Evidence-based Practice Center Systematic Review Protocol

Project Title: Smoking Cessation Interventions During Pregnancy and the Postpartum Period

I. Background and Objectives for the Systematic Review

Nearly 443,000 U.S. deaths are attributable annually to cigarette smoking, making tobacco, including secondhand smoke, the most preventable cause of disease, disability, and death in the United States.[1, 2] Globally, smoking-related deaths are estimated to exceed 8 million by 2030.[3] Smoking is linked to cancer, heart disease, lung disease, and stroke[1] and places women at greater overall risk for disease than men.[4, 5] Smoking also raises a woman's risk for breast, cervical, and ovarian cancer; infertility; and early menopause.[6] 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.[7] 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] Self-report may lead to an overestimation of cessation rates in pregnancy.[8]

When compared with nonsmokers, women 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 assistance from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) during pregnancy.[9] 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 both the mother and fetus. Smoking is associated with increased risk of placental abruption, anemia, preterm birth, chronic hypertension, and placenta previa.[10-13] Health risks to the fetus include low birth weight, restricted growth, and fetal death.[12,14-20] Infants and children of women who smoke face a higher risk of sudden infant death syndrome (SIDS)[21, 22] and other conditions including respiratory infections, impaired lung growth, otitis media, necrotizing enterocolitis, and infectious diseases.[23-27] Infants and children are also affected by secondhand or environmental tobacco smoke. 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 SIDS, acute respiratory infections, otitis media, and more severe asthma.[28] Passive smoke exposure has also been associated with bronchiolitis and bronchitis.[29,30] Recent global estimates suggest that 165,000 children under age 5 die annually from lower respiratory infection caused by exposure to secondhand smoke.[31]

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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®).

Previous systematic reviews have typically reported limited effectiveness for most interventions in pregnant smokers, though some have reported positive results. A 2012 Cochrane review[32] of pharmacologic agents for cessation included six trials of NRT agents and reported insufficient evidence to permit conclusions about benefits and harms. The 2012 meta-analysis by Myung and colleagues included six trials of NRT and one of bupropion.[33] In contrast to the Cochrane review, Myung et al. 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, however, included a large study judged to have high risk of bias in the Cochrane review and thus was excluded by the Cochrane group.

A 2011 review conducted by the British Columbia Centre for Excellence in Women's Health reviewed 97 studies 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."[34] 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.[35] A 2007 review of randomized controlled trials found no evidence that providing advice materials and counseling affected postpartum smoking cessation.[36] 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.[36]

Overall, the findings from existing systematic reviews suggest that nicotine replacement therapy, behavioral and educational cessation strategies, and multicomponent interventions may be beneficial to women who smoke in pregnancy or the postpartum period. 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.[37-49] 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.

Rationale for Conducting This Systematic Review

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 will update the evidence from prior systematic reviews, include child outcomes, and attempt to characterize patient and intervention characteristics that modify the effects of interventions.

II. The Key Questions (KQs)

Our Key Questions (KQs) are as follows:

KQ1. What is the effectiveness of interventions intended to achieve or maintain smoking cessation abstinence in women who are pregnant or postpartum for promoting smoking cessation, relapse prevention, and continuous abstinence?

KQ2. 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?

KQ3. What are the harms of interventions intended to achieve or maintain smoking cessation in women who are pregnant or postpartum?

KQ4. What are the effects 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?

KQ5. What are the effects of patient characteristics on outcomes of smoking cessation interventions (successful/unsuccessful cessation, relapse) in women who are pregnant or postpartum?

Table 1 outlines the PICOTS (**P**opulation, **I**ntervention, **C**omparator, **O**utcomes, **T**iming, and **S**etting) elements for each KQ.

Table 1. PICOTS

PICOTS	Criteria
Population	• Pregnant or postpartum (≤6 months postbirth) women who smoke or quit smoking in the index pregnancy • Infants and children of pregnant or postpartum (≤6 months postbirth) women receiving smoking cessation interventions • Subgroups of pregnant and/or postpartum women based on level of nicotine dependence, previous 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

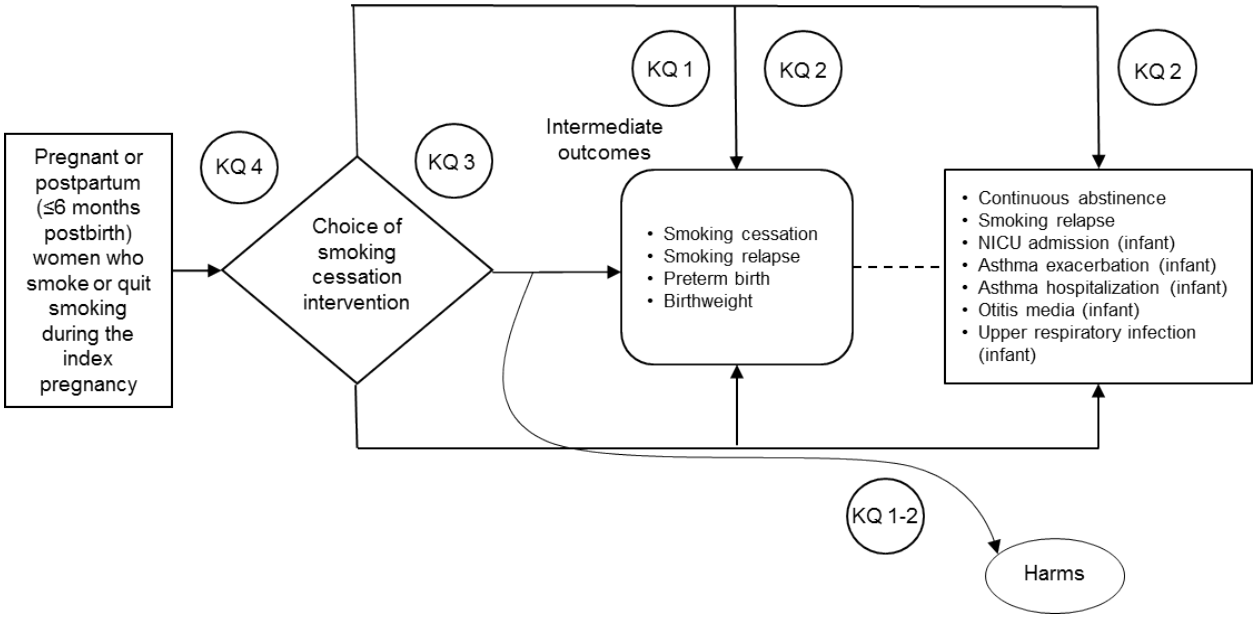
PICOTS	Criteria			
Outcomes	**KQ 1** • Smoking cessation (biochemically validated) • Continuous abstinence (biochemically validated) • Relapse	**KQ 2** • Preterm birth • Gestational age • Birthweight • Neonatal death • NICU admission • Asthma exacerbation • Asthma hospitalization • Otitis media • Upper respiratory infection	**KQ 3** • Harms (e.g., weight gain, emotional stress, adverse events associated with medication to the mother or fetus)	**KQ 4 & 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, Outcomes, Timing, and Setting

III. Analytic Framework

The analytic framework illustrates the population, interventions, and outcomes that will guide the literature search and synthesis.

Figure 1. Analytic framework



Abbreviations: KQ = key question; NICU = neonatal intensive care unit

IV. Methods

A. Criteria for Inclusion/Exclusion of Studies in the Review

The inclusion and exclusion criteria for the review are derived from our understanding of the literature and refinement of the review topic with the Task Order Officer and the topic

nominators (Table 2). We will include studies of pregnant or postpartum (i.e., within 6 months of birth) smokers or smokers who quit during the index pregnancy.

We will not limit the search to studies conducted during any specific time period. We will include 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 our 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. The team will evaluate any non–English-language studies that appear relevant to determine how or if these studies should be addressed in the review.

Studies must 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 for studies with sample sizes large enough to measure effects of the intervention.

Table 2: Inclusion/Exclusion Criteria

Category	Criteria
Study population	Pregnant or postpartum (up to 6 months postbirth 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, 2, and 3: RCT
	• KQs 4 and 5: RCT or 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:
	  ○ Treatment modality aimed at smoking cessation in a relevant population
	  ○ Outcomes related to interventions; primary outcomes of interest include smoking cessation, continuous abstinence, smoking relapse, harms of the intervention to the mother or fetus, gestational age, NICU admission, birthweight, 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

B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies To Answer the Key Questions (KQs)

Search strategies and databases

To ensure comprehensive retrieval of relevant studies of smoking cessation interventions in our target population, we will use three key databases: the MEDLINE medical literature database via the PubMed® interface, the PsycINFO® psychology and psychiatry database, and the Cumulative Index of Nursing and Allied Health Literature (CINAHL®). The search strategies for each of these databases will focus specifically on terms related to smoking cessation, pregnancy, and the postpartum period. Preliminary search strategies are presented in Appendix B. We will carry out hand searches of the reference lists of recent related systematic reviews or meta-analyses; the investigative team will also scan the reference lists of included articles for additional studies eligible for inclusion.

Search updates

During our review of abstracts and full-text articles, we will update the literature search quarterly and add relevant studies. We will update the literature search and add relevant studies while the draft report is undergoing peer review.

Grey literature

We will request Scientific Information Packets and regulatory information searches addressing medications with FDA-approval for smoking cessation including bupropion (Zyban), varenicline (Chantix), and over-the-counter and prescription-only nicotine replacement products. Pharmacologic interventions are listed in Appendix C.

C. Data Extraction and Data Management

Screening and extraction forms

We will develop data collection forms for abstract review, full-text review, and data extraction. The abstract review form will contain questions about the primary exclusion and inclusion criteria for initial screening. The full-text screening form will be used to examine the full text of papers that met initial criteria for inclusion in the abstract review. Data extraction forms will collect those data necessary to create evidence tables and perform data synthesis. After reviewing a sample of relevant articles, the team will test and revise the screening and data collection forms before beginning each stage of screening or data extraction.

Initial review of abstracts

We will review all the titles and abstracts retrieved by the searches against pre-established inclusion and exclusion criteria. Each abstract will be assigned for review by two members of the investigative team. Both reviewers must agree to exclude an abstract. We will promote abstracts for full-text review when one or both reviewers determine that the abstract meets criteria for inclusion. Abstracts with insufficient information will be promoted for full-text review.

Retrieving and reviewing articles

We will retrieve and review the full text from all abstracts screened for inclusion and abstracts for which we were unable to make a decision about eligibility. Each article will be reviewed by at least two members of the investigative team. Disagreements between

the reviewers will be adjudicated by the lead investigator or via investigative team consensus. We will use a simple categorization scheme to code the reasons for exclusion for papers that are not included in the report. The reviewer will note the reason(s) for exclusion on the screening form. We will record the exclusion reasons using prespecified codes in an EndNote® (Thomson Reuters, New York, NY) bibliographic database so that we can compile a list of excluded articles with exclusion reasons.

Data extraction

For studies that meet the conditions of the second-round assessment, we will record study characteristics (i.e., study design, year, location, randomization, intervention characteristics, and related publications). We will also extract key data and study quality elements for each study.

We developed a list of characteristics from our preliminary scan of the literature, clinical experience, and discussion with the Technical Experts, the Task Order Officer, and the topic nominators. We anticipate that these data will include study participant characteristics (e.g., age, race/ethnicity, socioeconomic status, smoking status [number of cigarettes/day, partner smoking status, previous quit attempts], etc.), intervention characteristics (e.g., who provided the intervention, components of the intervention, and where the intervention was provided), and outcomes.

For primary assessment of smoking behavior, we will record biochemically validated smoking cessation/abstinence rates. We will not extract outcome data obtained exclusively via self-report, given the evidence base indicating variability and relatively low accuracy of self-assessed smoking status among pregnant women.[9,50] Although there is no currently available biologic measure for verifying continuous abstinence during pregnancy, biochemical measurements (e.g., urinary or serum cotinine, expired carbon monoxide, serum thiocyanate) are accepted standards for evaluating smoking status.[9,50,51]

We will extract the information outlined in Table 3 from included studies when reported. A second reviewer will review the data extraction forms against the original articles for quality control. Differences in data coding between the abstractor and the reviewer will be resolved by consensus.

Table 3. Outcomes of interest

KQ	Characteristics	Primary Outcomes	Secondary Outcomes
1	• Maternal age • Parity • Smoking status (number of cigarettes/day, years smoked, previous quit attempts) • Insurance status • Race/ethnicity • Partner/household smoking status • Maternal education level	• Smoking cessation/abstinence (biochemically validated) • Relapse	• NA
2	• Maternal age • Parity	• Birthweight • Gestational age	• Otitis media • Asthma exacerbation

KQ	Characteristics	Primary Outcomes	Secondary Outcomes
	• Smoking status (number of cigarettes/day, years smoked, previous quit attempts) • Insurance status • Race/ethnicity • Partner/household smoking status • Maternal education level	• Preterm birth • Neonatal death • NICU admission	• Asthma hospitalization • Upper respiratory tract infection
3	• Maternal age • Parity • Smoking status (number of cigarettes/day, years smoked, previous quit attempts) • Insurance status • Race/ethnicity • Partner/household smoking status • Maternal education level	• Harms to mother • Harms to fetus	• NA
4	• Intervention provider (e.g., physician, nurse, midwife, social worker) • Intervention components • Intervention setting (place of delivery [e.g., clinic, hospital])	• Smoking cessation/abstinence (biochemically validated) • Relapse	• NA
5	• Maternal age • Parity • Smoking status (number of cigarettes/day, years smoked, previous quit attempts) • Insurance status • Race/ethnicity • Partner/household smoking status • Education level • Employment status • Concomitant alcohol/substance abuse	• Smoking cessation/abstinence (biochemically validated) • Relapse	• NA

Abbreviations: NA = not applicable; NICU = neonatal intensive care unit

Evidence tables

We will enter data into evidence tables by using predetermined abbreviations and acronyms consistently across all entries. The dimensions (i.e., areas of special focus or the columns) of each evidence table may vary by KQ as appropriate, but the tables will contain common elements, such as author, year of publication, study location and time period, population description, sample size, study type, intervention(s) and comparator(s), population characteristics, baseline data, and outcomes.

D. Assessment of Methodological Risk of Bias of Individual Studies

We will assess the quality of studies for the primary outcomes specified in Table 3 using criteria from established tools and the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[52] We will use the Cochrane Risk of Bias tool[53] for randomized controlled trials and the Newcastle-Ottawa scale[54] for cohort studies. Two senior investigators will independently assess each included study. Disagreements between

assessors will be resolved through discussion. We will retain poor-quality studies as part of the evidence base.

E. Data Synthesis

Synthesizing results

Given the relatively robust state of the literature on smoking cessation interventions during pregnancy or the postpartum period, we expect that a meta-analysis or a meta-regression will be possible. The specific meta-analysis or meta-regression will depend on the data available.

Analyses will be combined using hierarchical random effects. This analytic approach will allow both an estimate of the overall (population) effect, as well as an estimate of the variance of the effect across studies. These estimations are preferable to the use of an arbitrary variance cutoff value or statistical tests for heterogeneity, such as Q statistics or I^2 scores. The decision of whether to partially pool a set of studies in a random (or mixed) effects meta-analysis depends not on how heterogeneous their outcomes are, but rather on whether they can be considered exchangeable studies from a population of studies of the same phenomenon. This decision should be based on the design and quality of the studies, independently of the relative effect sizes of the studies. Newer approaches to random effects meta-analysis allow for robust (e.g., nonparametric) estimates of variation that do not rely on the assumption of normal random effects. This permits us to account for "outlier" studies in the meta-analytic model without discarding them unnecessarily.

As an example, a primary metric for evaluating smoking cessation interventions is the reduction of smoking point prevalence for any given intervention, relative to usual care. We anticipate, given the fundamental differences among them, that classes of interventions (e.g., psychotherapeutic, pharmacologic, telephone counseling, informational, etc.) are not exchangeable and, hence, would require separate meta-analytic models. Within classes, however, we may be able to partially pool a subset of studies, conditional on a suite of covariates that, properly modeled, would allow use to consider them exchangeable (conditionally independent). These covariates may include factors such as geographic location, which might cause variation in outcomes indirectly as the consequence of several unmeasured variables (e.g., cultural, legal, economic); these are typically best handled using random effects in a multilevel model, provided that there are sufficient numbers of groups in each case. Other more direct associations may be modeled as fixed effects, including age or indices of socioeconomic status, if available. Care must be taken in choosing the membership of each study within a reasonably small set of intervention classes. It will be important to test the sensitivity of our meta-analytic models to misclassification error or pooling of studies into the same class for analytic purposes when they ought not to be.

Analysis of subgroups will be done formally by using a statistical model or by stratifying results and organizing the report in such a way that end-users are provided both with overall outcomes data and with information specific to subgroups that can be easily

identified and stand alone as needed. Subgroup analysis may be used to evaluate the intervention effect in a defined subset of the participants in a trial or in complementary subsets. Subgroup analysis can be undertaken in a variety of ways, from completely separate models at one extreme, to simply including a subgroup covariate in a single model at the other, with multilevel and random effects models somewhere in the middle.[55,56] Generally, trial sizes are too small for subgroup analyses within individual studies to have adequate statistical power.

Meta-regression models describe associations between the summary effects and study-level data; that is, it describes only between-study and not between-patient variation. We would use multilevel models, which boost the power of the analysis by sharing strengths across subgroups for variables where it makes sense to do so, or subgroup analysis (with random effects meta-analysis) to explore heterogeneity if there are a sufficient number of studies. When the sizes of the included studies are moderate or large, each subgroup should have at least 6 to 10 studies for a continuous study-level variable and a minimum of 4 studies for a categorical study-level variable. These numbers serve as a rule of thumb for the lower bound for number of studies that investigators would consider for a meta-regression, but power will vary according to the size and variability of the effect.

F. Grading the Strength of Evidence for Individual Outcomes

We will use explicit criteria for rating the overall strength of the evidence for the primary outcomes specified in Table 3.

We will use established concepts of the quantity of evidence (e.g., numbers of studies, aggregate ending-sample sizes), the quality of evidence (from the quality ratings on individual articles), and the coherence or consistency of findings across similar and dissimilar studies and in comparison to known or theoretically sound ideas of clinical or behavioral knowledge. We will make these judgments as appropriate for each of the KQs.

The strength of evidence evaluation will be that stipulated in the Effective Health Care Program's *Methods Guide for Effectiveness and Comparative Effectiveness Reviews,*[57] which emphasizes the following 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). Risk of bias is derived from the quality assessment of the individual studies that addressed the KQ and specific outcome under consideration. Each key outcome on each comparison of interest will be given an overall evidence grade based on the ratings for the individual domains.

The overall strength of evidence will be graded as "high" (indicating high confidence that the evidence reflects the true effect and further research is very unlikely to change our confidence in the estimate of effect), "moderate" (indicating moderate confidence that the evidence reflects the true effect and further research may change our confidence in the estimate of effect and may change the estimate), "low" (indicating low confidence that the evidence reflects the true effect and further research is likely to change our

confidence in the estimate of effect and is likely to change the estimate), or "insufficient" (indicating that evidence is either unavailable or does not permit estimation of an effect). When no studies are available for an outcome or comparison of interest, we will grade the evidence as insufficient.

Two senior staff will independently grade the body of evidence; disagreements will be resolved as needed through discussion or third-party adjudication. We will record strength of evidence assessments in tables, summarizing for each outcome.

G. Assessing Applicability

In addition to characteristics of study participants, we will assess characteristics of the environment and health systems for their potential to facilitate or present barriers to implementation of effective interventions. Many women at highest risk for smoking, failure to quit smoking during pregnancy and postpartum relapse receive care in resource-poor environments. Interventions developed and tested in academic medical centers that tend to be located in urban centers may differ from those evaluated in health departments and other community clinical settings. In addition, it will be important to fully characterize the resources needed (including types of providers or involvement of nonclinical providers or families) to implement effective interventions in order to provide end-users with adequate data on feasibility and for implementation planning.

Furthermore, as noted above, other aspects of the "environment" including social networks or familial support are likely to affect cessation success rates; where possible, we will extract those data. Where the data are not presented in the research, we feel that it is essential to comment on the degree to which such factors may have affected outcomes and encourage future research to fully capture these data.

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43. Madan AK, Barden CB, Beech B, et al. Multivariate analysis of factors associated with smoking cessation in women. J La State Med Soc 2005 Mar-Apr;157(2):112-5. PMID: 16022278.

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52. Viswanathan M, Ansari MT, Berkman ND, et al. Assessing the risk of bias of individual studies in systematic reviews of health care interventions. In: Methods Guide for Effectiveness and Comparative Effectiveness Reviews. Rockville, MD: Agency for Healthcare Research and Quality; April 2012. AHRQ Publication No. 10(12)-EHC063-EF. Available at www.effectivehealthcare.ahrq.gov/methodsguide.cfm

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54. Wells G, Shea B, O'Connell D, et al. Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. Ottawa, Canada: Ottawa Hospital Research Institute; 2011. Available at www.ohri.ca/programs/clinical_epidemiology/oxford.asp

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55. Sun X, Briel M, Busse JW, et al. Subgroup Analysis of Trials Is Rarely Easy (SATIRE): a study protocol for a systematic review to characterize the analysis, reporting, and claim of subgroup effects in randomized trials. Trials 2009 Nov 9;10:101. PMID: 19900273.

56. Fu R, Gartlehner G, Grant M, et al. Conducting quantitative synthesis when comparing medical interventions: AHRQ and the Effective Health Care Program. J Clin Epidemiol 2011 Nov;64(11):1187-97. PMID: 21477993.

57. Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions—Agency for Healthcare Research and Quality and the Effective Health-Care Program. J Clin Epidemiol 2010 May;63(5):513-23. PMID: 19595577.

VI. Definition of Terms

Biochemical verification/confirmation/validation: A test to check for the presence of a smoking related substance (e.g., cotinine, nicotine, thiocyanate, carbon monoxide) in the saliva, blood, urine, or exhaled breath of an individual.

Cessation: The goals of treatment to help an individual achieve abstinence.

Continuous abstinence: A measure of cessation involving avoidance of all tobacco use since the quit day until the time the assessment is made.

Point prevalence abstinence: A measure of cessation based on behavior at a particular point in time or during a brief specified period (e.g., 24 hours, 7 days).

Relapse: A return to regular smoking following a period of abstinence.

VII. Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

VIII. Review of Key Questions

For all EPC reviews, Key Questions are reviewed and refined as needed by the EPC with input from the Technical Expert Panel to assure that the questions are specific and explicit about what information is being reviewed.

IX. Key Informants

Key Informants are the end-users of research, including patients and caregivers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience in making health care decisions. Within the EPC program, the Key Informant role is to provide input into identifying the Key Questions for research that will inform health care decisions. The EPC solicits input from Key Informants when developing questions for systematic review or when identifying high-priority research gaps and needed new research. Key Informants are not involved in analyzing the evidence or writing the report and have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The Task Order Officer and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

X. Technical Experts

Technical Experts comprise a multidisciplinary group of clinical, content, and methodological experts who provide input in defining populations, interventions, comparisons, or outcomes, as well as identifying particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design, and/or methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and recommend approaches to specific issues as requested by the EPC. Technical Experts do not do analysis of any kind nor contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the public review mechanism.

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 are invited to serve as Technical Experts and those who present with potential conflicts may be retained. The Task Order Officer and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

XI. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodological expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will, for Comparative Effectiveness Reviews and Technical Briefs, be published 3 months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

XII. EPC Team Disclosures

We will identify team members by their role and provide disclosures for those that may contribute to a manuscript submission.

XIII. Role of the Funder

This project was funded under Contract No. 290-2007-10065 from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The Task Order Officer reviewed contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Appendix A. Non–English-Language Studies Retrieved by a MEDLINE® Search (1990–Present)

Citation	Notes/Comments
1. Pituch A, Hamulka J, Wawrzyniak A, et al. [Assessment of stimulant use especially caffeine intake in selected group of the breastfeeding women]. Rocz Panstw Zakl Hig 2012;63(2):171-8. PMID: 22928364.	Cross-sectional study, no intervention
2. Chehab G, El-Rassi I, Adhami A, et al. [Parental smoking during early pregnancy and congenital heart defects]. J Med Liban 2012 Jan-Mar;60(1):14-8. PMID: 22645896.	Parental smoking; retrospective study
3. [Update on current care guidelines: tobacco dependence and cessation]. Duodecim 2012;128(3):324-5. PMID: 22428386.	Not original research
4. Blondel B, Lelong N, Kermarrec M, et al. [Trends in perinatal health in France between 1995 and 2010: Results from the National Perinatal Surveys]. J Gynecol Obstet Biol Reprod (Paris) 2012 Apr;41(2):151-66. PMID: 22197351.	Not relevant to the CER
5. Muro S. [Cigarette smoking is the most important causal factor for developing chronic obstructive pulmonary disease (COPD)]. Nihon Rinsho. 2011 Oct;69(10):1735-40. PMID: 22073565.	Not relevant to the CER, not original research
6. Pytka D, Doboszyńska A. [Smoking among patients of selected specialist clinics of Miedzylesie Specialist Hospital in Warsaw]. Przegl Lek 2011;68(5):243-7. PMID: 21961410.	Cross–sectional study
7. Wang CY, Kuo SC. [Pregnancy and the struggle to quit smoking]. Hu Li Za Zhi 2011 Jun;58(3):87-92. PMID: 21678258.	No intervention
8. Prejbeanu I, Rada C, Indrei LL, et al. [Smoking, alcohol consumption and pregnancy in a population of south-western Romania]. Rev Med Chir Soc Med Nat Iasi 2010 Oct-Dec;114(4):1148-54. PMID: 21500472.	Cross-sectional study
9. Maalouf D, El Hachem H, Kesrouani A, et al. [Awareness and knowledge about risks of drinking during pregnancy in pregnant Lebanese women]. Encephale 2011 Apr;37(2):94-100. PMID: 21482226.	Cross–sectional study
10. Dechanet C, Belaisch-Allart J, Hédon B. [Prognosis criteria for the management of the infertile couple]. J Gynecol Obstet Biol Reprod (Paris) 2010 Dec;39(8 Suppl 2):S9-26. PMID: 21185491.	Not original research
11. Valdes-Socin H, Vroonen L, Latta AI, et al. [The endocrine effects of smoking]. Rev Med Liege 2010 Sep;65(9):498-501. PMID: 21086580.	Not original research
12. Lelong N, Blondel B, Kaminski M. [Smoking during pregnancy in France between 1972 to 2003: results from the national perinatal surveys]. J Gynecol Obstet Biol Reprod (Paris) 2011 Feb;40(1):42-9. PMID: 20864276.	Cross-sectional study
13. Brándli O. [Smoking history worldwide—cigarette smoking, passive smoking and smoke free environment in Switzerland]. Ther Umsch 2010 Aug;67(8):391-8. PMID: 20687040.	Not specific to smoking during pregnancy
14. Sbrogiò L, Frison G, Tagliapietra L, et al. [Observed smoking in car: results of a study of the Regional Health Prevention Service of Veneto, Northern Italy]. Epidemiol Prev 2010 Jan-Apr;34(1-2):43-7. PMID: 20595735.	Cross–sectional study
15. Kouketsu T, Matsuda N. [Postpartum smoking behavior in women and related factors]. Nihon Koshu Eisei Zasshi 2010 Feb;57(2):104-12. PMID: 20415240.	Cross–sectional study

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Citation	Notes/Comments
16. Poletta FA, López-Camelo JS, Gili JA, et al. [Smoking and exposure to tobacco smoke among pregnant women in Ecuador]. Rev Panam Salud Publica 2010 Jan;27(1):56-65. PMID: 20209233.	Cross–sectional study
17. Braillon A, Dubois G, Bernady-Prud'homme A. [Smoking during pregnancy and smoking clinics]. Gynecol Obstet Fertil 2010 Mar;38(3):179-82. PMID: 20153681.	Not an intervention study
18. Fleitmann S, Dohnke B, Balke K, et al. [Women and smoking. A challenge for the tobacco control policy in Germany]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2010 Feb;53(2):117-24. PMID: 20069267.	Not original research
19. Hrubá D, Fiala J, Soska V, et al. [Risk of smoking for the cardiovascular diseases starts even before the birth]. Ceska Gynekol 2009 Oct;74(5):365-8. PMID: 20063841.	Not original research
20. Nowakowska-Glab A, Nowakowska D, Wilczyński J, et al. [Determinants of smoking cessation during pregnancy]. Przegl Lek 2010;67(10):1025-8. PMID: 21360954.	Cross–sectional study
21. Kleszczewska E, Logwiniuk K, Jaszczuk A. [The evaluation study of knowledge and attitudes related to smoking habit among students of Cosmetology]. Przegl Lek 2010;67(10):969-71. PMID: 21360939.	Cross–sectional study
22. Strycharz-Dudziak M, Nakonieczna-Rudnicka M, Bachanek T. [Tobacco smoking-related attitudes of dental students of the Medical University of Lublin]. Przegl Lek 2010;67(10):965-8. PMID: 21360938.	Cross–sectional study
23. Laskowska-Klita T, Chelchowska M, Oltarzewski M, et al. [The effect of tobacco smoking during pregnancy on birth mass on the basis of population studies—preliminary results]. Przegl Lek 2010;67(10):830-4. PMID: 21360908.	Cross–sectional study
24. Huang CM, Guo JL, Guo HJ, et al. [Using the transtheoretical model to develop educational media to promote smoking cessation in pregnant and postpartum women]. Hu Li Za Zhi 2009 Dec;56(6):87-94. PMID: 19953461.	Not original research
25. Matsumura T, Taniguchi C, Hamagashira N. [Current state of smoking and alcohol drinking among pregnant women in Kyoto City]. Nihon Koshu Eisei Zasshi 2009 Sep;56(9):655-61. PMID: 19891365.	Cross–sectional study
26. Friguls B, Garcia-Algar O, Puig C, et al. [Perinatal exposure to tobacco and respiratory and allergy symptoms in first years of life]. Arch Bronconeumol 2009 Dec;45(12):585-90. PMID: 19822388.	Not an intervention study
27. Andersen MR, Simonsen U, Uldbjerg N, et al. [Smoking cessation during pregnancy, newborn size, and NO-synthase activity in endothelial cells of the umbilical cord—secondary publication]. Ugeskr Laeger 2009 Jun 15;171(25):2088-91. PMID: 19678433.	Not an intervention study
28. Braillon A, Robillart H, Delcroix M, et al. [A regional plan against tobacco smoking during pregnancy]. J Gynecol Obstet Biol Reprod (Paris) 2009 Oct;38(6):488-92. PMID: 19647956.	Not a study design of interest
29. Tschabitscher P, Homaier I, Lichtenschopf A, et al. [Varenicline - pharmacological therapy of tobacco dependence]. Wien Med Wochenschr 2009;159(1-2):17-23. PMID: 19225731.	Not original research
30. Polańska K, Hanke W, Ligocka D, et al. [Effectiveness of antismoking counseling for postpartum women]. Przegl Lek 2008;65(10):631-3. PMID: 19189566.	May be relevant

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Citation	Notes/Comments
31. Pirogowicz I, Szerszeń M, Gwiazda E, et al. [Cigarette smoking in medical personnel and evaluation of this problem by smoking and non-smoking patients]. Przegl Lek 2008;65(10):595-9. PMID: 19189557.	Cross–sectional study
32. Gajewska J, Ceran A, Chelchowska M, et al. [Effect of maternal smoking on concentrations of the pregnancy-associated plasma protein A (PAPP-A) and free beta subunit of chorionic gonadotropin (beta hCG) in the first trimester of pregnancy]. Przegl Lek 2008;65(10):479-82. PMID: 19189527.	Not an intervention study
33. Kaleta D, Polańska K, Dziankowska-Zaborszczyk E, et al. [Smoke-free environment—nurse attitudes towards smoke-free regulations]. Przegl Lek 2009;66(10):844-7. PMID: 20301950.	Cross–sectional study
34. Dziankowska-Zaborszczyk E, Polańska K, Bak-Romaniszyn L, et al. [Evaluation of nurses' knowledge about health effects of active and passive smoking and their attitude towards providing smoking cessation activities]. Przegl Lek 2009;66(10):841-3. PMID: 20301949.	Cross–sectional study
35. Kowalska A, Stelmach W, Szymański P, et al. [Knowledge about influence of smoking tobacco on health condition and developing fetus of the patients of women health center in urban and rural areas]. Przegl Lek 2009;66(10):773-6. PMID: 20301934.	Cross–sectional study
36. Hozyasz KK, Mostowska A, Jagodziński PP. [Lack of association between metabolic and antioxidant gene polymorphisms (GSTM1, GSTT1, CAT, MnSOD, GPX1) and maternal quitting of smoking in pregnancy—preliminary results]. Przegl Lek 2009;66(10):622-3. PMID: 20301895.	Not an RCT; not relevant for the CER
37. Aranda Regules JM, Mateos Vilchez P, González Villalba A, et al. [Validity of smoking measurements during pregnancy: specificity, sensitivity and cut-off points]. Rev Esp Salud Publica 2008 Sep-Oct;82(5):535-45. PMID: 19039506.	Not an intervention study
38. Houdebine E, Guillaumin C, Rouquette A, et al. [Pregnant women and smoking: descriptive study and prognostic factors to stop smoking during pregnancy]. J Gynecol Obstet Biol Reprod (Paris) 2009 Apr;38(2):155-60. PMID: 19010606.	Cross–sectional study
39. Bergmann RL, Bergmann KE, Schumann S, et al. [Smoking during pregnancy: rates, trends, risk factors]. Z Geburtshilfe Neonatol 2008 Jun;212(3):80-6. PMID: 18709626.	Not an RCT; not relevant to the CER
40. Siedentopf JP. [Pathophysiological aspects of smoking in pregnancy]. Z Geburtshilfe Neonatol 2008 Jun;212(3):77-9. PMID: 18709625.	Not original research or SR of interest
41. Charrier L, Serafini P, Zanetti M, et al. [Smoking habits in pregnant women after the ban: a study on a sample of puerperae in Piedmont region]. Ann Ig 2008 May-Jun;20(3):279-86. PMID: 18693404.	Cross–sectional study
42. Kukla L, Hrubá D, Tyrlik M, et al. [Conduct disorders in seven-year-old children—results of ELSPAC study. 3. Postnatal development]. Cas Lek Cesk 2008;147(7):387-91. PMID: 18678098.	Not a study design of interest
43. Rosewich M, Adler S, Zielen S. [Effects of active and passive smoking on the health of children and adolescents]. Pneumologie 2008 Jul;62(7):423-9. PMID: 18600616.	Not original research
44. Althabe F, Colomar M, Gibbons L, et al. [Smoking during pregnancy in Argentina and Uruguay]. Medicina (B Aires) 2008;68(1):48-54. PMID: 18416320.	Cross–sectional study

Citation	Notes/Comments
45. Kowalska A, Szymański P, Rzeźnicki A, et al. [Behaviour concerning smoking among the patients making use of advice in women health centres]. Przegl Lek 2007;64(10):837-41. PMID: 18409321.	Cross–sectional study
46. Przybylski G, Pasińska M, Pyskir J, et al. [Analysis of spreading of smoking habit among pregnant women admitted to the Prenatal Outpatient Clinic in 2005–2006]. Przegl Lek 2007;64(10):827-30. PMID: 18409319.	Retrospective study
47. Röske K, Lingnau ML, Hannöver W, et al. [Prevalence of smoking in women before and during pregnancy: population-based data]. Dtsch Med Wochenschr 2008 Apr;133(15):764-8. PMID: 18382949.	Cross–sectional study
48. Ferri P. [Effect of smoking in pregnancy and individuation of strategies for promote astention]. Prof Inferm 2007 Jul-Sep;60(3):160-5. PMID: 18272060.	Not original research
49. [Patient information. Finally smoke-free!]. MMW Fortschr Med 2007 Nov 1;149(44):35-6. PMID: 18078168.	Not original research
50. Lanting CI, Segaar D, Crone MR, et al. [Slight decrease in the prevalence of smoking around pregnancy]. Ned Tijdschr Geneeskd 2007 Nov 17;151(46):2566-9. PMID: 18074727.	Cross–sectional study
51. Raynal P, Panel P, Fuchs F, et al. [Investigation on smoking during pregnancy in the Versailles suburbs]. J Gynecol Obstet Biol Reprod (Paris) 2008 Feb;37(1):33-40. PMID: 18006246.	Cross–sectional study
52. Godá T, Marcos T, Corominas J, et al. [Efficiency and risk factors in the cognitive-behavioural treatment for smoking cessation in pregnancy]. Med Clin (Barc) 2007 Nov 3;129(16):607-11. PMID: 18001671.	Not an RCT or cohort study
53. Possato M, Parada CM, Tonete VL. [Representation of pregnant smokers on cigarette use: a study carried out at a hospital in the interior of the state of São Paulo]. Rev Esc Enferm USP 2007 Sep;41(3):434-40. PMID: 17977380.	Cross–sectional study
54. Salvador J, Cano-Serral G, Rodríguez-Sanz M, et al. [Trends in social inequalities in pregnancy care in Barcelona (Spain), 1994–97 versus 2000–03]. Gac Sanit 2007 Sep-Oct;21(5):378-83. PMID: 17916301.	Not an RCT or cohort study
55. Correia S, Nascimento C, Gouveia R, et al. [Pregnancy and smoking: an opportunity to change behaviours]. Acta Med Port 2007 May-Jun;20(3):201-7. PMID: 17868528.	Cross–sectional study
56. Hummel M, Baumgarten A, Hummel S, et al. [Smoking behavior during pregnancy of women with type 1 or gestational diabetes]. Dtsch Med Wochenschr 2007 May 25;132(21):1153-8. PMID: 17506009.	Cross–sectional study
57. Houfflin-Debarge V. [Nicotine substitutes during pregnancy]. Gynecol Obstet Fertil. 2007 Jan;35(1):74-6. PMID: 17342795.	Appears not to be original research
58. Zysnarska M, Biskupska M, Polocka-Molińska M. [Students of nursing and nicotine dependence]. Przegl Lek 2006;63(10):1048-51. PMID: 17288213.	Not relevant to the CER
59. Zysnarska M, Biskupska M, Polocka-Molińska M. [Students of midwifery and nicotine dependence]. Przegl Lek 2006;63(10):1045-7. PMID: 17288212.	Not relevant to the CER
60. Florek E, Piekoszewski W, Lechowicz W, et al. [Determination of 4-(methylnirosamino)-4-(3-pyridyl)-1-butanol (NNA) in urine of pregnant women by means of LC/MS/MS]. Przegl Lek 2006;63(10):926-31. PMID: 17288186.	Not an intervention study

Citation	Notes/Comments
61. Polanska K, Hanke W, Sobala W, et al. [Environmental tobacco smoke exposure in pregnancy and postpartum period]. Przegl Lek 2006;63(10):907-10. PMID: 17288181.	Not an intervention study
62. Nau JY. [Pregnancy and nicotine substitution treatment: what to do?]. Rev Med Suisse 2006 Oct 25;2(84):2442. PMID: 17121254.	Appears not to be original research
63. Grangé G, Borgne A, Ouazana A, et al. [Prevalence of smoking cessation during pregnancy according to trimester]. Gynecol Obstet Fertil 2006 Dec;34(12):1126-30. PMID: 17113811.	Cross–sectional study
64. Nau JY. [Pregnancy and nicotine substitution treatments: what to do?]. Rev Med Suisse 2006 Oct 18;2(83):2377. PMID: 17112092.	Appears not to be original research
65. Charrier L, Serafini P, Stroppiana G, et al. [Smoking habits and smoking cessation in pregnancy: a study in Piedmont region]. Ann Ig 2006 Sep-Oct;18(5):407-15. PMID: 17089956.	Cross–sectional study
66. Pérez-Ríos M, Santiago-Pérez MI, Alonso B. [Smoking cessation in Galician [Spain] smokers during pregnancy and breast feeding, 1954–2004]. Gac Sanit 2006 Sep-Oct;20(5):392-5. PMID: 17040649.	Cross–sectional study
67. Barbour B, Salameh P, Ziadeh F. [Smoking among Lebanese mothers: knowledge, attitudes and practices]. East Mediterr Health J 2006 May-Jul;12(3-4):405-16. PMID: 17037710.	Cross–sectional study
68. Borkowski W, Mielniczuk H. [Determinants of smoking and cessation during pregnancy]. Przegl Epidemiol 2005;59(4):987-95. PMID: 16729441.	Not an intervention study
69. Decroisette C, Decroisette E, Gazaille V, et al. [Smoking cessation in the pregnant woman: descriptive study in Limousin]. Gynecol Obstet Fertil 2006 May;34(5):397-402. PMID: 16675278.	Cross–sectional study
70. Röske K, Hannöver W, Thyrian JR, et al. [Why woman postpartum resume smoking]. Gesundheitswesen. 2006 Mar;68(3):171-5. PMID: 16575697.	Not an intervention study
71. Cano-Serral G, Rodríguez-Sanz M, Borrell C, et al. [Socioeconomic inequalities in the provision and uptake of prenatal care]. Gac Sanit 2006 Jan-Feb;20(1):25-30. PMID: 16539990.	Cross–sectional study
72. Polańska K, Hanke W, Sobala W. [Characteristic of the smoking habit among pregnant women on the base of the test "Why am I smoker?"]. Przegl Lek 2005;62(10):1095-8. PMID: 16521963.	May be relevant
73. Depa-Martynów M, Pawelczyk L, Taszarek-Hauke G, et al. [The effect of smoking on infertility treatment in women undergoing assisted reproduction cycles]. Przegl Lek 2005;62(10):973-5. PMID: 16521930.	Not an intervention study
74. Perz S, Kara-Perz H. [Cigarette smoke as a risk factor of sudden infant death syndrome (SIDS)—assessment of knowledge and behavior of women]. Przegl Lek 2005;62(10):960-4. PMID: 16521927.	Not an intervention study
75. Lepage M, Dumas L, Renaud L. [Fight against tobacco and promote breastfeeding: a distinctive challenge]. Sante Publique 2005 Dec;17(4):637-47. PMID: 16485444.	Not original research
76. Schultze-Werninghaus G, Kardos P, Berdel D, et al. [Guidelines for diagnosis and therapy of patients with asthma 2005.	Not relevant to the CER

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The most important aspects for adults]. Med Klin (Munich) 2006 Jan 15;101(1):60-4. PMID: 16418815.	
77. Heilbronner C, Berlin I. [Nicotine replacement therapies during pregnancy: what do we know about the balance between benefits and risks?]. J Gynecol Obstet Biol Reprod (Paris) 2005 Nov;34(7 Pt 1):679-86. PMID: 16270006.	Not original research
78. Grangé G, Borgne A, Ouazana A, et al. [Obstetrical ultrasound screening and motivation to stop smoking]. J Gynecol Obstet Biol Reprod (Paris) 2005 Nov;34(7 Pt 1):674-8. PMID: 16270005.	Cross–sectional study
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Appendix B. Preliminary Search Strategies

Table B-1. PubMed® search strategies

Search terms		Resul
#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]	37,8
#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]	823,5
#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)	1,7
#4	#3 AND English[la] AND humans[mh]	1,4

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

Table B-2. CINAHL® search strategies (EBSCO Host interface)

Search terms		Resul
#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))	14,7
#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	124,2
#3	#1 AND #2	1,1
#4	#3 AND limiters: English Language; Peer Reviewed; Research Article; Exclude MEDLINE records	

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

Table B-3. PsycINFO® (ProQuest interface)

Search terms		Resul
#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"	23,8
#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	51,7
#3	#1 AND #2, limited to human, English language, peer-reviewed scholarly journals	1,1

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

Source: www.effectivehealthcare.ahrq.gov
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Appendix C. Pharmacologic Interventions for Smoking Cessation in Pregnancy

Table C-1. Nicotine replacement therapy products

Product	Company	Administration
Prescription NRT products		
Nicotrol® Nasal Spray	Pfizer	Nasal spray (0.5 mg, two sprays)
Nicotrol® Inhaler	Pfizer	Oral inhaler (4 mg delivered)
OTC NRT products		
Nicorette®	GlaxoSmithKline	Chewing gum (2 mg or 4 mg)
NicoDerm® CQ®	GlaxoSmithKline	Skin patch (7, 14, or 21 mg per 24 hrs.)
Nicorette® Lozenge (formerly Commit®)	GlaxoSmithKline	Lozenge (2 mg or 4 mg)

Abbreviations: NRT = nicotine replacement therapy; OTC = over the counter

Table C-2. Non-nicotine replacement therapy drugs

Drug	Trade Name	Company	Administration	FDA Pregnancy Category
Varenicline	Chantix®	Pfizer	1-week titration then 1 mg twice a day	C[a]
Bupropion	Zyban®	GlaxoSmithKline	150 mg twice a day	C

[a] In humans, there are no good studies. In animals, pregnant animals treated with the medicine had some babies with problems. However, sometimes the medicine may still help the human mothers and babies more than it might harm; or, no animal studies have been done, and there are no good studies in pregnant women. See the U.S. Food and Drug Administration (FDA) Web site for additional information (available at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=201.57).