:** NR **Race/ethnicity, n (%):** White **G1:** 109 (70.3) **G2:** 94 (64.4) Asian/pacific islander **G1:** 1 (0.7) **G2:** 0 Black **G1:** 30 (19.4) **G2:** 22 (15.1) Hispanic **G1:** 13 (8.3) **G2:** 16 (11.0) American Indian, Aluet or Eskimo **G1:** 2 (1.3) **G2:** 1 (0.7) Other **G1:** 12 (7.7) **G2:** 29 (19.9) **Socioeconomic status:** NR **Smoking history, n (%):** Age of first smoke 13 years or younger **G1:** 48 (30.8) **G2:** 50 (34.3) 14 to 17 years		Asthma hospitalization: NR Upper respiratory infection: NR **Adverse events:** NR	

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G1: 67 (43.0) **G2:** 75 (51.4) 18 years or older **G1:** 39 (25.0) **G2:** 20 (13.7) Smoked during previous pregnancy, n (%): **G1:** 55 (72.4) **G2:** 63 (80.8)			

Table H17. Evidence table (Reference ID #463)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Albrecht et al., 2006 **Country:** USA **Enrollment period:** NR **Setting:** 5 hospital-based and 2 community based prenatal clinics **Funding:** Grant (Federal) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** *Teen FreshStart (TFS):* 8-week group smoking abstinence program with peer buddy, peer co-leader, group setting, individual support, peer modeling, and peer sanctions to promote smoking cessation *Teen FreshStart-Buddy (TFS-B):* TFS plus participants required to bring a nonsmoking female of similar age (buddy) to sessions. **Intervention provider:** PhD or masters level registered nurse **Intervention setting:** Antenatal clinic or community site **Comparator:** Usual care **Followup:** 8 weeks post randomization (end of intervention) and 1 year post study entry **Groups:** **G1:** TFS **G2:** TFS-B **G3:** Usual care	**Inclusion criteria:** • Pregnant teens aged 14 to 19 years • 12 to 28 weeks gestation • Able to read, write and understand English • Smoking at least one cigarette per day • Single marital status • No previous live births • Capable of being reached by telephone **Exclusion criteria:** • Signs of pregnancy complications • Required home confinement by physician • Development of pregnancy complications after enrollment cause for removal **Enrollment, n:** **G1:** 47 **G2:** 45 **G3:** 50 **Followup, n:** Completed intervention **G1:** 32 **G2:** 38 **G3:** 41 Completed 1-year followup **G1:** 27 **G2:** 24 **G3:** 30 **Age, mean years ± SD:** **G1:** 16.73 ± 1.05	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 7.04 ± 4.38 **G2:** 7.31 ± 4.52 **G3:** 6.76 ± 5.00	**Maternal smoking status** Change in smoking behavior (short term), OR (95% CI) p-value **G3 vs. G1:** 2.106 (0.542 to 8.191) p=0.158 **G3: vs. G2:** 3.730 (1.001 to 13.893) p=0.010 **G1 vs. G2:** 1.771 (0.549 to 5.708) p=0.208 Change in smoking behavior (long term), Exp (β) (95% CI) p-value **G3 vs. G1:** 1.260 (0.296 to 5.370) p=0.681 **G3: vs. G2:** 0.599 (0.108 to 3.312) p=0.440 **G1 vs. G2:** 0.476 (0.089 to 2.550) p=0.254 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Good **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G2: 17.02 ± 1.34 **G3:** 16.95 ± 1.35 **Education, n (%):** 6th grade **G1:** 1 (2.1) **G2:** 0 **G3:** 0 7th grade **G1**: 0 **G2:** 0 **G3:** 3 (6.0) 8th grade **G1:** 3 (6.4) **G2:** 4 (8.9) **G3:** 3 (6.0) 9th grade **G1:** 12 (25.5) **G2:** 13 (28.9) **G3:** 4 (8.0) 10th grade **G1:** 9 (19.1) **G2:** 12 (26.7) **G3:** 13 (26.0) 11th grade **G1:** 7 (14.9) **G2:** 5 (11.1) **G3:** 14 (28.0) 12th grade **G1:** 5 (10.6) **G2:** 7 (15.6) **G3:** 5 (10) GED **G1:** 1 (2.1) **G2:** 2 (4.4) **G3:** 6 (12.0) **Gestation, mean weeks ± SD:** **G1:** 19.49 ± 7.25 **G2:** 19.43 ± 6.95 **G3:** 20.31 ± 7.44 **Insurance status:** NR **Parity:** NR **Partner smoking status:** NR **Race/ethnicity, n (%):** White **G1:** 24 (51.1) **G2**: 24 (53.3)			

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G3: 22 (44.0) Black **G1:** 18 (38.3) **G2:** 17 (37.8) **G3:** 21 (42.0) Other **G1**: 3 (6.4) **G2:** 2 (4.4) **G3:** 2 (4.0) **Socioeconomic status:** Annual household income, n (%) Less than $5,000 **G1:** 6 (12.8) **G2:** 12 (26.7) **G3:** 10 (20.0) $5,000 to $14,999 **G1:** 3 (6.4) **G2:** 7 (15.6) **G3:** 8 (16.0) $15,000 to $24,999 **G1:** 7 (14.9) **G2:** 1 (2.2) **G3**: 0 $25,000 to $34,999 **G1:** 1 (2.1) **G2**: 2 (4.4) **G3:** 1 (2.0) $35,000 to $44,999 **G1:** 1 (2.1) **G2:** 1 (2.2) **G3:** 0 $45,000 to $60,000 **G1:** 1 (2.1) **G2:** 0 **G3**: 0 Do not know **G1:** 23 (48.9) **G2:** 16 (35.6) **G3:** 25 (50.0) **Smoking history:** Family smokers, mean number ± SD **G1:** 2.36 ± 2.60 **G2:** 2.09 ± 1.86 **G3:** 2.13 ± 2.45 Started smoking, mean age ± SD **G1:** 13.82 ± 1.50 **G2:** 13.40 ± 1.96 **G3:** 12.88 ± 2.44 Cigarettes per day before pregnancy, mean ± SD **G1:** 14.08 ± 7.22		

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G2: 14.62 ± 9.72 **G3:** 15.75 ± 10.38			

Table H18. Evidence table (Reference ID #495)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Dornelas et al., 2006 **Country:** USA **Enrollment period:** NR **Setting:** Prenatal clinic from tertiary care community hospital **Funding:** Grant **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** *Counseling:* one 90-minute psychotherapy session followed by bimonthly telephone calls after delivery **Intervention provider:** Masters-prepared mental health counselors trained in smoking cessation **Intervention setting:** Clinic/home **Comparator:** *Usual care:* standard smoking cessation guidelines, training of residents and nurses, chart prompt, personalized quit message, education booklet **Followup:** End of pregnancy and 6 months postpartum **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • ≥ 18 years old • ≤ 30 weeks gestation • Current smokers **Exclusion criteria:** • Recent history (previous 6 months) of abuse or dependence on alcohol or other non-nicotine substance • Major psychiatric illness • Lack of telephone **Enrollment, n:** **G1:** 53 **G2:** 52 **Followup, n (%):** End of pregnancy **G1:** 53 (100) **G2:** 52 (100) 6 months postpartum **G1 + G2:** 86 (82) **Age, mean years ± SD:** **G1 + G2:** 26.1 ± 5.8 **Education:** Less than high school, % **G1 + G2:** 54 **Gestation:** 12 to 24 weeks, % **G1 + G2**: 71 **Insurance status:** NR **Parity:** 1 or more children, % **G1 + G2:** 77	**Maternal smoking status** Number of cigarettes per day: **G1 + G2:** 10.93 ± 8.90 10 or fewer cigarettes per day, %: **G1 + G2**: 70.5	**Maternal smoking status** Abstinence at end of pregnancy, %: **G1:** 28.3 **G2:** 9.6 **G1 vs. G2:** p=0.015 Abstinence at 6 months postpartum, %: **G1:** 9.4 **G2:** 3.8 **G1 vs. G2:** p=0.251 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Fair **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		First pregnancy, % **G1 + G2:** 11.4 **Partner status:** Married/ live-in partner, % **G1 + G2**: 35 Unmarried, % **G1 + G2**: 60 **Partner smoking status:** NR **Race/ethnicity, %:** Hispanic **G1 + G2**: 66 Caucasian **G1 + G2:** 17 African American **G1 + G2**: 11 Multi-racial or other **G1 + G2**: 6 **Socioeconomic status:** Household income $15,000/year or less, % **G1 + G2**: 49 **Smoking history:** Pre-pregnancy smoker, mean ± SD **G1 + G2**: 20.8 ± 12.37			

Table H19. Evidence table (Reference ID #497)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Rigotti et al., 2006 **Country:** USA **Enrollment period:** September 2001 to July 2004 **Intervention setting:** Managed care organization and community based prenatal practices **Funding:** Federal grant and Robert Wood Johnson **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Proactive, pregnancy tailored telephone counseling intervention, series of telephone calls accompanied by additional written materials. **Intervention provider:** Counselors **Intervention setting:** Home **Comparator:** Best practice (control) **Followup:** End of pregnancy and 3 months post-partum Assessment by telephone interview (conducted by research assistant). Participants who reported nonsmoking for past 7 days were asked to mail in saliva sample and received $50 for each sample. **Groups:** **G1:** Telephone counseling **G2:** Control	**Inclusion criteria:** • Pregnant women ≤ 26 weeks gestation • Smoked at least 1 cigarette in past 7 days • Age 18 or older • Willing to consider altering their smoking during pregnancy • Reachable by telephone • English speaking • Expected to live in New England for next year **Enrollment, n:** **G1:** 220 **G2:** 222 **Followup, n:** End of pregnancy **G1:** 152 **G2:** 156 Postpartum assessment **G1:** 141 **G2:** 152 Intention to treat analysis for end of pregnancy **G1:** 209 **G2:** 212 Intention to treat analysis for 3 months postpartum **G1:** 209 **G2:** 210 **Age, mean years ± SD:** **G1:** 28.9 ± 6.7 **G2:** 28.1 ± 5.8 **Education, mean years ± SD:** **G1:** 13.1 ± 2.2	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 10.4 ± 7.4 **G2:** 10.0 ± 7.1	**Maternal smoking status** Abstinence at end of pregnancy, n (%): **G1:** 21 (10.0) **G2:** 16 (7.5) **G1 vs. G2:** OR=1.37 (95% CI: 0.69 to 2.70), p=0.39 Abstinence at 3 months postpartum, n (%): **G1:** 14 (6.7) **G2:** 15 (7.1) **G1 vs. G2:** OR=0.93 (95% CI: 0.44 to 1.99), p=1.00 Abstinence at end of pregnancy and at 3 months postpartum[8], n (%): **G1:** 10 (4.8) **G2:** 7 (3.3) **G1 vs. G2:** OR=1.46 (95% CI: 0.54 to 3.90), p=0.47 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Good **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

[8] Cotinine validated at both timepoints

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G2: 13.0 ± 1.9 **Gestation, mean weeks ± SD:** **G1:** 13.1 ± 4.8 **G2:** 12.2 ± 4.4 **Insurance status, n (%):** Private **G1:** 166 (75) **G2:** 156 (70) Public **G1:** 44 (20) **G2:** 52 (23) Other **G1:** 10 (5) **G2:** 14 (6) **Parity, n (%):** Nulliparous **G1:** 112 (51) **G2:** 94 (42) **Race/ethnicity, n (%):** Non-Hispanic white **G1:** 194 (88) **G2:** 192 (87) **Partner status, n (%):** Married or living with partner **G1:** 167 (76) **G2:** 158 (71) **Partner smoking status, n (%):** Smoker **G1:** 149 (71) **G2:** 130 (62) **Socioeconomic status, n (%):** Employed in past year **G1:** 192 (87) **G2:** 201 (91) **Smoking history:** Age started smoking regularly, mean age ± SD **G1:** 15.3 ± 3.0 **G2:** 15.2 ± 2.9 Cigarettes smoked per day before			

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		current pregnancy, mean number ± SD **G1:** 20.9 ± 9.1 **G2:** 20.8 ± 8.3 First morning cigarette within 30 minutes, n (%) **G1:** 100 (45) **G2:** 89 (40) Made quit attempt in this pregnancy, n (%) **G1:** 113 (51) **G2:** 91 (41) Plan to quit in next 30 days, n (%) **G1:** 188 (86) **G2:** 181 (82)			

Notes: Paper also reports subgroup analysis by baseline characteristics (cigarettes/day at study entry; made quit attempt since start of pregnancy; confidence in ability to quit; spouse smoking status.

Table H20. Evidence table (Reference ID# 547)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Suplee, 2005 **Country:** USA **Enrollment period:** NR **Setting:** Medical center and 2 prenatal care sites **Funding:** Grant **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Relapse prevention counseling (Motivational Interviewing) and educational materials **Intervention provider:** Researcher **Intervention setting:** In hospital during postpartum stay **Comparator:** Usual care **Followup:** 6 weeks postpartum **Groups:** **G1:** Intervention **G2:** Usual care	**Inclusion criteria:** • Age 14 to 45 • Self-reported giving up smoking during pregnancy • Received prenatal care • Delivered infant at designated institution • English speaking **Exclusion criteria:** • Adverse pregnancy outcome **Enrollment, n:** **G1:** 30 **G2:** 32 **Followup, n (%):** 6-week postpartum visit **G1 + G2:** 53 (85) **Age, mean years:** **G1 + G2:** 22.6 **Education:** NR **Gestation, weeks:** NA **Insurance:** NR **Parity, %:** No other children at home **G1 + G2:** 52 **Partner status, %:** Single **G1 + G2:** 84 **Partner smoking status:** NR **Race/ethnicity, %:**	**Maternal smoking status** Quit within 3 months of becoming pregnant, %: **G1 + G2:** 10 Quit during 0 to 3 months gestation, %: **G1 + G2:** 52 Quit during 3 to 6 months gestation, %: **G1 + G2:** 23 Quit last 6 to 10 months gestation, %: **G1 + G2:** 15 Positive cotinine value at baseline, %: **G1 + G2**: 39	**Maternal smoking status** Relapse prevention, n (%) **G1:** 11 (37) **G2:** 8 (25) **G1 vs. G2:** p=NS **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Fair **Risk of bias** Randomization: Unclear Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		African-American **G1 + G2:** 81 **Socioeconomic status:** NR **Smoking history, %:** Fewer than 10 cigarettes per day, %: **G1 + G2:** 59			

Notes: Baseline results not reported by intervention group

Table H21. Evidence table (Reference ID# 564)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Tappin et al., 2005 **Country:** Scotland **Enrollment period:** March 2001 to May 2003 **Setting:** 2 hospitals **Funding:** Scottish Executive, Scottish Cot Death Trust, and Bupa Foundation **Author industry relationship disclosures:** 0/9 **Study Design:** RCT **Blinding:** Assessment (administrator collecting primary outcome data)	**Intervention:** Motivational Interviewing in home **Intervention provider:** Midwives **Intervention setting:** Home **Comparator:** *Control:* standard health promotion information **Followup:** 36 weeks gestation **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Women booking at two hospitals in Glasgow who were current smokers • ≤ 24 weeks gestation **Enrollment, n:** **G1:** 351 **G2:** 411 **Followup, n (%):** **G1:** 351 **G2:** 411 **Age, mean years ± SD:** **G1:** 26.5 ± 5.8 **G2:** 26.9 ± 6.6 **Education** NR **Gestation, mean weeks ± SD**: **G1:** 13.3 ± 2.2 **G2:** 13.5 ± 2.7 **Insurance status:** NR **Parity, n (%):** No previous children **G1:** 146 (42) **G2:** 177 (43) One previous child **G1:** 105 (30) **G2:** 143 (35) Two or more previous children **G1:** 99 (28) **G2:** 91 (22) **Partner status:** NR **Partner smoking status:** At least one other smoker in house, n (%) **G1:** 228/351 (56) **G2:** 268/409 (66)	**Maternal smoking status** Number of cigarettes per day: NR Cotinine, mean ng/ml ± SD: **G1:** 128 ± 71 **G2:** 135 ± 82	**Maternal smoking status** Abstinence at end of pregnancy, n (%): **G1:** 17 (4.8) **G2:** 19 (4.6) **G1 vs. G2:** RR=1.05 (95% CI: 0.55 to 1.98) Relapse: NR **Child/infant outcomes** Gestational age, mean weeks ± SD: **G1:** 38.7 ± 4.1 **G2:** 39.1 ± 2.8 **G1 vs. G2:** Δ=−0.39 (95% CI: −0.91 to 0.13) Birthweight, mean grams ± SD: **G1:** 3078 ± 602 **G2:** 3048 ± 642 **G1 vs. G2:** Δ=30 (95% CI: −60 to 121) NICU admission, n (%): **G1:** 32/351 (9.1) **G2:** 53/411 (12.9) **G1 vs. G2:** RR=0.71 (95% CI: 0.47 to 1.07), p=NS Asthma exacerbation: NR Asthma hospitalization: NR	**Overall quality:** Poor **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: High Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Race/ethnicity: NR **Socioeconomic status:** NR **Smoking history:** Age started smoking, mean year (range) **G1:** 15.1 (8 to 26) **G2:** 14.7 (6 to 28) Made at least one previous quit attempt, n (%) **G1:** 231/349 (66) **G2:** 286/411 (70) Smoking level before pregnancy, n (%) Less than 10 **G1:** 57 (16) **G2:** 67 (16) 10 to 20 **G1:** 190 (54) **G2:** 215 (53) 20 or more **G1:** 104 (30) **G2:** 129 (31)		Upper respiratory infection: NR **Adverse events:** Antenatal admission, n (%) **G1:** 57/351 (16.2) **G2:** 53/411 (12.9)	

Table H22. Evidence table (Reference ID# 578)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Hotham et al., 2006 **Country:** Australia **Enrollment period:** NR **Setting:** Women's and children's hospital **Funding:** Australian Department of Health **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Nicotine replacement therapy patch, counseling, and brochures **Intervention provider:** Researchers, midwives **Intervention setting:** Hospital/clinic **Comparator:** *Control:* counseling only **Followup:** Last prenatal visit **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Self-report of smoking 15 or more cigarettes per day • Gestation between 12 and 28 weeks • Interested in quitting **Enrollment, n:** **G1:** 20 **G2:** 20 **Followup, n:** **G1:** 13 **G2:** 13 **Age, mean years:** **G1:** 28.5 **G2:** 30.2 **Education:** NR **Gestation, mean weeks:** **G1:** 19.4 **G2:** 22.8 **Insurance status:** NR **Parity:** Previous pregnancies, mean **G1:** 1.6 **G2:** 2.8 **Partner status:** NR **Partner smoking status:** NR **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:** NR	**Maternal smoking status** Fagerstrom nicotine dependence, mean score: **G1:** 5.4 **G2:** 5.3 Number of cigarettes per day, mean: **G1:** 19.9 **G2:** 19.6	**Maternal smoking status** Abstinence at end of pregnancy, %: **G1:** 15 **G2:** 0 Relapse: NR **Child/infant outcomes** NR **Adverse events:** 5 reported adverse reactions to patches: rash all over body (1); arm felt dead (1); Ill and nauseous (1); increase in morning sickness symptoms (1); exacerbation of postnatal depression (1)	**Overall quality:** Poor **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: High Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality

Table H23. Evidence table (Reference ID# 675)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Pbert et al., 2004 **Country:** USA **Enrollment period:** May 1997 to November 2000 **Setting:** 6 community health clinics with WIC programs **Funding:** Grant (NIH) **Author industry relationship disclosures:** NR **Study Design:** RCT Clinic was unit of randomization **Blinding:** None	**Intervention:** Quit Together (provider training in delivery of smoking cessation intervention; office practice management system with documentation and reminders; coordination of document sharing among clinics) **Intervention provider:** Clinic health care provider **Intervention setting:** Clinic **Comparator:** Usual care **Followup:** End of pregnancy, 1 month postpartum, 3 months postpartum, and 6 months postpartum **Groups:** **G1:** Intervention **G2:** Usual care **Ga:** Current smokers **Gb:** Spontaneous quitters	**Inclusion criteria:** • Receiving prenatal care and WIC services and planning to receive pediatric care at one of the CHCs • English or Spanish speaking • At least 2 months before due date • Current smoker or spontaneous quitter(quit after learning of pregnancy) • Planning to remain in area 6 months after delivery **Enrollment, n:** **G1:** 272 **G1a:** 191 **G1b:** 81 **G2:** 278 **G2a:** 201 **G2b:** 77 **Followup, n (%):** End of pregnancy **G1:** 214 (78.7) **G2:** 254 (91.4) 1 month postpartum **G1:** 174 (70.0) **G2**: 230 (82.7) 3 months postpartum **G1:** 117 (43.0) **G2:** 158 (56.8) 6 months postpartum **G1:** 120 (44.1) **G2:** 161 (57.9) **Age, mean years ± SD:** **G1:** 25.7 ± 6.1	**Maternal smoking status** Smoking status, n (%) Smoker **G1:** 191 (70.2) **G2:** 201 (72.3) Spontaneous quitter **G1:** 81 (29.8) **G2:** 77 (27.8)	**Maternal smoking status** Abstinence at end of pregnancy, %: **G1a:** 26 **G2a:** 12 **G1a vs. G2a:** OR=2.57, p=0.05 Abstinence at 3 months postpartum, %: **G1a:** 10 **G2a**: 5 **G1a vs. G2a:** OR=1.91, p=0.65 Relapse prevention at end of pregnancy, %: **G1b:** 85 **G2b:** 86 **G1b vs. G2b:** OR=1.34, p=0.75 **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G2: 25.8 ± 6.4 **Education, n (%):** Less than high school **G1**: 127 (46.7) **G2:** 173 (62.2) High school **G1:** 145 (53.3) **G2:** 105 (37.8) **Gestation, mean weeks ± SD:** **G1:** 16.45 ± 7.8 **G2:** 15.73 ± 7.5 **Insurance status, n (%):** Medicaid **G1:** 169 (65.5) **G2:** 173 (63.1) Other **G1:** 89 (34.5) **G2:** 101 (36.9) **Parity, n (%):** No previous births **G1:** 116 (43.3) **G2:** 138 (49.8) One previous birth **G1:** 61 (22.8) **G2:** 62 (22.4) Two or more previous births **G1:** 91 (34.0) **G2:** 77 (27.8) **Partner status, n (%):** Married/living with partner **G1:** 85 (31.3) **G2:** 109 (39.2) Not married **G1:**187 (68.8) **G2:** 169 (60.8) **Partner smoking status:** NR **Race/ethnicity, n (%):** White Non-Hispanic **G1:** 62 (22.8) **G2:** 228 (78.6) Black Non-			

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Hispanic **G1:** 106 (39.0) **G2:** 5 (1.8) Hispanic **G1:** 75 (27.6) **G2:** 30 (10.9) Other **G1:** 29 (10.7) **G2:** 13 (4.7) **Socioeconomic status:** NR **Smoking history:** Cigarettes per day prior to pregnancy, mean number ± SD: **G1:** 14.89 ± 11.50 **G2:** 18.43 ± 11.63			

Table H24. Evidence table (Reference ID# 708)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Cope et al., 2003 **Country:** UK **Enrollment period:** NR **Setting:** 3 inner city hospital prenatal clinics **Funding:** Department of Health **Author industry relationship disclosures:** 1/3 **Study Design:** RCT **Blinding:** None	**Intervention:** Point of care urine test for smoking with results, quit date, and leaflet **Intervention provider:** Research staff, midwives **Intervention setting:** Clinic **Comparator:** Anti-smoking counseling as part of routine care **Followup:** 36 weeks gestation	**Inclusion criteria:** • Pregnant • Current smokers and positive urine cotinine result **Enrollment, n:** **G1:** 164 **G2:** 116 **Followup, n:** **G1:** 109 **G2:** 83 **Age, mean years ± SD:** NR **Education:** NR **Weeks gestation:** NR **Insurance status:** NR **Parity:** NR **Partner status:** NR **Partner smoking status:** NR **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:** NR	**Maternal smoking status** Number of cigarettes per day, mean: **G1:** 11.8	**Maternal smoking status** Abstinence at 36 weeks, n (%) **G1:** 22 (22.2) **G2:** 4 (6.8) Relapse: NR **Child/infant outcomes** Birthweight, mean kg: **G1:** 3.26 **G2:** 3.08 **G1 vs. G2:** p=0.03[9] **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: High Allocation concealment: High Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

[9] Analysis adjusted for nicotine metabolites

Table H25. Evidence table (Reference ID# 725)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Hegaard et al., 2003 **Country:** Denmark **Enrollment period:** November 1996 to April 1998 **Setting:** Midwifery center at large university hospital **Funding:** Ministry of Health, City of Copenhagen, Danish Lung Association, Danish Cancer Society, Pharmacia A/S **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Individual counseling on smoking cessation, invitation to join smoking cessation program (9 appointments individual or group), optional nicotine replacement therapy (NRT) (chewing gum or patch) **Intervention provider:** Midwife **Intervention setting:** Hospital **Comparator:** Usual care, included routine information about risk of smoking in pregnancy and general advice on smoking cessation/reduction **Followup:** 37 weeks gestation **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Pregnant women at aying first visit to Midwifery Center at university hospital **Exclusion criteria:** • Inability to speak Danish • < 18 years old • Gestation > 22 weeks • Verified psychiatric diseases • Alcohol or drug abuse **Enrollment, n:** **G1:** 348 **G2:** 347 **Followup, n:** **G1:** 327 **G2:** 320 **Age, mean years ± SD:** **G1:** 29 ± 4.7 **G2:** 29 ± 4.6 **Education, %:** 12 or more years **G1:** 45 **G2:** 43 **Gestation, weeks:** **G1:** 16 ± 2.7 **G2:** 16 ± 2.9 **Insurance status:** NR **Parity, %:** Primiparous **G1:** 52 **G2:** 53 **Partner status, %:**	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 11 ± 4.9 **G2:** 11 ± 5.3 Cotinine (saliva), median ng/ml: **G1:** 141 **G2:** 139	**Maternal smoking status** Abstinence at 37 weeks gestation, n (%): **G1:** 23 (7.0) **G2:** 7 (2.2) **G1 vs. G2:** p=0.004 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: High Allocation concealment: High Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Married or cohabitating **G1:** 87 **G2:** 90 **Partner smoking status, %:** Daily smoker **G1:** 70 **G2:** 63 **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:** Smoking consumption before pregnancy **G1:** 18 ± 5.3 **G2:** 18 ± 5.8 Previously stopped smoking, % **G1:** 37 **G2:** 40 Started smoking, mean age ± SD **G1:** 16 ± 2.7 **G2:** 16 ± 2.6 Fagerstrom score, mean ± SD **G1:** 3.1 ± 2.1 **G2**: 3.3 ± 2.7			

Table H26. Evidence table (Reference ID# 736)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Lawrence et al., 2003 **Country:** UK **Enrollment period:** July 1998 to July 2000 **Setting:** Prenatal clinics **Funding:** West Midlands Regional Levies Board **Author industry relationship disclosures:** NR **Study Design:** Cluster RCT Practices were unit of randomization **Blinding:** None	**Intervention:** *Manuals:* 6 stage based self-help manual, transtheoretical model training for midwives, state of change assessment *Computer delivered*: Same as manuals intervention except participants used computer on 3 occasions **Intervention provider:** Midwives **Intervention setting:** Clinic **Comparator:** *Control*: Standard smoking cessation advice and booklet **Followup:** NR **Groups:** **G1:** Manuals **G2:** Computer delivered **G3:** Control	**Inclusion criteria:** • Pregnant women aged ≥16 • Current smoker **Exclusion criteria:** • Not fluent in English **Enrollment, n:** **G1:** 305 **G2:** 324 **G3:** 289 **Followup, n:** NR **Age, median years:** **G1:** 26.3 **G2:** 25.4 **G3:** 26.7 **Education, n (%):** Has degree **G1:** 7 (2.3) **G2:** 4 (1.2) **G3**: 3 (1.0) A-levels **G1:** 39 (12.8) **G2:** 25 (7.7) **G3:** 30 (10.4) O-levels **G1:** 103 (33.8) **G2:** 92 (28.4) **G3:** 86 (29.8) None **G1:** 69 (22.6) **G2:** 75 (23.1) **G3:** 60 (20.8) Other **G1:** 25 (8.2) **G2:** 50 (15.4) **G3:** 44 (15.2) Don't know **G1:** 62 (20.3) **G2:** 78 (24.1) **G3:** 66 (22.8) **Gestation, median weeks:** **G1:** 11.9 **G2:** 13.0	**Maternal smoking status** Smoking status at baseline, n (%): Fewer than 5 cigarettes per day **G1:** 67 (22.0) **G2:** 38 (11.7) **G3:** 49 (17.0) 5 to 9 cigarettes per day **G1:** 106 (34.8) **G2:** 117 (36.1) **G3:** 106 (36.7) 10 to 19 cigarettes per day **G1:** 103 (33.8) **G2:** 128 (39.5) **G3:** 90 (31.1) 20 to 29 cigarettes per day **G1:** 15 (4.9) **G2:** 21 (6.5) **G3:** 19 (6.6) 30 or more cigarettes per day **G1:** 2 (0.7) **G2:** 1 (0.3) **G3:** 4 (1.4) Unknown number of cigarettes per day **G1:** 12 (3.9) **G2:** 19 (5.9) **G3:** 21 (7.3)	**Maternal smoking status** Abstinence at 30 weeks gestation, %: **G1:** 4.3 **G1 vs. G3:** OR=2.53 (95% CI: 0.89 to 7.19) **G2:** 5.6 **G2 vs. G3:** OR=3.34 (95% CI: 1.22 to 9.11) **G3:** 1.7 **G1 vs. G2 vs. G3:** p=0.06 Abstinence at 10 days postpartum, %: **G1:** 4.7 **G1 vs. G3:** OR=1.34 (95% CI: 0.54 to 3.31) **G2:** 8.1 **G2 vs. G3:** OR=2.42 (95% CI: 1.05 to 5.57) **G3:** 3.5 **G1 vs. G2 vs. G3:** p=0.08 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: High Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G3: 11.7 **Insurance status:** NR **Parity, n (%):** Nulliparous **G1:** 120 (39.3) **G2:**118 (36.4) **G3:** 92 (31.8) Multiparous **G1:** 171 (56.1) **G2:** 185 (57.1) **G3:** 171 (59.2) Missing **G1:** 14 (4.6) **G2:** 21 (6.5) **G3:** 26 (9.0) **Partner status, n (%):** Partner **G1:** 273 (89.5) **G2:** 274 (84.6) **G3:** 246 (85.1) No partner **G1:** 22 (7.2) **G2:** 32 (9.9) **G3:** 21 (7.3) Unknown **G1:** 10 (3.3) **G2:** 18 (5.6) **G3:** 22 (7.6) **Partner smoking status, n (%):** Smokes **G1:** 206 (67.5) **G2:** 186 (57.4) **G3:** 181 (62.6) Does not smoke **G1**: 87 (28.5) **G2:** 119 (36.7) **G3:** 84 (29.1) Unknown or no partner **G1:** 12 (3.9) **G2:** 19 (5.9) **G3:** 24 (8.3) **Race/ethnicity, n (%):** White **G1:** 273 (89.5) **G2:** 292 (90.1) **G3:** 250 (86.5) Don't know **G1:** 16 (5.2)			

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G2: 23 (7.1) **G3:** 28 (9.7) All other **G1:** 16 (5.2) **G2:** 9 (2.8) **G3:** 11 (3.8) **Socioeconomic status, n (%):** Less than £100 per week **G1:** 70 (23.0) **G2:** 70 (21.6) **G3:** 53 (18.3) £100 to £200 per week **G1:** 84 (27.5) **G2:** 76 (23.5) **G3:** 76 (26.3) £200 to £300 per week **G1:** 55 (18.0) **G2:** 61 (18.8) **G3:** 55 (19.0) £300 to £400 per week **G1:** 41 (13.4) **G2:** 44 (13.6) **G3:** 34 (11.8) £400 or more per week **G1:** 36 (11.8) **G2:** 33 (10.2) **G3:** 32 (11.1) Weekly income unknown **G1:** 19 (6.2) **G2:** 40 (12.3) **G3:** 39 (13.5) **Smoking history, n (%):** NR			

Table H27. Evidence table (Reference ID# 746)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Malchodi et al., 2003 **Country:** USA **Enrollment period:** January 1998 to February 2000 **Setting:** Community hospital **Funding:** Hospital grant **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Peer counseling **Intervention provider:** Health care provider **Intervention setting:** Clinic **Comparator:** Usual care **Followup:** 36 weeks gestation **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Current smoker (at least one cigarette per day the week before learning of pregnancy) • Documented pregnancy with intent to carry to term • < 20 weeks gestation • English or Spanish speaker • ≥ 18 years old **Exclusion criteria:** • Used smokeless tobacco or nicotine replacement products • Current substance abuse or dependence **Enrollment, n:** **G1:** 67 **G2:** 75 **Followup, n (%):** 36 weeks gestation **G1:** 42 **G2:** 33 **Age, mean years ± SD:** **G1:** 25 ± 6 **G2:** 26 ± 6 **Education, %:** Grade 8 or lower **G1:** 10.5 **G2:** 12 Grades 9 to 11 **G1:** 46.3 **G2:** 48.0 Grade 12 **G1:** 21.0 **G2:** 25.0 Higher than grade 12	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 13.3 ± 8.2 **G2:** 11.2 ± 8.4 Expired carbon monoxide, mean ppm ± SD: **G1:** 5.12 ± 5.01 **G2:** 7.25 ± 7.18	**Maternal smoking status** Abstinence at 36 weeks gestation, n %: **G1:** 16 (24) **G2:** 16 (21) **G1 vs. G2:** p=0.84 Relapse: NR **Child/infant outcomes** Gestational age: NR Birthweight: NR NICU admission: NR **Adverse events:** NR	**Overall quality:** Good **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G1: 12.0 **G2:** 8.0 GED **G1:** 10.5 **G2:** 7.0 **Gestation, weeks:** NR **Insurance status:** NR **Parity, mean ± SD :** Previous births **G1:** 3 ± 2 **G2:** 3 ± 2 **Partner status, %:** Married **G1:** 1.5 **G2:** 10.7 Single **G1:** 98.5 **G2:** 86.7 Separated **G1:** 0 **G2:** 2.7 **Partner smoking status:** Smokers in household, mean number ± SD **G1:** 1.1 ± 1.2 **G2:** 1.3 ± 1.2 **Race/ethnicity, %:** Black **G1:** 12 **G2:** 13 Hispanic **G1:** 63 **G2:** 63 White **G1:** 24 **G2:** 23 Other **G1:** 1 **G2:** 1 **Socioeconomic status:** NR **Smoking history:** Years smoking, mean ± SD			

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G1: 7.6 ± 5.5 **G2:** 8.5 ± 5.5 Quit attempts, mean number ± SD **G1:** 1.6 ± 1.9 **G2:** 1.4 ± 1.7			

Table H28. Evidence table (Reference ID# 761)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Moore et al., 2002 **Country:** UK **Enrollment period:** May 1998 to September 1999 (Trust A and B) January 2000 to July 2000 (Trust C) **Setting:** 3 NHS hospital trusts **Funding:** Medical Research Council **Author industry relationship disclosures:** 0/7 **Study Design:** Cluster RCT Midwife was unit of randomization **Blinding:** None	**Intervention:** Self-help smoking cessation, 5 booklets **Intervention provider:** Midwife **Intervention setting:** Hospital **Comparator:** Usual care **Groups:** **G1:** Intervention **G2:** Control **Followup:** End of second trimester (26 weeks gestation)	**Inclusion criteria:** • Pregnant women attending first appointment • Smoked before becoming pregnant (current smokers, cut down since becoming pregnant; or quit smoking since becoming pregnant) • Age ≥ 16 years • < 17 weeks gestation • English speaking **Enrollment, n:** **G1:** 724 **G2:** 803 **Followup, n:** 36-week visit **G1:** 610 **G2:** 707 **Age, mean years ± SD:** **G1:** 27.2 ± 6.0 **G2:** 26.7 ± 5.6 **Education, n (%):** Up to age 16 **G1:** 431 (61.0) **G2:** 499 (63.6) Age 17 to 18 **G1:** 162 (22.9) **G2:** 179 (22.8) More than age 18 **G1:** 109 (15.4) **G2:** 100 (12.8) Currently in full time education **G1:** 6 (0.8) **G2:** 4 (0.5) **Gestation, mean weeks ± SD:** **G1:** 11.8 ± 2.3 **G2:** 11.8 ± 2.3	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1**: 6.4 ± 6.6 **G2:** 5.5 ± 5.8 Smoking status, n (%): Current smoker **G1:** 97 (13.4) **G2:** 97 (12.1) Current smoker but cut down since becoming pregnant **G1:** 445 (61.5) **G2:** 464 (57.8) Stopped smoking since becoming pregnant **G1:** 182 (25.1) **G2:** 242 (30.1)	**Maternal smoking status** Abstinence at end of second trimester, n (%): **G1:** 113/600 (18.8) **G2:** 144/695 (20.7) **G1 vs. G2:** Δ=1.9 (95% CI: −3.5 to 7.3) Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Good **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Insurance status: NR **Parity, n (%):** First pregnancy **G1:** 224 (30.9) **G2:** 280 (34.9) **Partner status:** NR **Partner smoking status:** NR **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:** Number of cigarettes per day before pregnancy, mean ± SD **G1:** 16.0 ± 8.5 **G2:** 15.1 ± 8.0			

Table H29. Evidence table (Reference ID# 807)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Stotts et al., 2002 **Country:** USA **Enrollment period:** NR **Setting:** 21 satellite locations for 3 large multispecialty clinics **Funding:** NR **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** Outcome assessors	**Intervention:** *Counseling:* Motivational Interviewing (MI), telephone calls, feedback letter **Intervention provider:** Master's level counselors and nurse health educators **Intervention setting:** Home **Comparator:** Usual care **Followup:** 34 weeks gestation[10] **Groups:** **G1:** Intervention **G2:** Usual care	**Inclusion criteria:** • Fluent in English • Age ≥ 18 years • Smoke ≥5 cigarettes per week before pregnancy • First prenatal visit ≤ 20 weeks • Reported at least a puff in previous 28 days at 28 weeks gestation • Telephone access **Enrollment, n:** **G1:** 134 **G2:** 135 **Followup, n (%):** 34 weeks gestation with anonymous cotinine sample **G1:** 86 (64) **G2:** 89 (66) **Age, mean years ± SD:** **G1:** 28.6 ± 5.1 **G2:** 28.1 ± 5.7 **Education, %:** Less than high school graduate **G1:** 9.0 **G2:** 11.1 High school graduate **G1:** 33.6 **G2:** 39.3 Some college **G1:** 47.8 **G2:** 40.7 College graduate **G1:** 9.7 **G2:** 9.0 **Gestation, weeks:** NR **Insurance status:**	**Maternal smoking status** Number of cigarettes per day: NR	**Maternal smoking status** Abstinence at 34 weeks gestation,%: **G1:** 32 **G2:** 34 **G1 vs. G2:** p≤0.64 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: High

[10] Later followup based on self-reported smoking status only

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		NR **Parity, %:** No prior live births **G1:** 37.8 **G2:** 44.8 One prior live birth **G1:** 35.6 **G2:** 34.3 Two prior live births **G1:** 17.0 **G2:** 14.9 Three or more prior live births **G1:** 9.6 **G2:** 6.0 **Partner status, %:** Lives with partner or husband **G1:** 85.5 **G2:** 84.1 **Partner smoking status, %:** **G1:** 69.6 **G2:** 62.5 **Race/ethnicity, %:** White **G1:** 81.3 **G2:** 76.3 African American **G1:** 12.7 **G2:** 12.6 Hispanic **G1:** 3.7 **G2:** 8.2 Other **G1:** 2.2 **G2:** 3.0 **Socioeconomic status, %:** Employed outside home **G1:** 81.7 **G2:** 74.6 **Smoking history, %:** Cigarettes per week before pregnancy 5 to 60 **G1:** 42.1 **G2:** 57.0			

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		61 or more **G1:** 57.9 **G2:** 43.0 **G1 vs. G2:** p<0.01 Smoked less than 5 years **G1:** 18.7 **G2:** 20.2 Smoked 6 to10 years **G1:** 26.9 **G2:** 29.1 Smoked 11 to 15 years **G1:** 41.0 **G2:** 37.3 Smoked 16 years or more **G1:** 13.4 **G2:** 13.4			

Table H30. Evidence table (Reference ID# 850)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Hajek et al., 2001 **Country:** UK **Enrollment period:** NR **Setting:** 9 hospital and community trusts **Funding:** Grant Health Education Authority and Department of Health **Author industry relationship disclosures:** NR **Study Design:** RCT Midwives were unit of randomization **Blinding:** Provider	**Intervention:** Counseling intervention with feedback and self-help support **Intervention provider:** Midwife **Intervention setting:** Hospital and community trusts **Comparator:** Usual care **Followup:** 6 and 12 months **Groups:** **G1:** Intervention **G2:** Control **Ga:** Current smoker **Gb:** Ex-smoker	**Inclusion criteria:** • Current smokers or recent ex-smokers (stopped smoking in previous 3 months) **Enrollment, n:** **G1a:** 431 **G1b:** 114 **G2a:** 440 **G2b:** 135 **Followup, n (%):** 36 weeks gestation **G1:** 545 **G2:** 575 **Age, mean years ± SD:** **G1a:** 27.6 ± 6.0 **G2a:** 26.9 ± 6.1 **G1b:** 28.2 ± 5.3 **G2b:** 27.7 ± 5.5 **Education, %:** No educational qualifications **G1a:** 27.4 **G2a:** 26.1 **G1b:** 9.8 **G2b:** 15.8 **Gestation:** NR **Insurance status:** NR **Parity:** NR **Partner status, %:** Married/living with partner **G1a:** 71.9	**Maternal smoking status** Time since last cigarette, mean weeks ± SD **G1a:** NA **G2a:** NA **G1b**: 6.6 ± 3.6 **G2b:** 7.3 ± 3.6 Want to quit smoking, % **G1a:** 75.9 **G2a:** 80.7 **G1b:** NA **G2b:** NA	**Maternal smoking status** Abstinence at birth, % **G1a:** 11 **G2a:** 10 **G1b:** 65 **G2b:** 53 **G1a vs. G2a:** p=NS **G1b vs. G2b:** p<0.05 Abstinence (continuous) at birth[11], % **G1a:** 6 **G2a:** 7 **G1b:** 58 **G2b:** 50 **G1a vs. G2a:** p=NS **G1b vs. G2b:** p=NS Abstinence (continuous) at 6 months postpartum[12], % **G1a:** 3 **G2a:** 3 **G1b:** 23 **G2b:** 25 **G1a vs. G2a:** p=NS **G1b vs. G2b:** p=NS Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Good **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

[11] Defined as self-reported abstinence during previous 12 weeks and exhaled carbon monoxide less than 10 ppm at postbirth interview

[12] Defined as continuous abstinence at the postbirth interview, self-reported abstinence from birth and exhaled carbon monoxide less than 10 ppm at postpartum interview

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G2a: 71.1 **G1b:** 77.2 **G2b:** 81.5 **Partner smoking status:** NR **Race/ethnicity:** NR **Socioeconomic status, %:** Unemployed **G1a:** 24.3 **G2a:** 24.6 **G1b:** 16.0 **G2b:** 14.5 **Smoking history:** Cigarettes per day, mean ± SD: **G1a:** 10.1 ± 6.2 **G2a:** 9.7 ± 6.7 **G1b:** 12.6 ± 7.0 **G2b:** 10.9 ± 6.9			

Table H31. Evidence table (Reference ID# 880)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Ershoff et al., 1999 **Country:** USA **Enrollment period:** November 1996 to June 1997 **Setting:** Large group HMO **Funding:** Grant (Robert Wood Johnson) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** Provider	**Intervention:** *Motivational Interviewing (MI):* counseling, telephone calls *Interactive voice recognition (IVR)*: computerized interactive telephone support plus booklet **Intervention provider:** Nurse educators **Intervention setting:** NR **Comparator:** Booklet only **Followup:** End of pregnancy **Groups:** **G1:** MI **G2:** IVR **G3:** Booklet only	**Inclusion criteria:** • Pregnant smokers (smoked within 7 days of interview) • Aged 18 or older • Beginning prenatal care at or before 26th week • English speaking • 7 or more cigarettes per week before pregnancy **Enrollment, n:** **G1:** 126 **G2:** 133 **G3:** 131 **Followup, n:** **G1:** 101 **G2:** 120 **G3:** 111 **Age, mean years ± SD:** **G1:** 29.0 ± 6.0 **G2:** 29.6 ± 6.7 **G3:** 29.6 ± 5.7 **Education, mean ± SD:** **G1:** 13.0 ± 2.2 **G2:** 12.9 ± 2.1 **G3:** 12.8 ± 2.1 **Gestation, weeks:** NR **Insurance status:** NR **Parity, %:** Primiparous **G1:** 35.6 **G2:** 34.2 **G3:** 30.6 **Partner status:** NR **Partner smoking**	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 6.3 ± 6.5 **G2:** 6.7 ± 6.5 **G3:** 6.6 ± 7.3	**Maternal smoking status** Abstinence at end of pregnancy, % : **G1:** 20.8 **G2:** 16.7 **G3:** 22.5 **G1 vs. G2 vs. G3:** p=0.57 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Fair **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		status, %: **G1:** 50.5 **G2:** 56.7 **G3:** 57.7 **Race/ethnicity, n (%):** White **G1:** 61.4 **G2:** 58.3 **G3:** 63.1 Black **G1:** 14.9 **G2:** 14.2 **G3:** 17.1 Hispanic **G1:** 19.8 **G2:** 15.0 **G3:** 14.4 **Socioeconomic status:** NR **Smoking history:** Pre-pregnancy smoking, mean ± SD **G1:** 16.3 ± 7.6 **G2:** 17.6 ± 9.8 **G3:** 17.1 ± 9.7			

Table H32. Evidence table (Reference ID# 886)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Solomon et al., 2000 **Country:** USA **Enrollment period:** 1996 to 1997 **Setting:** Obstetric practice in Vermont **Funding:** Grant (Robert Wood Johnson Foundation) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Telephone peer support, plus cessation advice and printed materials **Intervention provider:** Ob/Gyn or midwife (cessation advice); trained ex-smoker (telephone peer support) **Intervention setting:** Clinic, home **Comparator:** Brief smoking cessation advice and printed materials **Followup:** End of pregnancy (28 to 34 weeks) **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Pregnant • Reported smoking at least one cigarette in past week when screened at first prenatal visit **Enrollment, n:** **G1:** 77 **G2:** 74 **Followup, n:** **G1:** 77 **G2:** 74 **Age, mean years ± SD:** **G1:** 23.1 ± 5.6 **G2:** 23.7 ± 6.7 **Education, mean (%):** **G1:** 11.7 ± 2.0 **G2:** 11.5 ± 2.1 **Gestation, mean weeks ± SD:** **G1:** 11.6 ± 5.5 **G2:** 11.6 ± 5.0 **Insurance status, n (%):** Medicaid **G1:** 55 (77.5) **G2:** 47 (74.6) **Parity, n (%):** Primigravida **G1:** 37 (48.7) **G2:** 30 (41.7) **Partner status** NR **Partner smoking status:** Other smokers in household, mean ± SD **G1:** 1.3 ± 1.9 **G2:** 1.5 ± 1.9 **Race/ethnicity, n (%):**	**Maternal smoking status** Cigarettes per day, mean ± SD: **G1:** 10.5 ± 9.6 **G2:** 9.8 ± 7.8 Expired carbon monoxide, mean ppm ± SD: **G1:** 11.3 ± 7.9 **G2:** 11.3 ± 8.7	**Maternal smoking status** Abstinence at end of pregnancy, n (%): **G1:** 14 (18.2) **G2:** 11 (14.9) **G1 vs. G2:** p=NS Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: High

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		White **G1:** 73 (94.8) **G2:** 71 (96.0) Non-Hispanic **G1:** 74 (98.7) **G2:** 73 (98.7) **Socioeconomic status:** NR **Smoking history:** Started smoking, mean age ± SD **G1:** 14.1 ± 3.4 **G2:** 14.5 ± 2.8 Cigarettes per day before pregnancy, mean ± SD **G1**: 22.6 ± 11.3 **G2:** 20.2 ± 10.1 Prior quit attempts, mean ± SD **G1:** 2.6 ± 6.5 **G2:** 1.5 ± 2.7		

Table H33. Evidence table (Reference ID# 887)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Donatelle et al., 2000 **Country:** USA **Enrollment period:** June 1996 to June 1997 **Setting:** 4 WIC sites **Funding:** Grant (Robert Wood Johnson Foundation) 10 community partners provided funding for vouchers and general support **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Treatment vouchers, bolstered social support, verbal and written materials, self-help kit **Intervention provider:** Educational intervention: trained WIC or research study program staff **Intervention setting:** 4 WIC sites **Comparator:** Verbal and written materials and self-help kit **Followup:** 8th month gestation and 2 months postpartum **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Age ≥ 15 • Self reported smoker (even a puff in past 7 days) • English speaker/reader • WIC eligible • ≤ 28 weeks gestation **Enrollment, n:** **G1:** 112 **G2:** 108 **Followup, n (%):** 8 months gestation **G1:** 105 **G2:** 102 2 month postpartum **G1:** 103 **G2:** 102 **Age, mean years ± SD:** **G1:** 23.5 ± 5.7 **G2:** 24.0 ± 5.8 **Education, mean years ± SD:** **G1:** 11.6 ± 2.0 **G2:** 11.8 ± 1.7 **Gestation, weeks** **G1:** 16.6 ± 6.6 **G2:** 16.4 ± 7.4 **Insurance status:** NR **Parity:** NR **Partner status** Married or living with partner, % **G1:** 53 **G2:** 58 **Partner smoking status:** NR **Race/ethnicity, %:**	**Maternal smoking status** Number of cigarettes per day: NR Saliva thiocyanate, mean µg/ml ± SD: **G1:** 184.9 ± 79.5 **G2:** 183.0 ± 91.2 (n=107) Cotinine, mean ng/ml ± SD: **G1:** 45.4 ± 40.1 **G2:** 45.7 ± 47.5	**Maternal smoking status** Abstinence at 8 months gestation, %: **G1:** 32 **G2:** 9 **G1 vs. G2:** p<0.0001 Abstinence at 2 months postpartum, %: **G1:** 21 **G2:** 6 **G1 vs. G2:** p<0.0009 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Fair **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Non-white **G1:** 10 (n=110) **G2:** 12 Latino or Hispanic **G1:** 8 (n=109) **G2:** 7.5 (n=107) **Socioeconomic status:** Household income less than $20,000, % **G1:** 87 **G2:** 89 **Smoking history:** NR			

Table H34. Evidence table (Reference ID# 928)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Johnson et al., 2000 **Country:** Canada **Enrollment period:** 7 month period (dates not specified) **Setting:** 5 hospitals **Funding:** Grant from National Health Research and Development Program **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** Research assistants at 6 month f/u visit	**Intervention:** Postpartum relapse prevention counseling **Intervention provider:** Nurses/ research assistants **Intervention setting:** Hospital and home **Comparator:** Usual care no information on effects of smoking or prevention of smoking relapse **Followup:** Home visit at 6 months	**Inclusion criteria:** • Postpartum women who gave birth at one of 5 hospitals • Smoker before pregnancy • Ceased smoking at least 6 weeks before delivery (or smoked < 6 times during that period) • Healthy infant • Remaining in hospital 24 hours • Able to read and comprehend English • Contact by telephone **Enrollment, n:** **G1:** 125 **G2:** 126 **Followup, n:** **G1:** 121 **G2:** 120 **Age, mean years:** **G1:** 27.8 **G2:** 27.4 **Education, %:** Less than high school **G1**: 14.4 **G2:** 17.5 High school or equivalent **G1**: 28.8 **G2**: 23.0 Some or completed trade/ community college **G1:** 40.0 **G2**: 33.3 Some or completed university **G1:** 16.8	**Maternal smoking status** Number of cigarettes per day: NR Intend to remain nonsmoking postpartum, %: **G1:** 90.4 **G2:** 91.3 No/don't know, %: **G1:** 9.6 **G2:** 8.7	**Maternal smoking status** Abstinence at 6 months postpartum, %: **G1:** 37.6 **G2:** 27.0 **G1 vs. G2:** OR=1.63 (95% CI: 0.96 to 2.78) **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Good **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G2: 26.2 **Gestation, weeks:** NA **Insurance status:** NR **Parity, %:** First child **G1:** 78.4 **G2:** 69.8 **Partner status, %:** Married and living with spouse **G1:** 57.6 **G2:** 62.7 Common-law/live-in **G1:** 25.6 **G2:** 22.2 Separated, divorced, widowed, or single **G1:** 16.8 **G2:** 15.1 **Partner smoking status, %:** Current smoker **G1:** 44.8 **G2:** 50 **Race/ethnicity:** NR **Socioeconomic status, %:** Annual household income $29,999 or less **G1:** 24.8 **G2**:29.8 $30,000 to $49,999 **G1**:28.3 **G2**: 23.7 $50,000 to $69,9999 **G1:** 18.6 **G2**: 21.1 $70,000 or more **G1**: 28.3 **G2**: 25.4 **Smoking history:** Number of		

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		previous quit attempts, mean **G1:** 3.2 **G2:** 2.8 Number of cigarettes per day while smoking, mean **G1:** 10.5 **G2:** 10.4			

Table H35. Evidence table (Reference ID# 929)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Windsor et al., 2000 **Country:** USA **Enrollment period:** October 1997 to January 1998 **Setting:** Medicaid clinics **Funding:** NR **Author industry relationship disclosures:** NR **Study Design:** NR **Blinding:** None	**Intervention:** Patient education, video, publication, brief counseling session **Intervention provider:** Prenatal care staff **Intervention setting:** Clinic **Comparator:** Advise to quit smoking **Groups:** **G1:** Intervention **G2:** Control **Followup:** End of pregnancy	**Inclusion criteria:** • Pregnant smokers **Enrollment, n:** **G1:** 139 **G2:** 126 **Followup, n:** NR **Age, mean years:** **G1:** 23 **G2:** 23 **Education:** NR **Gestation, months:** **G1:** 2.2 **G2:** 3.0 **Insurance status:** NR **Parity:** NR **Partner status:** Smoker in home, % **G1:** 77 **G2:** 84 **Partner smoking status:** NR **Race/ethnicity:** Black, % **G1:** 18 **G2:** 14 **Socioeconomic status:** NR **Smoking history:** NR	**Maternal smoking status** Number of cigarettes per day, mean: **G1:** 10 **G2:** 10 Cotinine, mean ng/ml: **G1:** 204 **G2:** 201	**Maternal smoking status** Abstinence at end of pregnancy, %: **G1:** 17.3 **G2:** 8.8 **G1 vs. G2:** OR=2.2 (95% CI: 2.2 to 4.1) Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:**

Table H36. Evidence table (Reference ID# 939)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Panjari et al., 1999 **Country:** Australia **Enrollment period:** April 1994 to June 1996 **Setting:** Royal Women's Hospital **Funding:** Grant (National Health and National Research Council of Australia) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Personalized smoking cessation intervention, cognitive behavioral counseling **Intervention provider:** Midwife **Intervention setting:** **Comparator:** Standard prenatal care, including pamphlet **Followup:** Mid pregnancy (24 to 28 weeks) and late pregnancy (34 to 36 weeks) **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Current smoker • Less than 20 weeks gestation • Singleton pregnancy • Ability to speak and read English • No drug dependency that would prompt referral to Chemical Dependency Unit **Enrollment, n:** **G1:** 439 **G2:** 502 **Followup, n (%):** **G1:** 339 (77) **G2:** 393 (78) **Age, mean years ± SD:** **G1 + G2:** 26 **Education:** NR **Gestation, mean weeks:** **G1 + G2:** 12 **Insurance status:** NR **Parity, %:** Nulliparous **G1 + G2:** 50 **Partner status:** NR **Partner smoking status:** Smokers, % **G1 + G2:** 74 **Race/ethnicity:** NR **Socioeconomic status:**	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:**11.1 ± 7.9 **G2:**11.1 ± 8.2 Cotinine, mean ng/ml ± SD: **G1:** 909 ± 881 **G2:** 910 ± 897	**Maternal smoking status** Abstinence in late pregnancy, n (%): **G1:** 33 (11.9) **G2:** 31 (9.8) **G1 vs. G2:** p=0.41 Relapse: NR **Child/infant outcomes** Gestational age: NR Birthweight (all), mean grams ± SD: **G1:** 3250 ± 526 **G2:** 3166 ± 589 **G1 vs. G2:** p=0.04 Birthweight (full term), mean grams ± SD: **G1:** 3301 ± 460 **G2:** 3272 ± 458 **G1 vs. G2:** p=0.41 NICU admission: NR Asthma exacerbation: NR Asthma hospitalization: NR Upper respiratory infection: NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		NR **Smoking history:** Cigarettes smoked per day before pregnancy, mean number **G1:** 21 **G2:** 21 Years smoking, mean **G1:** 10 **G2:** 10			

Table H37. Evidence table (Reference ID #974)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Wisborg et al., 1998 **Country:** Denmark **Enrollment period:** October 1994 to September 1995 **Setting:** **Funding:** Danish Cancer Society Ministry of Health **Author industry relationship disclosures:** NR **Study Design:** Cohort **Blinding:** None	**Intervention:** Nurse midwife education; patient materials; smoking cessation counseling **Intervention provider:** NR **Intervention setting:** NR **Comparator:** NR **Followup:** 30 weeks gestation **Groups:** **G1:** Experimental **G2:** Control	**Inclusion criteria:** • Danish speaking pregnant women • First antenatal visit between 14 and 16 weeks gestation **Enrollment, n:** **G1:** 527 **G2:** 2629 **Followup, n:** NA **Age, n (%):** 15 to 19 years **G1:** 11 (2) **G2:** 46 (2) 20 to 24 years **G1:** 84 (16) **G2:** 399 (15) 25 to 29 years **G1:** 228 (43) **G2:** 1081 (41) 30 to 34 years **G1:** 158 (30) **G2:** 789 (30) 35 or more years **G1:** 46 (9) **G2:** 310 (12) **Education, n (%):** 7 to 9 years of school **G1:** 56 (11) **G2:** 255 (10) 10 years of school **G1:** 158 (30) **G2:** 699 (26) 11 or more years of school **G1:** 295 (56) **G2:** 1548 (59) **Insurance status:** NR **Parity, n (%):** 1 previous birth **G1:** 295 (56) **G2:** 1354 (52) 2 previous births **G1:** 184 (35) **G2:** 884 (34) 3 or more previous	**Maternal smoking status** Number of cigarettes per day: NR	**Maternal smoking status** Abstinence at 30 weeks gestation, n %: **G1:** 10 (2) **G2:** 41 (2) Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:**

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		births **G1:** 48 (9) **G2:** 391 (15) **Partner status, n (%):** Cohabitating **G1:** 485 (92) **G2:** 2421 (92) Single **G1:** 27 (5) **G2:** 143 (5) **Partner smoking status:** NR **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history, n (%):** No cigarettes per day before pregnancy **G1:** 342 (65) **G2:** 1737 (66) 1 to 9 cigarettes per day before pregnancy **G1:** 50 (9) **G2:** 202 (8) 10 or more cigarettes per day before pregnancy **G1:** 135 (26) **G2:** 690 (26)			

Table H38. Evidence table (Reference ID# 992)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Secker-Walker et al., 1998 **Country:** USA **Enrollment period:** October 1988 to October 1992 **Setting:** University affiliated clinic **Funding:** Grant (Federal) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Relapse prevention counseling and structured physician counseling **Intervention provider:** Physician and nurses **Intervention setting:** Clinic **Comparator:** Usual physician advice **Followup:** 36 weeks gestation **Groups:** **G1:** Intervention **G2:** Usual care	**Inclusion criteria:** • Pregnant women smoked one or more cigarettes per day early in pregnancy but reported not smoking at first prenatal visit **Enrollment, n:** **G1:** 62 **G2:** 63 **Followup, n (%):** 36-week visit **G1:** 44 (71) **G2:** 48 (76) **Age, mean years ± SD:** **G1:** 20.9 ± 4.0 **G2:** 21.9 ± 4.5 **Education, n (%):** Less than high school **G1:** 16 (36.4) **G2:** 13 (27.1) High school **G1:** 17 (38.6) **G2:** 23 (47.9) More than high school **G1:** 11 (25) **G2:** 12 (25) **Gestation, mean weeks ± SD:** **G1:** 17.7 ± 9.0 **G2:** 14.8 ± 7.0 **Insurance status, n (%):** Medicaid **G1**: 28 (65.1) **G2**: 32 (68.1) **Parity, n (%):** Primigravida **G1:** 27 (61.4) **G2**: 24 (50.0) **Partner status, n (%)**	**Maternal smoking status** Expired carbon monoxide, mean ppm ± SD: **G1:** 4.3 ± 4.7 **G2:** 4.1 ± 3.7	**Maternal smoking status** Relapse prevention at 36 weeks gestation, n (%): **G1:** 28 (64) **G2:** 33 (69) **G1 vs. G2:** p=NS **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Married **G1:** 13 (29.5) **G2**: 14 (29.2) **Partner smoking status, n (%):** Smokers in household **G1:** 31 (70.4) **G2:** 31 (64.6) **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:** Started smoking, mean age ± SD **G1:** 15.3 ± 2.9 **G2:** 15.2 ± 2.5 Quit attempts, n (%) 1 **G1:** 5 (11.4) **G2:** 11 (22.9) 2 **G1:** 11 (25.0) **G2:** 12 (25.0) 3 or more **G1:** 28 (63.6) **G2:** 25 (52.1) Cigarettes per day prior to pregnancy, mean ± SD **G1:** 13.4 ± 9.2 **G2:** 14.1 ± 8.4			

Table H39. Evidence table (Reference ID# 997)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Secker-Walker et al., 1998 **Country:** USA **Enrollment period:** October 1988 to October 1992 **Setting:** University affiliated clinic **Funding:** Grant (Federal) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Structured advice and individual behavior change counseling **Intervention provider:** Trained nurse **Intervention setting:** Clinic **Comparator:** Usual care **Followup:** 36 weeks gestation **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Women smoking one or more cigarettes per day at first prenatal visit **Enrollment, n:** **G1:** 197 **G2:** 202 **Followup, n (%):** 36-week visit **G1:** 135 **G2:** 141 **Age, mean years ± SD:** **G1:** 22.6 ± 5.2 **G2:** 22.5 ± 5.1 **Education, n (%):** Less than high school **G1:** 65 (48.2) **G2:** 58 (41.1) High school **G1:** 57 (42.2) **G2:** 64 (45.4) More than high school **G1:** 13 (9.6) **G2:** 19 (13.5) **Gestation, mean weeks ± SD:** **G1:** 15.4 ± 7.4 **G2:** 14.4 ± 7.1 **Insurance status, n (%):** Medicaid, **G1:** 97 (71.9) **G2:** 103 (73.1) **Parity, n (%):** Primigravida **G1:** 60 (44.4) **G2:** 61 (43.3) **Partner status, n (%)** Married **G1:** 37 (27.4) **G2:** 37 (26.2)	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 13.4 ± 7.2 **G2:** 11.8 ± 6.6	**Maternal smoking status** Abstinence at 36 weeks gestation, n (%): **G1:** 19 (14.1) **G2:** 14 (9.9) **G1 vs. G2:** OR=1.49 (95% CI: 0.71 to 3.10), p=NS Continuously quit since second visit (reported not smoking at 2nd visit and all CO ≤ 6 ppm), n (%): **G1:** 11 (8.1) **G2:** 5 (3.5) **G1 vs. G2:** p=NS Relapse: NR **Child/infant outcomes** Gestational age : NR Birthweight, mean grams ± SD: **G1:** 3256 ± 452 **G2:** 3221 ± 506 **G1 vs. G2:** p=NS Low birthweight, n (%): **G1:** 7 (5.2) **G2:** 12 (9.0) **G1 vs. G2:** OR=0.56 (95% CI: 0.21 to 1.46) NICU admission : NR Asthma exacerbation : NR Asthma	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Unclear

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Partner smoking status: 1 or more smokers in household **G1:** 106 (78.5) **G2:** 115 (82.6) **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:** Age started smoking, mean years ± SD **G1:** 14.7 ± 2.8 **G2:** 14.4 ± 2.6 Number previous quit attempts, n (%) 0 **G1:** 47 (34.8) **G2:** 32 (22.7) 1 or more **G1:** 88 (65.2) **G2:** 109 (77.3) Cigarettes per day prior to pregnancy, mean ± SD **G1:** 26.1 ± 11.7 **G2:** 25.1 ±1 1.5		hospitalization: NR Upper respiratory infection: NR **Adverse events:** NR	

Table H40. Evidence table (Reference ID# 1023)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Walsh et al., 1997 **Country:** Australia **Enrollment period:** January 1990 to May 1991 **Setting:** Prenatal clinic of urban teaching hospital **Funding:** Grant (National Health and Medical Research Council) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Cognitive behavioral therapy smoking cessation program, physician advice, counseling, self-help material **Intervention provider:** Midwife, physician **Intervention setting:** Prenatal clinic **Comparator:** *Control:* Midwife advice and package of anti-smoking materials (stickers, pamphlet, cessation guide) **Followup:** 4 weeks after first visit, 34 weeks gestation, and 6 to 12 weeks postpartum **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Current smoker at first prenatal clinic visit **Exclusion criteria:** • > 26 weeks gestation • Too ill or psychologically unstable • Other reasons not specified (n=11) **Enrollment, n:** **G1 + G2:** 293 **Followup, n:** **G1:** 127 **G2:** 125 **Age, mean years ± SD:** NR **Education:** NR **Weeks gestation** NR **Insurance** NR **Parity:** NR **Partner status** NR **Partner smoking status:** NR **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:** NR	**Maternal smoking status** Number of cigarettes per day: NR	**Maternal smoking status** Abstinence at 4 weeks after first visit, n (%): **G1:** 20 (16.0) **G2:** 2 (2.0) **G1 vs. G2:** p=0.0001 Abstinence at end of pregnancy, n (%): **G1**: 17 (13.0) **G2:** 7 (6.0) **G1 vs. G2:** p=0.0353 Abstinence at 6 to 12 weeks postpartum, n (%): **G1:** 13 (10.0) **G2:** 1 (1.0) **G1 vs. G2:** p=0.0011 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Good **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Table H41. Evidence table (Reference ID# 1028)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Gielen et al., 1997 **Country:** USA **Enrollment period:** NR **Setting:** Outpatient clinic at Johns Hopkins Hospital **Funding:** Grant (Federal)t **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Quit guide, counseling, education materials, clinic reinforcement **Intervention provider:** Nurse, peer health counselor, clinic staff **Intervention setting:** Clinic **Comparator:** *Control:* Usual clinic information **Followup:** Over 28 weeks gestation, in hospital after delivery, and 3 months and 6 months postpartum (by telephone) **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Smoked a cigarette (even a puff) in past 7 days • African-American or white **Exclusion criteria:** • ≥ 28 weeks pregnant • Changing to another prenatal clinic or could not complete baseline interview at first prenatal visit **Enrollment, n:** **G1:** 232 **G2:** 235 **Followup, n:** NR **Age, mean years:** **G1:** 23.3 **G2:** 24.1 **Education, %:** Less than high school education **G1:** 58 **G2:** 48 **Gestation, mean months:** **G1:** 4.1 **G2:** 4.2 **Insurance status:** NR **Parity, %:** First pregnancy **G1:** 40 **G2:** 42 **Partner status:** NR **Partner smoking**	**Maternal smoking status** Number of cigarettes per day, mean: **G1:** 9.7 **G2:** 7.5 Cotinine, mean ng/ml: **G1:** 155.6 **G2:** 146.0	**Maternal smoking status** Abstinence at end of pregnancy, n (%): **G1:** 12 (6.2) **G2:** 11 (5.6) Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Fair/Poor **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Unclear Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		status: NR **Race/ethnicity, %:** African American **G1:** 81 **G2:** 89 **Socioeconomic status:** Predominately low-income **Smoking history, %:** More than 3 prior quit attempts **G1:** 32 **G2:** 28			

Table H42. Evidence table (Reference ID# 1041)

Study Description	Intervention(s)/ Comparator(s)	Patient Population[13]	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Lowe et al., 1997 **Country:** USA **Enrollment period:** NR **Setting:** 4 public health maternity clinics **Funding:** Grant (Federal) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Multicomponent smoking relapse prevention **Intervention provider:** Health educator and clinic nurses and physicians **Intervention setting:** Clinic **Comparator:** Usual prenatal care **Followup:** Mid pregnancy and end of pregnancy **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Recent quitters • Pregnant **Enrollment, n:** **G1:** 52 **G2:** 54 **Followup, n (%):** **G1:** 40 (76.9) **G2:** 38 (70.4) Baseline data not shown in paper. See Note below. **Age, mean years ± SD:** NR **Education, n (%):** NR **Gestation, weeks:** NR **Insurance status:** NR **Parity:** NR **Partner status:** NR **Partner smoking status:** NR **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:** NR	**Maternal smoking status** Number of cigarettes per day: NR	**Maternal smoking status** Abstinence (relapse prevention) at end of pregnancy, %: **G1:** 29 **G2:** 44 **G1 vs. G2:** p=0.1 **Child/infant outcomes** NR **Adverse Events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: High

[13] Authors report no significant differences in age, race, months pregnant or smoking history between groups.

Table H43. Evidence table (Reference ID# 1046)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Secker-Walker et al., 1997 **Country:** USA **Enrollment period:** November 1992 to April 1993 **Setting:** Prenatal clinic **Funding:** Grant (Federal) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Smoking cessation advice from ob/midwife; self-help videotape; tip sheet on quitting **Intervention provider:** Ob/Gyn, nurse midwife, resident physicians **Intervention setting:** Prenatal clinic **Comparator:** Smoking advice and tip sheet only **Groups:** **G1:** Videotape **G2:** Control **Followup:** 36 weeks gestation	**Inclusion criteria:** • Smoking one or more cigarettes per day at first prenatal visit **Enrollment, n:** **G1:** 30 **G2:** 30 **Followup, n (%):** 36-week visit **G1:** 19 **G2:** 27 **Age, mean years ± SD:** **G1 + G2:** 23.0 ± 5.5 **Education, n (%):** Less than high school **G1 + G2:** 33 **Gestation, weeks;** NR **Insurance status:** NR **Parity, %:** Primigravida **G1 + G2:** 45 **Partner status, %:** Married **G1 + G2:** 30 **Partner smoking status, %:** Other smokers in household **G1 + G2:** 70 **Race/ethnicity, %:** White **G1 + G2:** 98 Non-white **G1 + G2:** 2 **Socioeconomic status:** NR **Smoking history:**	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1 + G2:** 11.4 ± 6.1	**Maternal smoking status** Abstinence at 36 weeks gestation, n (%): **G1:** 5 (19.2) **G2:** 0 **G1 vs. G2:** p=0.02 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: High

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Started smoking, mean age ± SD **G1 + G2:** 14.1 ± 3.3 Cigarettes smoked per day prior to pregnancy, mean number ± SD **G1 + G2:** 22.6 ± 7.4 Previous quit attempts, mean number ± SD **G1 + G2:** 2.7 ± 3.4			

Table H44. Evidence table (Reference ID# 1077)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Hartmann et al., 1996 **Country:** USA **Enrollment period:** August 1991 to January 1993 **Setting:** Academic clinic **Funding:** NR **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** Enrolling nurse, patient	**Intervention:** Counseling and Windsor cessation manual; prescription to quit and letter of support; Resident physicians used scripts for followup visits **Intervention provider:** Resident physicians **Intervention setting:** Clinic **Comparator:** Usual care control **Followup:** End of pregnancy **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Pregnant woman who report smoking at least once in previous week • Consent to breath carbon monoxide testing **Exclusion criteria:** • More than 36 weeks gestation • Psychiatric diagnosis incompatible with participation **Enrollment, n:** **G1 + G2:** 250 **Followup, n:** **G1:** 107 **G2:** 100 **Age, mean years ± SD:** **G1:** 24.7 ± 5.6 **G2:** 26.0 ± 5.3 **Education, %:** Less than 12 years **G1:** 48 **G2:** 43 12 years **G1:** 38 **G2:** 42 More than 12 years **G1:** 14 **G2:** 14 **Gestation, mean weeks ± SD:** **G1:** 14.6 ± 6.9 **G2:** 14.7 ± 6.8 **Insurance status:** NR **Parity, %:** Prior childbirth **G1:** 62 **G2:** 71	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 13.5 ± 9.5 **G2:** 14.4 ± 13.1 Expired carbon monoxide, mean ppm ± SD: **G1:** 15.8 ± 9.9 **G2:** 18.0 ± 11.4	**Maternal smoking status** Abstinence at end of pregnancy, n (%): **G1:** 21 (20) **G2:** 10 (10) **G1 vs. G2:** OR=2.20 (95% CI: 0.98 to 4.94), p=0.052 Relapse NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Good **Risk of bias** Randomization: Low Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Partner status, % : Married **G1:** 42 **G2:** 38 Single **G1:** 47 **G2:** 44 Other **G1:** 11 **G2:** 18 **Partner smoking status, %:** Smokers in household **G1:** 78 **G2:** 73 **Race/ethnicity, %:** White **G1:** 78 **G2**: 74 Black **G1:** 22 **G2:** 26 Other **G1:** 0 **G2:** 0 **Socioeconomic status:** NR **Smoking history:** Years smoking, mean ± SD **G1:** 9.5 ± 5.5 **G2:** 9.9 ± 5.0 Prior quit attempt, % **G1:** 52 **G2:** 47		

Table H45. Evidence table (Reference ID# 1109)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Ershoff et al., 1995 **Country:** USA **Enrollment period:** July 1985 to June 1987 **Setting:** HMO **Funding:** NR **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** Health educator was blind to group assignment until the end of data collection. Prenatal care providers were blind to group assignment.	**Intervention:** Self-help written materials 8 booklets total. First 4 delivered by health educator with brief overview of program. The rest were mailed weekly for 4 weeks. All women were given a two page pamphlet on hazards of smoking during pregnancy. **Intervention provider:** Health educator **Intervention setting:** Clinic **Comparator:** One page tip sheet on behavioral techniques to help avoid relapse. **Followup:** Telephone interview at 26 weeks, and urine samples collected at prenatal visits. Urine cotinine analyzed from 34 week pregnancy. Maintenance at end of pregnancy was confirmed with three urine samples[b]. **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • English speaking • < 18 weeks pregnant • Obtaining prenatal care at one of 5 health centers of HMO group • Quit smoking since becoming pregnant **Enrollment, n:** **G1:** 110 **G2:** 108 **Followup, n for analysis[a]:** **G1:** 87 **G2:** 84 **Age, mean years:** **G1:** 25.3 **G2:** 25.4 **Education, mean years:** **G1:** 12.7 **G2:** 12.9 **Gestation, mean weeks:** **G1:** 10.3 **G2:** 10.2 **Insurance status:** **G1:** HMO 100% **G2:** HMO 100% **Parity:** Primigravida, % **G1:** 32.6 **G2:** 13.1 1 or more children, % **G1:** 39.1 **G2:** 51.2 1 or more miscarriages, % **G1:** 13.8 **G2:** 16.7 **Partner status** Married, %	**Maternal smoking status:** Smoking abstinence, mean days **G1:** 33.7 **G2:** 29.6 No puffs since quitting, %: **G1:** 79.3 **G2:** 66.7 No puff and more than 7 days of abstinence, %: **G1:** 62.1 **G2:** 53.6	**Maternal smoking status** Relapse prevention at end of pregnancy, %: **G1:** 83.9 **G2:** 79.8 **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Fair **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G1: 67.8 **G2:** 66.7 **Partner smoking status:** Smoker, % **G1:** 54.0 **G2:** 47.6 **Race/ethnicity, n (%):** White **G1:** 56.3 **G2:** 54.8 Black **G1:** NR **G2:** NR Other **G1:** NR **G2:** NR **Socioeconomic status:** NR **Smoking history:** Started smoking, mean age: **G1:** 17.2 **G2:** 17.3 Number of cigarettes per day before pregnancy, mean: **G1:** 10.7 **G2:** 10.1		

[a] The number for analysis excludes women who had an abortion (n=5), miscarriage (n=17) or transferred to another medical group (n=25).
[b] Maintenance of cessation was defined as presence of at least one urine cotinine value ≤ 10 ng/mL and no values ≥ 80 ng/mL

Table H46. Evidence table (Reference ID# 1117)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Secker-Walker et al., 1995 **Country:** USA **Enrollment period:** May 1984 to June 1987 **Setting:** University affiliated clinic **Funding:** Grant (NIH) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Relapse prevention counseling **Intervention provider:** Trained counselor **Intervention setting:** NR **Comparator:** Usual care **Followup:** 36 weeks gestation **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Pregnant women who had quit smoking spontaneously before first prenatal visit **Enrollment, n:** **G1:** 89 **G2:** 86 **Followup, n (%):** **G1:** 68 **G2:** 65 **Age, mean years ± SD:** **G1:** 25.9 ± 5.6 **G2:** 24.9 ± 5.4 **Education, n (%):** Less than high school **G1:** 8 (11.8) **G2:** 8 (12.5) High school **G1:** 27 (39.7) **G2:** 27 (42.2) More than high school **G1:** 33 (48.5) **G2:** 29 (45.3) **Gestation, mean weeks ± SD:** **G1:** 12.7 ± 4.0 **G2:** 12.9 ± 4.0 **Insurance status, n (%):** Medicaid **G1:** 9 (13.2) **G2:** 5 (7.7) **Parity, n (%):** Primigravida **G1:** 37 (54.4) **G2:** 34 (52.3) **Partner status:** NR	**Maternal smoking status** Number of cigarettes per day: NR Urine cotinine/creatinine ratio ng/mg, mean ± SD: **G1:** 64 ±151 **G2:** 116 ± 273 Ratio > 80 ng/ml, n (%) **G1:** 7 (13.5) **G2:** 11 (20.0)	**Maternal smoking status** Relapse at 36 weeks, n (%): **G1:** 13/44 (29.5) **G2:** 12/43 (27.9) Urine Cotinine/creatinine ratio ng/mg, mean ± SD: **G1:** 186 ± 440 **G2:** 181 ± 391 **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Partner smoking status, n (%): 1 or more smokers in household **G1:** 32 (47.8) **G2:** 31 (48.4) **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:** Age started smoking, mean years ± SD: **G1:** 16.7 ± 3.5 **G2:** 16.2 ± 2.8 Cigarettes per day prior to pregnancy, n (%): 1-10 **G1:** 24 (36.8) **G2:** 26 (40.0) 11-20 **G1:** 36 (52.9) **G2:** 32 (49.2) 21 or more **G1:** 7 (10.3) **G2:** 7 (10.8) Tried to quit in past, n (%) **G1:** 53 (77.9) **G2:** 53 (81.5)			

Table H47. Evidence table (Reference ID# 1118)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Kendrick et al., 1995 **Country:** USA **Enrollment period:** 1987/1988 to August 1991 **Setting:** WIC or other public prenatal clinics in 3 states **Funding:** Federal (CDC) **Author industry relationship disclosures:** NR **Study Design:** RCT- clinic was unit of randomization; stratified based on yearly enrollment, experience with low birthweight prevention program and minority women **Blinding:** None	**Intervention:** All interventions provided information on effects of smoking on fetus, benefits of quitting, quitting techniques, developing social support, and limiting exposure to environmental smoke **Intervention provider:** Medical and clinic staff **Intervention setting:** NR **Comparator:** Usual care **Followup:** 8th month pregnancy and postpartum visit **Groups:** **G1:** Intervention **G2:** Control **Ga:** Colorado **Gb:** Maryland **Gc:** Missouri	**Inclusion criteria:** • Pregnant smokers (one puff within 7 days before screening) or recent quitters (quit within 7 days before thought she was pregnant) at first prenatal visit **Enrollment, n:** **G1a:** 876 (7 clinics) **G1b:** 694 (14 clinics) **G1c:** 938 (11 clinics) **G2a:** 865 (7 clinics) **G2b:**1242 (14 clinics) **G2c:** 957 (11 clinics) **Followup, n (%):** NR **Age, n (%):** Less than 20 years **Ga:** 482 (27.7) **Gb:** 513 (26.5) **Gc:** 595 (31.4) **Education, n (%):** Less than 12 years **Ga:** 647 (37.2) **Gb:** 815 (42.1) **Gc:** 884 (46.6) **Gestation, mean weeks ± SD:675** **Ga:** 20.3 ± 7.6 **Gb:** 17.6 ± 7.4 **Gc:** 18.3 ±7.5 **Insurance status:** NR **Parity, n (%):** Nulliparous **Ga**: 803 (46.1) **Gb**: 881 (45.5)	**Maternal smoking status** Number of cigarettes per day: NR	**Maternal smoking status** Abstinence at 8th month among enrollment smokers, n (%): **G1:** 54/888 (6.1) **G2:** 69/1177 (5.9) **G1 vs. G2:** OR=1.0 (95% CI: 0.69 to 1.6) **G1a:** 19/233 (8.2) **G2a:** 26/284 (9.2) **G1a vs. G2a:** OR=1.0 (95% CI: 0.31 to 3.3) **G1b:** 22/307 (7.2) **G2b:** 28/546 (5.1) **G1b vs. G2b:** OR=1.2 (95% CI: 0.01 to 86.0) **G1c:** 13/348 (3.7) **G2c:** 15/347 (4.3) **G1c vs. G2c:** OR=0.88 (95% CI: 0.19 to 4.1) Relapse: NR **Child/infant outcomes** Gestational age: NR Birthweight: **G1 vs. G2:** p=0.186 NICU admission : NR Asthma exacerbation : Asthma	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Gc: 778 (41.1) **Partner status:** NR **Partner smoking status, n (%):** **Ga:** 850 (70.6) **Gb:** 1118 (71.6) **Gc:** 1028 (76.0) **Race/ethnicity, n (%):** White, non-Hispanic: **Ga:** 1361 (78.2) **Gb:** 1376 (71.1) **Gc:** 1480 (78.1) Hispanic **Ga:** 259 (14.9) **Gb:** 54 (2.8) **Gc:** 29 (1.5) Black **Ga:** 82 (4.7) **Gb:** 468 (24.2) **Gc:** 362 (19.1) Other: 39 (2.2) **Ga:** NR **Gb:** 38 (2.0) **Gc:** 24 (1.3) **Socioeconomic status:** NR **Smoking history:** NR		hospitalization : NR Upper respiratory infection: NR **Adverse events:** NR	

Table H48. Evidence table (Reference ID# 1134)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Secker-Walker et al., 1994 **Country:** USA **Enrollment period:** May 1984 to June 1987 **Setting:** University affiliated clinic **Funding:** Grant (NIH) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** Smoking cessation counseling intervention **Intervention provider:** Trained counselors **Intervention setting:** Clinic **Comparator:** Usual care **Followup:** 36-week visit **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Pregnant women who were smoking one or more cigarettes per day at first prenatal visit • Less than 25 weeks gestation **Enrollment, n:** **G1:** 300 **G2:** 300 **Followup, n:** **G1:** 188 **G2:** 226 **Age, mean years ± SD:** **G1:** 24.4 ± 5.1 **G2:** 24.1 ± 5.2 **Education, n (%):** Less than high school **G1:** 53 (28.2) **G2:** 69 (30.7) High school **G1:** 89 (47.3) **G2:** 100 (44.4) More than high school **G1:** 46 (24.5) **G2:** 56 (24.9) **Gestation, mean weeks ± SD:** **G1:** 13.8 ± 4.2 **G2:** 13.4 ± 4.1 **Insurance status, n (%):** Medicaid[14] **G1:** 47 (25.3) **G2:** 56 (23.2) **Parity, n (%):** Primigravida	**Maternal smoking status** Number of cigarettes per day, n (%): 1 to 10 **G1:** 90 (47.9) **G2:** 129 (57.1) 11 to 20 **G1:** 86 (45.7) **G2:** 85 (37.6) 21 or more **G1:** 12 (6.4) **G2:** 12 (5.3) Number of cigarettes per day, mean ± SD: **G1:** 14.1 ± 8.3 **G2:** 12.4 ± 7.6 Urine cotinine/creatinine ratio, mean ng/mg ± SD: **G1:** 1093 ±1373 **G2:** 930 ± 1126 Urine cotinine/creatinine ratio, median ng/mg: **G1:** 534 **G2:** 345	**Maternal smoking status** Abstinence[15] at 36 weeks gestation, %: **G1:** 11.8 **G2:** 12.5 **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: High

[14] Status missing for 2 in each group
[15] Urine Cotinine/creatinine ratio ≤ 80 ng/mg

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G1: 83 (44.1) **G2:** 118 (52.2) **Partner status:** NR **Partner smoking status, n (%):** 1 or more smokers in household **G1:** 129 (68.6) **G2:** 163 (72.8) **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:** Age started smoking, mean year ± SD: **G1:** 15.4 ± 3.0 **G2:** 15.2 ± 2.7 Cigarettes per day prior to pregnancy, n (%): 1 to 10 **G1:** 23 (12.2) **G2:** 30 (13.2) 11 to 20 **G1**: 89 (47.3) **G2:** 104 (46.0) 21 or more **G1:** 76 (40.4) **G2:** 92 (40.7) Tried to quit in past, n (%) **G1**: 115 (61.2) **G2:** 157 (69.5)			

Baseline data presented for the analysis subset with followup data from 36 weeks (n=414) Urinary cotinine/creatinine ratios were available for 340 (82%) of women seen at baseline and 312 (75%) of women seen at the 36 week visit

Table H49. Evidence table (Reference ID# 1187)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Windsor et al., 1993 **Country:** USA **Enrollment period:** September 1987 to November1989 **Setting:** 4 public health maternity clinics **Funding:** Grant (NCI) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** *Intervention:* Health education, quit guide, clinic reinforcement, buddy support **Intervention provider:** Health educator **Intervention setting:** Clinic **Comparator:** *Control*: Pamphlets and routine risk information **Followup:** After 32nd week gestation **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Current smoker (self-reported during first prenatal visit at least one puff of one cigarette in last 7 days) **Exclusion criteria:** • Not pregnant • Ineligible for care • Entered into care ≥ 32 weeks • Did not stay for first visit • Did not return • Were Trial 1 participants • Prisoners • Difficulty reading baseline questionnaire **Enrollment, n:** **G1:** 493 **G2:** 501 **Followup, n (%):** 36-week visit **G1:** 400 **G2:** 414 **Age, mean years:** **G1:** 24.1 **G2:** 24.7 **Education, mean years:** **G1:** 12.4 **G2:** 12.2 **Gestation, mean months:** **G1:** 3.9 **G2:** 4.1 **Insurance status:** NR **Parity:** NR	**Maternal smoking status** Cotinine, mean ng/ml ± SD: **G1:** 117 ± 100 **G2:** 109 ± 91	**Maternal smoking status** Abstinence at end of pregnancy, %: **G1:** 14.3 **G2:** 8.5 **G1 vs. G2:** (95% CI: 1.4 to 10.1) p=0.01 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Fair **Risk of bias** Randomization: Low Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Partner status: NR **Partner smoking status:** NR **Race/ethnicity:** Black, % **G1:** 50 **G2:** 54 **Socioeconomic status:** NR **Smoking history:** NR			

Table H50. Evidence table (Reference ID# 1203)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: O'Connor et al., 1992 **Country:** Canada **Enrollment period:** NR **Setting:** Large antenatal group practice clinic **Funding:** Ontario Ministry of Health and the Ontario Thoracic Society **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** None	**Intervention:** 3 to 5 minute counseling; provision of quit guide (*Windsor's 7-day self-help quit plan*); invitation to 2-hour group cessation class in the evening or at the clinic visit; nurse conducted individualized 20-minute counseling session and followup phone call **Intervention provider:** Public health nurse; research nurse **Intervention setting:** Clinic **Comparator:** *Control:* Usual care consisting of 3 to 5 minute counseling; provision of pamphlet; invitation to 2-hour group cessation class in the evening **Followup:** 1 month post-intervention, 36 weeks gestation, and 6 weeks postpartum **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Pregnant women who smoked at least one cigarette daily when screened at first prenatal visit • Less than 31 weeks gestation **Enrollment, n:** **G1:** 115 **G2:** 109 F**ollowup, n:** 1 month post-intervention **G1:** 101 **G2:** 101 36 weeks gestation **G1:** 90 **G2:** 84 Postpartum **G1:** 94 **G2:** 96 **Age, mean years ± SD:** **G1:** 26.6 ± 5.08 **G2:** 27.0 ± 4.89 **Education, mean years ± SD:** **G1:** 12.5 ± 2.56 **G2:** 12.3 ± 1.95 **Gestation, mean weeks ± SD:** **G1:** 14.2 ± 6.44 **G2:** 14.1 ± 6.36 **Insurance status:** NR **Parity:** NR **Partner status** NR **Partner smoking status:** NR **Race/ethnicity:**	**Maternal smoking status** Number of cigarettes per day, mean ± SD: **G1:** 13.0 ± 10.27 **G2:** 12.8 ± 9.42	**Maternal smoking status** Abstinence at 1 month post-intervention, n (%): **G1:** 15 (14.9) **G2:** 5 (5.0) **G1 vs. G2:** RR=3.00 (95% CI: 1.20 to 7.50), p=0.02 Abstinence at 36 weeks gestation, n (%): **G1:** 12 (13.3) **G2:** 5 (6.0) **G1 vs. G2:** RR=2.24 (95% CI: 0.85 to 5.89), p=0.10 Abstinence at postpartum, n (%): **G1:** 13 (13.8) **G2:** 5 (5.2) **G1 vs. G2:** RR=2.66 (95% CI: 1.03 to 6.84), p=0.04 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: High Allocation concealment: High Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Unclear Incomplete outcome reporting: High Other: Unclear

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		NR **Socioeconomic status[16]:** Scale rating, mean score ± SD: **G1:** 40.9 ± 12.56 **G2:** 39.5 ± 11.71 **Smoking history:** NR			

[16] Socioeconomic status scale (Blishen and McRoberts scale) range: 30 (low) to 70 (high)

Table H51. Evidence table (Reference ID# 1237)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Price et al., 1991 **Country:** USA **Enrollment period:** December 1987 to March 1989 **Setting:** Urban outpatient clinic **Funding:** Grant (Family Health Foundation of America) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** NR	**Intervention:** *Video:* Educational videotape, pamphlet and opportunity to ask questions of the health education *Self-help:* American Lung Association booklet and opportunity to ask questions from health educator **Intervention provider:** Health educator **Intervention setting:** Clinic **Comparator:** *Usual care:* Routine physician advice **Followup:** End of pregnancy **Groups:** **G1:** Video **G2:** Self-help **G3:** Usual care	**Inclusion criteria:** • Pregnant smokers **Exclusion criteria:** • > 28 weeks pregnant **Enrollment, n:** **G1:** 71 **G2:** 52 **G3:** 70 **Followup, n (%):** completed study **G1:** 46 (65) **G2:** 39 (75) **G3:** 24 (34) **Age, mean years ± SD:** **G1 + G2 + G3:** 22.6 ± 5.6 **Education, n (%):** Not graduated high school **G1 + G2 + G3:** 87 **Gestation, weeks:** NR **Insurance status:** NR **Parity:** NR **Partner status, n (%):** Single **G1 + G2 + G3:** 58 **Partner smoking status:** NR **Race/ethnicity:** White, % **G1 + G2 + G3: 70** **Socioeconomic status:** NR	**Maternal smoking status** Number of cigarettes per day: NR	**Maternal smoking status** Abstinence at end of pregnancy, n (%): **G1:** 4 (8.7) **G2:** 2 (5.1) **G3:** 1 (4.2) Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Unclear

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Smoking history: NR			

Table H52. Evidence table (Reference ID# 1239)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Hjalmarson et al.,1991 **Country:** Sweden **Enrollment period:** March 1987 to February 1988 **Setting:** 13 public health clinics in Sweden **Funding:** NR **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** NR	**Intervention:** Self-help manual **Intervention provider:** Obstetrician **Intervention setting:** Clinic **Comparator:** Control- given information sheet **Followup:** 12 to 14 weeks, 30 to 34 weeks, 8 weeks postpartum **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Pregnant women registered as daily smokers (at last one/cigarette/day) • Gestational age less than 12 weeks • Spoke Swedish **Enrollment, n:** **G1:** 492 **G2:** 231 **Followup, n (%):** 36-week visit **G1:** 444 **G2:** 209 **Age, mean years:** **G1:** 28.3 **G2:** 28.6 **Education, n (%):** NR **Gestation, weeks:** NR **Insurance status:** NR **Parity:** NR **Partner status:** NR **Partner smoking status:** NR **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:** Number of cigarettes per day before pregnancy, mean (95% CI):	**Maternal smoking status** Number of cigarettes per day at first visit, mean (95% CI): **G1:**10.8 (10.3 to 11.3) **G2:**10.8 (10.4 to 11.2)	**Maternal smoking status** Abstinence at 30 to 34 weeks gestation, n (%) **G1:** 56 (12.6) **G2:** 18 (8.6) **G1 vs. G2:** OR=0.7 (95% CI: 0.4 to 1.1), p=NS Abstinence at hospital, n (%): **G1:** 134 (30.2) **G2:** 51 (24.4) **G1 vs. G2:** OR=0.8 (95% CI: 0.5 to 1.1), p=NS Abstinence at 8 weeks postpartum, n (%): **G1:** 70 (15.8) **G2:** 19 (9.1) **G1 vs. G2:** OR=0.5 (95% CI: 0.3 to 0.9), p<0.05 Relapse: NR **Child/infant outcomes** Gestational age less than 36 weeks, n (%): **G1:** 13/421 (3.1) **G2:** 8/197 (4.1) **G1 vs. G2:** OR=0.8 (95% CI: 0.3 to 1.8), p=NS Birthweight, mean (95% CI): **G1:** 3430 (3378 to 3483) **G2:** 3359 (3286 to 3433) **G1 vs. G2:**	**Overall quality:** Poor **Risk of bias** Randomization: High Allocation concealment: High Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Unclear

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G1: 16.7 (16.2 to 17.2) **G2:** 16.3 (15.9 to 16.7)		p=NS Birthweight less than 2500 grams, n (%): **G1:** 14/422 (3.3) **G2:** 11/198 (5.6) **G1 vs. G2:** OR=0.6 (95% CI: 0.3 to 1.3), p=NS NICU admission: NR Asthma exacerbation: NR Asthma hospitalization: NR Upper respiratory infection: NR **Adverse events:** NR	

Table H53. Evidence table (Reference ID# 1285)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Ershoff et al., 1989 **Country:** USA **Enrollment period:** July 1985 to June 1987 **Setting:** HMO **Funding:** National Center for Health Services Research and Health Care Technology Assessment and Maxicare Health Plans **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** Health educator blind until end of data collection Prenatal care providers	**Intervention:** Self-help smoking cessation program **Intervention provider:** Health educator **Intervention setting:** Clinic **Comparator:** Usual care **Followup:** 26 weeks gestation, 34 to 35 weeks gestation **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • English speaking • < 18 weeks pregnant • Obtaining prenatal care at one of 5 health centers of HMO group • Report currently smoking ≥ 7 cigarettes per week **Enrollment, n:** **G1:** 165 **G2:** 158 **Followup, n:** NR **Age, %:** 18 to 19 years **G1:** 7.2 **G2:** 9.5 20 to 29 **G1:** 71.4 **G2:** 59.5 30 and older **G1:** 21.4 **G2:** 31.0 **Education, n (%):** Less than high school **G1:** 16.7 **G2:** 19.8 High school/some college **G1:** 73.8 **G2:** 72.4 College graduate **G1:** 9.5 **G2:** 7.8 **Gestation weeks:** Less than 9 **G1:** 31.0 **G2:** 31.9 9 to 13 **G1:** 50 **G2:** 44.8 14 or more **G1:** 19.0 **G2:** 23.3	**Maternal smoking status:** Number of cigarettes per day, %: 1 to 10 **G1:** 72.2 **G2:** 71.6 11 to 19 **G1:** 13.5 **G2:** 16.4 20 or more **G1:** 14.3 **G2:** 12.1 Cut down from pre-pregnancy rate, % Yes **G1:** 78.6 **G2:** 79.3	**Maternal smoking status** Abstinence at delivery, mean %: Early quitters **G1:** 22.2 **G2:** 8.6 **G1 vs. G2:** adjOR=2.80 (95% CI: 1.17 to 6.69) Middle quitters **G1:** 0.8 **G2:** 1.7 Late quitters **G1:** 3.2 **G2:** 6.9 Early Relapsers **G1:** 1.6 **G2:** 0 Late Relapsers **G1:** 0.8 **G2:** 0 Non-Quitter **G1:** 71.4 **G2:** 82.8 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Fair **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Insurance status, %: HMO **G1 + G2:** 100 **Parity, %:** No previous births **G1:** 20.6 **G2:** 17.2 1 previous birth **G1:** 27.8 **G2:** 18.1 2 or more previous births **G1:** 51.6 **G2:** 64.7 **Partner status:** NR **Partner smoking status:** Partner smokes, % **G1:** 52.4 **G2:** 67.2 **Race/ethnicity, n (%):** White **G1:** 65.9 **G2:** 62.1 Black **G1:** 25.4 **G2:** 26.7 Other **G1:** 8.7 **G2:** 11.2 **Socioeconomic status:** NR **Smoking history:** Age began smoking, % Younger than 16 **G1:** 37.3 **G2:** 31.9 16 to 18 **G1:** 46.8 **G2:** 45.7 19 or older+ **G1:** 15.9 **G2:** 22.4 Number of cigarettes per day before pregnancy,			

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		%			
		1 to10			
		G1: 30.2			
		G2: 24.1			
		11 to 19			
		G1: 13.5			
		G2: 14.7			
		20 or more			
		G1: 56.3			
		G2: 61.2			

Comments: additional smoking history data: minutes to first cigarette; previous quit attempts; longest time off cigarettes

Authors categorized outcome groups into 6 quit categories

Early quitter: Not currently smoking, quit < 20 weeks pregnant; Cotinine: at least one value ≤ 10ng/ml and no value ≥ 30 ng/ml; 34th week value < 30 ng/ml

Middle quitter: Not currently smoking, quit between 20-26 weeks pregnant; Cotinine: at least one value ≤ 10ng/ml and no value ≥ 30 ng/ml; 34th week value < 30 ng/ml

Late quitter: Currently smoking, and no quit before interview ; Cotinine: 34th and 35th week value ≤ 10 ng/ml

Early relapser: Currently smoking and a quit prior to interview; Cotinine: at least one value ≤ 10ng/ml and no value ≥ 30 ng/ml; 34th week value ≥ 30 ng/ml

Late relapser: Currently not smoking and a quit prior to interview; Cotinine: at least one value ≤ 10ng/ml and no value ≥ 30 ng/ml; 34th week value ≥ 30 ng/ml

Non-Quitter: Currently smoking and no quit prior to interview; Cotinine at 34th week > 10 ng/ml

Table H54. Evidence table (Reference ID# 1332)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Windsor et al., 1985 **Country:** USA **Enrollment period:** October 1983 to September 1984 **Setting:** 3 public health maternity clinics **Funding:** Grant (National Health Services Research and National March of Dimes Birth Defects Foundation) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** NR	**Intervention:** Self-help manual **Intervention provider:** Individual with bachelor's degree in community health education **Intervention setting:** Clinic **Comparator:** Health Education: ALA Freedom from Smoking Program Manual; booklet and counseling as above **Followup:** Mid-point and end of pregnancy **Groups:** **G1:** Windsor guide **G2:** ALA manual **G3:** Control	**Inclusion criteria:** • Current smoker at first prenatal visit (at least one cigarette in past 7 days) **Exclusion criteria:** • ≥32 weeks gestation **Enrollment, n:** **G1:** 102 **G2:** 103 **G3:** 104 **Followup, n:** **G1:** 102 **G2:** 103 **G3:** 104 **Age, mean years:** **G1:** 23.1 **G2:** 23.5 **G3:** 24.1 **Education, mean years:** **G1:** 11.4 **G2:** 11.5 **G3:** 11.7 **Gestation, mean months:** **G1:** 3.5 **G2:** 3.8 **G3:** 3.8 **Insurance status:** NR **Parity:** NR **Partner status:** NR **Partner smoking status:** NR **Race/ethnicity, %:** Black **G1:** 62 **G2:** 49	**Maternal smoking status** Number of cigarettes per day: NR Saliva thiocyanate, mean ± SD: **G1:** 150.8 **G2:** 157.9 **G3:** 166.5	**Maternal smoking status** Abstinence, % (95% CI): **G1:** 14 (0.07 to 0.21) **G2:** 6 (0.01 to 0.11) **G3:** 2 (0.00 to 0.05) **G1 vs. G3:** ? **G2 vs. G3:** ? Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Fair **Risk of bias** Randomization: Low Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G3: 54 **Socioeconomic status:** NR **Smoking history:** NR			

Table H55. Evidence table (Reference ID# 1359)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Bauman et al., 1983 **Country:** USA **Enrollment period:** February 1981 to August 1981 **Setting:** Gilford County health department **Funding:** NR **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** NR	**Intervention:** Feedback on participant expired carbon monoxide level with 135-word script on relationships among cigarette smoking, carbon monoxide, and harmful consequences of smoking during pregnancy **Intervention provider:** Health educators **Intervention setting:** Clinic **Comparator:** Script but no feedback on participant exhaled carbon monoxide level **Followup:** 6 weeks **Groups:** **G1:** Intervention **G2:** Control **Ga:** Smoker **Gb:** Nonsmoker	**Inclusion criteria:** • Women admitted for prenatal care • Included smokers and non-smokers **Enrollment, n:** **G1 + G2:** 226 **Followup, n:** **G1 + G2:** 170 **G1a:** 36 **G2a:** 43 **Age, mean years:** **G1a + G2a:** 20 **Education:** Completed high school or more, % **G1a + G2a:** 43 **Gestation:** First trimester, % **G1a + G2a:** 38 Second trimester, % **G1a + G2a:** 46% **Insurance status:** NR **Parity:** First child, % **G1a + G2a:** 44 **Partner status:** Married, % **G1a + G2a:** 40 **Partner smoking status:** NR **Race/ethnicity:** Black, % **G1a + G2a:** 56 **Socioeconomic status:** NR **Smoking history:** NR	**Maternal smoking status** Current smokers, n (%): **G1a + G2a:** 79 (47) Number of cigarettes per day: NR	**Maternal smoking status** Abstinence at 6 weeks after orientation, %: **G1a:** 24.0 **G2b:** 23.0 Expired carbon monoxide ≥9 ppm, % **G1a:** 76.0 **G2a:** 77.0 Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: Low Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

Table H56. Evidence table (Reference ID# 1640)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Burling et al., 1991 **Country:** USA **Enrollment period:** NR **Setting:** OB/GYN clinic of large municipal hospital **Funding:** Grant (Federal) **Author industry relationship disclosures:** NR **Study Design:** RCT **Blinding:** NR	**Intervention:** Stop smoking intervention **Intervention provider:** Clinic nurse **Intervention setting:** Clinic/home **Comparator:** Usual care- clinic's standard educational program **Followup:** Approximately 24, 28, and 34 weeks gestation **Groups:** **G1:** Intervention **G2:** Control	**Inclusion criteria:** • Classified as smokers at first study contact **Enrollment, n:** **G1:** 70 **G2:** 69 **Followup, n (%):** NR **Age, mean years ± SD:** NR **Education, n (%):** NR **Gestation, weeks:** NR **Insurance status:** NR **Parity:** NR **Partner status** NR **Partner smoking status:** NR **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:** NR	**Maternal smoking status** Number of cigarettes per day: NR	**Maternal smoking status** Abstinence at second study contact, %: **G1:** 11.6 **G2:** 1.4 **G1 vs. G2:** p<0.01 Abstinence at last study contact, %: **G1:** 13.0 **G2:** 5.7 **G1 vs. G2:** p=NS Relapse: NR **Child/infant outcomes:** NR **Adverse events:** NR	**Overall quality:** Fair **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Unclear Other: Low

Table H57. Evidence table (Reference ID# 2284)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: El-Mohandes et al., 2012 **Country:** USA	**Intervention:** Nicotine replacement therapy plus SCRIPT **Intervention**	**Inclusion criteria:** • English speaking • D.C. metropolitan area residents • Self-identified	**Maternal smoking status** Number of cigarettes per day ≤ 7, mean	**Maternal smoking status** Abstinence at visit 6, n (%): **G1:** 5 (19) **G2:** 0	**Overall quality:** Good **Risk of bias** Randomization: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Enrollment period: July 2006 to December 2009 **Setting:** 3 prenatal care sites **Funding:** Grant (Federal) **Author industry relationship disclosures:** 0/6 **Study Design:** RCT **Blinding:** Telephone interviewers blinded	**provider:** NR **Intervention setting:** NR **Comparator:** SCRIPT only **Followup:** 10 weeks **Groups:** **G1:** Intervention **G2:** Control	ethnic minority • ≥ 18 years • < 30 weeks pregnant • Smoker with desire to quit (CO levels≥ 8 ppm, salivary cotinine ≥ 20ng/ml or urinary cotinine ≥ 100 ng/ml) **Exclusion criteria:** • Under treatment for psychiatric illness, alcoholism or drug addiction **Enrollment, n:** **G1:** 26 **G2:** 26 **Followup, n:** **G1:** 26 **G2:** 26 **Age, mean years ± SD:** **G1:** 27.5 ± 5.0 **G2:** 27.6 ± 5.9 **Education, n (%):** Less than high school **G1:** 7 (27) **G2:** 10 (38) High school graduate/GED **G1:** 15 (58) **G2:** 11 (42) At least some college **G1:** 4 (15) **G2:** 5 (19) **Gestation, mean weeks ± SD:** **G1:** 19.6 ± 5.1 **G2:** 17.5 ± 4.7 **Insurance status, n (%):** Medicaid **G1:** 25 (96)	± SD: **G1:** 7.0 ± 7.4 **G2:** 5.1 ± 3.3 Expired carbon monoxide, mean ± SD: **G1:** 8.8 ± 6.1 **G2:** 9.0 ± 6.9 Cotinine (salivary), mean ± SD: **G1:** 171 ±143 **G2:** 158 ± 109	**G1 vs. G2:** p=0.05 Relapse: NR **Child/infant outcomes** Gestational age, mean weeks: **G1:** 39.4 **G2:** 38.4 **G1 vs. G2:** p=0.02 Birthweight, mean grams: **G1:** 3203 **G2:** 2997 **G1 vs. G2:** p=NS NICU admission, : NR Asthma exacerbation: NR Asthma hospitalization: NR Upper respiratory infection: NR **Adverse events:** NR	Allocation concealment: Low Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: Low Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		G2: 23 (96) **Parity:** Number live births, mean ± SD **G1:** 2.4 ± 1.6 **G2:** 2.5 ± 2.3 **Partner status, n (%):** Married or living with partner **G1:** 5 (19) **G2:** 1 (4) Single/never married **G1:** 19 (73) **G2:** 23 (88) **Partner smoking status:** NR **Race/ethnicity:** Ethnic minority, % **G1 + G2:** 100 **Socioeconomic status:** NR **Smoking history:** NR			

Table H58. Evidence table (Reference ID# 2285)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Jimenez-Muro et al., 2012 **Country:** Spain **Enrollment period:** January 2009 to March 2010 **Setting:** University clinic hospital **Funding:** Ministry of Health and Consumer Affairs **Author industry relationship disclosures:** 0/8 **Study Design:** RCT **Blinding:** NR	**Intervention:** *Postpartum relapse prevention*: Motivational interviewing, telephone support calls, booklet **Intervention provider:** Trained counselor **Intervention setting:** Hospital and home **Comparator:** *Control:* Booklet and 2-minute telephone calls at 3 and 12 weeks postpartum **Followup:** 3 months postpartum **Groups:** **G1:** Intervention **G2:** Control **Ga:** Smoker **Gb:** Recent quitter	**Inclusion criteria:** • Current smoker (smoked during pregnancy) or recent quitter (stopped smoking at beginning or during pregnancy) **Enrollment, n:** **G1:** 205 **G2:** 207 **G1a:** 117 **G2a:** 117 **G1b:** 88 **G2b:** 90 **Followup, n:** NR **Age, mean years ± SD:** **G1a:** 29.8 ± 5.5 **G2a:** 30.2 ± 4.9 **G1b:** 29.8 ± 6.2 **G2b:** 31.1 ± 5.2 **Education:** NR **Gestation, weeks:** NA **Insurance status** NR **Parity:** NR **Partner status:** NR **Partner smoking status:** NR **Race/ethnicity:** NR **Socioeconomic status:** NR **Smoking history:**	**Maternal smoking status** Number of cigarettes per day: NR	**Maternal smoking status** Abstinence at 3 months postpartum, n (%): **G1b:** 27/88 (31) **G2b:** 21/90 (23) **G1b vs. G2b:** p=NS Relapse: NR **Child/infant outcomes** NR **Adverse events:** NR	**Overall quality:** Poor **Risk of bias** Randomization: High Allocation concealment: High Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
		Age started smoking, mean years ± SD **G1a:** 15.7 ± 3.2 **G2a:** 15.8 ± 2.4 **G1b:** 16.7 ± 3.2 **G2b:** 16.5 ± 3.9 Cigarettes per day before pregnancy, mean number ± SD **G1a:** 17.4 ± 8.1 **G2a:** 16.0 ± 7.7 **G1b:** 11.3 ± 8.0 **G2b:** 9.7 ± 6.8			

Table H59. Evidence table (Reference ID# 3597)

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
Author: Tuten et al., 2012 **Country:** USA **Enrollment period:** May 2005 to January 2009 **Setting:** University based drug and alcohol treatment clinic for pregnant women **Funding:** Grant (Federal) **Author industry relationship disclosures:** 0/5 **Study Design:** RCT **Blinding:** None	**Intervention:** Contingent behavioral incentive (CBI) shaping schedule-participants were eligible to earn incentives contingent upon smoking reduction or abstinence for 12 weeks or until delivery Week 1: any reduction Weeks 2-4: 10% reduction Weeks 5-7: 25% reduction Weeks 8-9: 50% reduction Weeks 10-11: 75% reduction Week 12 until delivery: abstinence (CO < 4 ppm) Voucher was $7.50 for first target and increased by $1.00/day for each consecutive target. up to maximum $41.50 NCBI: Participants were yoked to randomly selected individual in pilot CBI condition who had submitted CO samples for at least a two week period. Required to leave CO and urine samples generated by yoked schedule. **Intervention provider:** NR **Intervention setting:**	**Inclusion criteria:** • Pregnant, ≤ 30 weeks gestation • Age ≥ 18 • Nicotine dependent or smoked 10 or more cigarettes daily • Capable of providing informed consent • Entered treatment at Center for Addiction and Pregnancy (CAP) **Exclusion criteria:** • See above **Enrollment, n:** **G1:** 42 **G2:** 28 **G3:** 32 **Followup, n:** **Neonatal outcomes** **G1:** 30 **G2:** 17 **G3:** 21 **Age, mean years ± SD:** **G1:** 32.2 ± 6.4 **G2:** 29.8 ± 5.6 **G3:** 30.0 ± 5.6 **Education, mean years ± SD:** **G1:** 11.2 ± 1.5 **G2:** 10.8 ± 1.5 **G3:** 11.3 ± 1.5 **Gestation, mean weeks ± SD:** **G1:** 16.9 ± 6.2 **G2:** 14.9 ± 7.3 **G3:** 17.6 ± 7.4 **Insurance status,**	**Maternal smoking status** Number of cigarettes per day in past 30 days, mean ± SD: **G1:** 17.1 ± 10.0 **G2:** 19.1 ± 7.9 **G3:** 17.9 ± 7.4 Expired carbon monoxide, mean ppm ± SD: **G1:** 12.1 **G2:** NR **G3:** NR Urinary cotinine, mean ng/ml ± SD: **NR**	**Maternal smoking status** Abstinence (exhaled CO < 4 ppm) at 12 weeks, % **G1:** 31 **G2:** 0 **G3:** 0 Expired carbon monoxide, mean ppm ± SD: **G1:** 4.0 ± 5.5 **G2:** 8.7 ± 2.8 **G3:** 8.4 ± 4.2 Relapse: NR **Child/infant outcomes** Gestational age at delivery, mean weeks ± SD: **G1:** 37.9 ± 3.6 **G2:** 37.0 ± 3.0 **G3:** 37.8 ± 2.7 **G1 vs. G2 vs. G3:** p=0.601 Preterm birth, % **G1:** 16.7 **G2:** 35.3 **G3:** 28.6 **G1 vs. G2 vs. G3:** p=0.330 Birthweight, mean grams ± SD: **G1:** 2863.3 ± 694.3 **G2:** 2695.6 ± 656.9 **G3:** 2701.3 ± 598.3 **G1 vs. G2 vs. G3:** p=0.597 Low birthweight	**Overall quality:** Poor **Risk of bias** Randomization: Unclear Allocation concealment: Unclear Selective reporting: Low Blinding patients/personnel: Low Blinding outcome assessment: Low Incomplete outcome reporting: High Other: Low

Study Description	Intervention(s)/ Comparator(s)	Patient Population	Baseline Measure(s)	Outcome Measure(s)	Quality
	Center for Addiction and Pregnancy (drug and alcohol residential and outpatient care) **Comparator:** • Non-contingent behavioral incentive (NCBI) • Treatment as usual (TAU) **Followup:** 1 month, 3 months and 6 weeks postpartum (self-report data only) **Groups:** **G1:** CBI **G2:** NCBI **G3:** TAU	**%:** NR **Parity, %:** NR **Partner status, n (%):** Currently single **G1:** 33 (89.2) **G2:** 25 (89.3) **G3:**23 (76.7) **Partner smoking status, %:** NR **Race/ethnicity, n (%):** Caucasian **G1:** 23 (54.8) **G2:** 22 (78.6) **G3:**21 (65.6) African American/other **G1:** 19 (45.2) **G2:** 6 (21.4) **G3:** 11 (34.4) **Socioeconomic status:** Unemployed **G1:** 35 (94.6) **G2:** 27 (96.4) **G3:**28 (93.3) **Smoking history:** **Nicotine use in last 30 days, mean days ± SD:** **G1:** 28.7 ± 5.9 **G2:** 30.0 ± 0.2 **G3:** 29.1 ± 5.1		(<2500 grams), %: **G1:** 20.0 **G2:** 37.5 **G3:** 42.9 **G1 vs. G2 vs. G3:** p=0.186 NICU admission, %: **G1:** 46.7 **G2:** 50.0 **G3:** 61.9 **G1 vs. G2 vs. G3:** p=0.551 **Adverse events:** NR	

Appendix I. Risk of Bias and Quality Score for Individual Studies

Table I1. Risk of bias and quality score for RCTs

Author, year	Random Sequence Generation	Allocation Conceal	Selective Reporting	Other Bias	Blinding (patients/ personnel)	Blinding (outcome assessment)	Incomplete Outcome Data	High	Low	Unclear	Quality Score
Eades, et al., 2012[1]	H	H	L	L	H	L	H	4	3	0	Poor
Coleman, et al., 2012[2]	L	L	L	L	L	L	L	0	7	0	Good
Naughton, et al., 2012[3]	L	L	L	L	L	L	L	0	7	0	Good
Ondersma, et al., 2012[4]	L	L	L	L	L	L	L	0	7	0	Good
Tuten, et al., 2012[5]	U	U	L	L	L	L	H	1	4	2	Poor
Phillips, et al., 2012[6]	L	L	L	L	L	L	L	0	7	0	Good
Windsor, et al., 2011[7]	L	L	L	U	H	L	L	1	5	1	Poor
Reitzel, et al., 2010[8]	L	L	L	L	H	L	L	1	6	0	Poor
Cinciripini, et al., 2010[9]	L	L	L	L	L	L	L	0	7	0	Good
Hennrikus, et al., 2010[10]	L	U	L	L	U	L	L	0	5	2	Fair
Stotts, et al., 2009[11]	L	U	L	L	L	L	L	0	6	1	Fair
Oncken, et al., 2008[12]	L	L	L	L	L	L	U	0	6	1	Fair
Bullock, et al., 2009[13]	L	L	L	L	L	L	H	1	6	0	Poor
Heil, et al., 2008[14]	L	U	L	L	L	L	L	0	6	1	Fair
Pollak, et al., 2007[15]	L	L	L	L	H	L	L	1	6	0	Poor
Ruger, et al., 2008[16]	U	U	L	L	U	L	H	1	3	3	Poor
Albrecht, et al., 2006[17]	L	L	L	L	L	L	L	0	7	0	Good
Dornelas, et al., 2006[18]	U	U	L	L	L	L	L	0	5	2	Fair
Rigotti, et al., 2006[19]	L	L	L	L	L	L	L	0	7	0	Good
Suplee, 2005[20]	U	L	L	L	L	L	L	0	6	1	Fair
Tappin, et al., 2005[21]	L	L	L	L	H	L	L	1	6	0	Poor
Hotham, et al., 2006[22]	L	L	L	L	H	L	H	2	5	0	Poor
Pbert, et al., 2004[23]	L	L	L	L	L	L	H	1	6	0	Poor
Cope, et al., 2003[24]	H	H	L	L	L	L	H	3	4	0	Poor
Hegaard, et al., 2003[25]	H	H	L	L	L	L	L	2	5	0	Poor
Lawrence, et al., 2003[26]	U	H	L	L	L	L	L	1	5	1	Poor
Malchodi, et al., 2003[27]	L	L	L	L	L	L	L	0	7	0	Good
Moore, et al., 2002[28]	L	L	L	L	L	L	L	0	7	0	Good
Stotts, et al., 2002[29]	L	L	L	H	L	L	H	2	5	0	Poor
Hajek, et al., 2001[30]	L	L	L	L	L	L	L	0	7	0	Good
Ershoff, et al., 1999[31]	U	U	L	L	L	L	L	0	5	2	Fair
Solomon, et al., 2000[32]	U	U	L	H	L	L	L	1	4	2	Poor
Donatelle, et al., 2000[33]	U	U	L	L	L	L	L	0	5	2	Fair
Johnson, et al., 2000[34]	L	L	L	L	L	L	L	0	7	0	Good
Panjari, et al., 1999[35]	U	U	L	L	L	L	H	1	4	2	Poor
Secker-Walker, et al., 1998[36]	U	U	L	L	L	L	H	1	4	2	Poor
Secker-Walker, et al.,	U	U	L	U	L	L	L	0	4	3	Fair

Author, year	Random Sequence Generation	Allocation Conceal	Selective Reporting	Other Bias	Blinding (patients/ personnel)	Blinding (outcome assessment)	Incomplete Outcome Data	High	Low	Unclear	Quality Score
1998[37]											
Walsh, et al., 1997[38]	L	L	L	L	L	L	L	0	7	0	Good
Gielen, et al., 1997[39]	U	U	L	L	L	L	L	0	5	2	Fair
Lowe, et al., 1997[40]	U	U	L	H	L	L	L	1	4	2	Poor
Secker-Walker, et al., 1997[41]	U	U	L	H	L	L	L	1	4	2	Poor
Hartmann, et al., 1996[42]	L	L	L	L	L	L	L	0	7	0	Good
Ershoff, et al., 1995[43]	U	U	L	L	L	L	L	0	5	2	Fair
Secker-Walker, et al., 1995[44]	U	U	L	L	L	L	H	1	4	2	Poor
Kendrick, et al., 1995[45]	U	U	L	L	L	L	H	1	4	2	Poor
Secker-Walker, et al., 1994[46]	U	L	L	H	L	L	H	2	4	1	Poor
Windsor, et al., 1993[47]	L	U	L	L	L	L	L	0	6	1	Fair
O'Connor, et al., 1992[48]	H	H	L	U	L	U	H	3	2	2	Poor
Price, et al., 1991[49]	U	L	L	U	L	L	H	1	4	2	Poor
Hjalmarson, et al., 1991[50]	H	H	L	U	L	L	L	2	4	1	Poor
Ershoff, et al., 1989[51]	U	U	L	L	L	L	L	0	5	2	Fair
Windsor, et al., 1985[52]	L	U	L	L	L	L	L	0	6	1	Fair
Bauman, et al., 1983[53]	L	U	L	L	L	L	H	1	5	1	Poor
Burling, et al., 1991[54]	U	U	L	L	L	L	U	0	4	3	Fair
El-Mohandes, et al., 2012[55]	L	L	L	L	H	L	L	1	6	0	Poor
Jimenez-Muro, et al., 2012[56]	H	H	L	L	L	L	H	3	4	0	Poor
High	6	7	0	5	7	0	17	**42**			
Low	29	26	56	46	47	55	37		**296**		
Unclear	21	23	0	5	2	1	2			**54**	

Table I2. Quality score for cohort studies

Author, year	Selection	Comparability	Outcome	Total Points	Quality Score
Gadomski, et al., 2011[57]	4/4	1/2	3/3	8	Fair
Windsor, et al., 2000[58]	4/4	1/2	3/3	8	Fair
Wisborg, et al., 1998[59]	2/4	2/2	1/3	5	Poor

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