

Review of Evidence on Effective Postpartum Smoking Relapse Prevention Interventions

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Key Messages

1. Provide support during pregnancy and the postpartum period to parents who have successfully quit smoking to prevent relapse.
2. Include partners and other household members in smoking cessation and relapse prevention interventions.
3. Use any appointment as an opportunity to ask pregnant or postpartum women and their partners if they smoke and to refer them to smoking cessation services.
4. Discuss with parents about the benefits of stopping smoking, the danger tobacco smoke poses to both parents and their babies, and the risks and benefits of pharmacotherapy before and after birth.
5. Establish cross-divisional initiatives for smoke-free homes and leverage with other working groups at Peel, such as *Workplace Tobacco Interventions*, *Smoke-Free Movies*, and *Smoke-Free Multi-Unit Dwellings*.
6. Ensure that any smoke-free homes initiative is equitable and will benefit all families living in smoking environment.

Executive Summary

Research Question

What are effective smoking relapse prevention interventions in pregnancy and the postpartum period up to twelve months?

Context

There are roughly 16,500 children born each year in Peel and in 2013 approximately 3% of pregnant women reported any smoking at their first prenatal visit, of which 31% reported at time of labour to having quit during pregnancy (1).

However, lifestyle changes and stresses that arise in the postpartum period may lead to smoking relapse. In Peel, approximately 27% of women who quit smoking during pregnancy later relapsed and are now current smokers (2).

Peel Public Health's 10-year Strategic Plan (2009-2019) outlines *Living Tobacco-Free* and *Nurturing the Next Generation* as strategic priorities. One of the first strategies of the *Smoke-Free Homes* workgroup is to focus on the prenatal period and the time of birth to ensure that the 16,500 children born each year in Peel are never exposed to second hand smoke and ultimately do not begin to smoke themselves.

Methods and Results of the Literature Review

A systematic search identified 44 papers. After assessing relevance and critical appraisal, three papers of strong quality were included in this rapid review: one Cochrane systematic review (3), one Agency for Healthcare Research and Quality (AHRQ) systematic review (4), and one National Institute for Care and Health Excellence (NICE) guideline (5).

Synthesis of Findings

Overall, there is no strong evidence of behavioural or pharmacological interventions that have shown significant effects in preventing tobacco relapse in the postpartum period. However, there are a few single studies of fair or good quality that had significant effects on relapse prevention for pregnant and postpartum women. As for partners, there are limited studies on this population, although the overall evidence suggests it is important to intervene with partners around the time of pregnancy. In the general population, pharmacotherapies such as nicotine gum or extended use of varenicline have shown positive effects on relapse prevention.

Recommendations

- Include partners and other household members in cessation and relapse prevention interventions.
- Use any appointment as an opportunity to ask pregnant or postpartum women and their partners if they smoke and refer them to smoking cessation services.
- Discuss with parents about the benefits of stopping smoking and about the danger tobacco smoke poses to both parents and their baby, before and after birth.
- Discuss the risks and benefits of pharmacotherapy during pregnancy and in the postpartum period. Recommend using NRT only if smoking cessation without it fails. Do not offer varenicline or bupropion to pregnant or breastfeeding women.
- Include aspects of relapse prevention as part of current smoking cessation interventions.

1 Issue

In Ontario, it is estimated that only 1.6% of smokers successfully quit each year, defined as remaining smoke-free for 12 consecutive months (6). In the Region of Peel in 2013, approximately 3% of pregnant women reported any smoking at their first prenatal appointment, of which 31% later reported at time of labour to quitting during pregnancy (1). There are important incentives to quit during pregnancy, as parenthood is a significant motivator for smoking cessation and continued abstinence (7).

However, lifestyle changes and stresses that arise in the postpartum period may lead to smoking relapse. In Peel, approximately 27% of women who quit smoking during pregnancy later relapsed and are now current smokers (2). The Canadian Maternal Experiences study in 2009 found as high as 47% of women relapsed in the postpartum period (8).

Peel Public Health wants to deliver interventions that support parents who have quit smoking before or during pregnancy. This rapid review will address the question of “what are effective smoking relapse prevention interventions for formerly smoking parents in the postpartum period up to twelve months.”

2 Anecdote

“M was 18 when she found out she was pregnant. She smoked 15-20 cigarettes a day prior to the pregnancy and was able to cut down during pregnancy. Once her child was born she decided to breastfeed and not to smoke. She explained that she found it easy at first.....she was so focused on the baby and feeding that she didn’t really want to smoke. Over the next few months M found it more challenging not to smoke as some of the friends she spent time with smoked when she

was with them. Health problems developed around the child's first birthday. She started smoking again....finding it helped relieve some of her stress, despite knowing how this could adversely affect him. She has continued to smoke since....up to 15-20 per day again.”

3 Context

The overall smoking rate has declined over time; however, tobacco use continues to be an issue that is having a population health impact in the Region of Peel. Approximately 16.6% of Peel residents in their childbearing years, 15 to 49 years, are current smokers, of which 21.2% are males and 11.7% are females (9). There are roughly 16,500 children born each year in Peel and in 2013 approximately 3.3% of pregnant women reported any smoking at the time of admission to labour (1).

In Peel, approximately 27% of women who quit during pregnancy relapsed and are now current smokers (2). Little is known about the characteristics of these women. However, the majority of these women were white (80.0%) and married (60.3%) (2). In general, barriers to relapse prevention in the postpartum period include stress, lack of sleep, concerns over weight, and having a partner who smokes (10).

Approximately 14.7% of Peel parents, corresponding to 19.0% of fathers and 10.6% of mothers, are current smokers (11). This is equivalent to 58,000 parents of children aged 0-18 years. An estimated 37,900 children are potentially exposed to environmental tobacco smoke as a function of living in a home where someone smokes (11).

The most significant risk factor for smoking in Peel is living with someone who smokes in the home. The odds of being a smoker are 4.4 times higher for males and 6.5 times higher for

females if someone else in the home smokes (12). In Peel, approximately 14% of pregnant women in 2013 reported that they resided with a smoker at time of admission to labour (1). An individual's smoking behaviour is influenced in particular by their partner's smoking status, and thus there is a need to target relapse prevention interventions at both mothers and their partners. When children are born into smoke-free homes, the likelihood of them smoking is reduced, as parents are not modeling smoking behaviours (13, 14).

Peel Public Health's 10-year Strategic Plan (2009-2019) outlines *Living Tobacco-Free* and *Nurturing the Next Generation* as strategic priorities. The goal is to decrease the number of parents who smoke to help improve their own health and the health of their children, as well as giving children the best start beginning with the prenatal period. In the interest of supporting smoke-free homes, a *Smoke-Free Homes* workgroup was established in November 2013 with the aim to develop health promotion strategies for parents and children. One of the first strategies of the *Smoke-Free Homes* initiative is to focus on the prenatal period and the time of birth to ensure that the 16,500 children born each year in Peel are never exposed to second hand smoke and ultimately do not begin to smoke themselves.

In 2013, approximately 31% of Peel women who were smokers and gave birth reported successfully quitting during pregnancy (1). The transition from pregnancy to the postpartum period may be a good time for Peel Public Health to provide support for these parents that have successfully quit smoking to prevent tobacco relapse. Helping parents maintain smoking abstinence and prevent relapse will lead to multiple health benefits for themselves, their families, and the community. Therefore, this rapid review will focus on effective smoking relapse prevention interventions during the pregnancy and postpartum period.

4 Conceptual Framework

The conceptual framework outlines for parents in the postpartum period the various barriers and facilitators of maintaining smoking cessation. In general, barriers to relapse prevention in the postpartum period include stress, lack of sleep, concerns over weight, and having a partner who smokes (10). Other factors such as nicotine dependence, number and duration of prior quit attempts, concomitant use of alcohol, employment and timing of return to work can also predict successful smoking cessation (4).

Pregnancy and the postpartum period are a time to potentially implement smoking relapse prevention interventions. This will lead to the following two child health outcomes: the child not being exposed to environmental tobacco smoke and the child having the desired behaviour role-modeled in the home. In the long term, implementing smoking relapse prevention interventions may aid in the normalization of smoke-free homes in Peel. Refer to Appendix A for the conceptual framework.

5 Literature Review Question

The research question for the literature review was “What are effective smoking relapse prevention interventions in pregnancy and the postpartum period up to twelve months?”

The literature review question is described in the PICOT format below:

P (Population)	Parents of infants that were former smokers
I (Intervention)	Smoking relapse prevention interventions
C (Comparison)	Parents receiving no intervention or usual care
O (Outcome)	Prevention of smoking relapse, maintaining smoking cessation
T (Time)	Pregnancy and the postpartum period up to 12 months

6 Literature Search

A search of published literature was conducted in May/June 2014. The search strategy was developed based on the PICOT question. The search was restricted to synthesized evidence in English published in the last ten years (i.e. 2004 onwards). The databases searched included National Institute of Health and Care Excellence (NICE), Health Evidence, The Cochrane Database of Systematic Reviews, PubMed, and TRIP database. To ensure that no reviews were missed, a Peel Public Health librarian conducted a supplementary search of both TRIP and Ovid Medline databases in June 2014. Refer to Appendix B for the detailed search strategy.

7 Relevance Assessment

Studies were determined relevant if they met the following criteria:

Inclusion criteria: English language, from any country, published in past ten years (i.e. 2004 onwards), focused on any age group and any cultural groups, aligned with the elements of the PICOT question and guidelines or synthesized evidence.

Exclusion criteria: A single study.

One individual reviewed and determined relevance based on the titles and abstracts of the 58 identified studies, with consultation from two other reviewers.

8 Results of the Search

Based on the databases and the inclusion/exclusion criteria, the search identified 58 studies. Fourteen duplicates were removed, and of the 44 remaining papers, 12 met the relevance criteria, including one guideline and 11 systematic reviews. Of the remaining 12 papers, although they met the inclusion criteria, eight systematic reviews were excluded based on their older date of publication and the amount of overlap between included primary studies. One systematic review

by Baxter *et al.* (2011) was excluded, as it was adapted from one of the supporting documents of the NICE guideline (2010), and was then published at a later date. Refer to Appendix C for the Literature Search Flowchart.

9 Critical Appraisal

The Health Evidence Quality Assessment tool and the AGREE II tool were used to critically appraise the three systematic reviews and one guideline, respectively. Three reviewers independently assessed each document and discussed their results to resolve any discrepancies. The systematic review by Fang *et al.* (2004) received a weak quality rating, based on the poor description of methodology and was thus excluded from this review. The two remaining systematic reviews (Hajek *et al.* (2013) (3), and Likis *et al.* (2014) (4)) both received strong quality ratings. The NICE guideline (2010) (5) also received a strong quality rating. Therefore, these two systematic reviews and the guideline were included in this rapid review.

10 Description of Included Studies

The following systematic reviews and guideline were included:

- Hajek, P., Stead, L.F., West, R., Jarvis, M., Hartmann-Boyce, J., and Lancaster, T. (2013). Relapse prevention interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, 2013(8), Art. No.: CD003999.
- Likis, F.E., Andrews, J.C., Fonnesebeck, C.J., Hartmann, K.E., Jerome, R.N., Potter, S.A., Surawicz, T.S., and McPheeters, M.L. (2014). Smoking cessation interventions in pregnancy and postpartum care. Evidence Report/Technology Assessment Number 214. Vanderbilt Evidence-based Practice Center, Agency for Healthcare Research and Quality
- National Institute for Health and Care Excellence (2010) Quitting smoking in pregnancy and following childbirth (PH26). London: National Institute for Health and Care Excellence.

It is important to note that many interventions have been researched; however, systematic reviews and meta-analyses were unable to statistically combine all of the results, as the interventions were heterogeneous. As a result, many of the findings are based on relatively few studies.

10.1 Cochrane Systematic Review, Hajek, P. *et al.* (2013)

The Cochrane systematic review by Hajek *et al.* in 2013 examined whether specific interventions reduce the number of individuals who relapse after quitting smoking. The authors identified 63 randomized or quasi-randomized controlled trials in their literature search; studies were conducted in Spain, Australia, Germany, the United Kingdom, Japan, Belgium, Canada, the Netherlands, and the majority were from the United States. All the interventions had a minimum follow-up of six months from quit date and the effectiveness was compared with no intervention or a shorter intervention not focused on relapse prevention. Interventions were divided into those assessing behavioural interventions and those assessing pharmacotherapy. Behavioural interventions were then further categorized as intensive, if they involved repeated face-to-face contact and less intensive if the coping skills were taught via written material and potentially one brief face-to-face session or telephone call. Pregnant and postpartum ex-smokers were a special population of interest in this review. Refer to Appendix D for the Data Extraction Table, which provides further detail on the systematic review by Hajek *et al.* in 2013.

10.2 AHRQ Systematic Review, Likis, F.E. *et al.* (2014)

The systematic review by Likis *et al.* in 2014 examined the effectiveness of smoking cessation interventions in pregnant and postpartum women. The review addressed five key questions, of which the first pertained to this rapid review: “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?” The authors identified 59 unique studies in 72 publications, of which 56 were randomized controlled trials and three were prospective cohort studies. The interventions from the studies involving randomized controlled trials were grouped into six categories based on the primary focus of the intervention: counselling, educational materials, multicomponent interventions, nicotine replacement therapy, peer support, and other interventions. The primary outcomes studied consisted of smoking cessation confirmed by biochemical measurements, continuous abstinence, and smoking relapse. The interventions were compared to no treatment or to a placebo where appropriate. Refer to Appendix D for the Data Extraction Table, which provides further detail on the systematic review by Likis *et al.* (2014).

10.3 NICE Guideline (2010; reviewed in 2013, no updates)

The NICE guideline in 2010 provided guidance on interventions aimed at stopping smoking in pregnancy and following childbirth. The guideline was produced for the National Health Service (NHS) in the United Kingdom, and for other commissioners, managers and practitioners who have a direct or indirect role in helping women to stop smoking in pregnancy and following childbirth. This could include local authorities, education and the wider public, private, voluntary, and community sectors. Other populations may also find the guideline of interest, such as women who are planning a pregnancy, who are pregnant or who already have children, their partners, and other members of the public. The evidence used to develop this guideline included: a fieldwork report, systematic review, an economic analysis review, a briefing paper, two rapid reviews, advice from experts, and comments from stakeholders and the Public Health

Interventions Advisory Committee (PHIAC). One rapid review included two Cochrane systematic reviews on relapse prevention published in 2009, one of which was the pre-updated Cochrane systematic review by Hajek *et al.* (2013); it included all but one study added to the update. The guideline was reviewed in 2013 and it remains current requiring no updates. Refer to Appendix D for the Data Extraction Table, which provides further detail on the NICE guideline (2010).

11 Synthesis of Findings

The included studies from the reviews assessed relapse prevention interventions, whether beginning at the moment of cessation or intervening with ex-smokers. The studies measured outcomes such as smoking cessation and relapse prevention.

Overall, there is no strong evidence of behavioural or pharmacological interventions that have shown significant effects in preventing tobacco relapse in the postpartum period.

However, there are some studies of fair or good quality that had significant effects on relapse prevention for pregnant and postpartum women. **As for partners, there are limited studies on this population, although the overall evidence suggests it is important to intervene with partners around the time of pregnancy.** In the general population, pharmacotherapies such as nicotine gum or extended use of varenicline have shown positive effects on relapse prevention.

The findings are divided into two sections: those directed at pregnant and postpartum women, and those addressing their partners. Within each section, the effectiveness of behavioural and pharmacological interventions is presented along with extracted results from the NICE effectiveness reviews and a summary of the NICE guideline recommendations. Refer to Appendix D for the individual data extraction tables.

Section I – Pregnant and Postpartum Women

The findings are categorized based on the primary focus of the intervention. A table summarizing the effectiveness of the interventions is outlined below (refer to Table 1).

Table 1: Summary of effectiveness of interventions directed at pregnant and postpartum women

Intervention	Results
<i>Counselling</i> (10 studies)	<ul style="list-style-type: none"> 10 studies - No significant effects on smoking cessation or relapse prevention at longest follow-up.
<i>Educational Materials</i> (10 studies)	<ul style="list-style-type: none"> 8 studies - No significant effects on smoking cessation or relapse prevention at longest follow-up. 1 study - Significant effect of computer-based 5 A's (Ask, Advise, Assess, Assist, Arrange) intervention tailored to participant's history and attitudes after ten weeks on smoking cessation among pregnant smokers (OR=10.2, 95% CI 1.4-75.0) (good quality). 1 study – Significant effect on smoking cessation using a video, advice, and tip sheets at 36 weeks gestation among pregnant smokers (poor quality).
<i>Multicomponent</i> (25 studies)	<ul style="list-style-type: none"> 19 studies - No significant effects of studies including primarily counselling, written materials, quit guide, clinic reinforcement, peer support, personal follow-up, and additional telephone calls at longest follow-up time on smoking cessation or relapse prevention at longest follow-up. 1 study – Significant effect on relapse prevention at 12 months postpartum using information pack, letters from pediatricians on risks, extended counselling, and written materials (RR=1.26, 95% CI 1.03-1.53) (good quality). 1 study – Significant effect on smoking cessation among pregnant smokers at 6-12 weeks postpartum using clinic reinforcement, counselling, incentives, information, peer support, personal follow-up, and quit guide (intervention 10% vs. control 1%, p=0.0011) (good quality). 3 studies – Significant effect on smoking cessation among pregnant smokers using primarily clinic reinforcement, counselling, information, and quit guides (6-32% of women abstinent at end of pregnancy in intervention and 2-9% in control) (fair quality). 1 study – Significant effect on smoking cessation at 37 weeks gestation using individual and group counselling, written information, and NRT (poor quality). <p><i>Note: Components in interventions demonstrating effectiveness were also included in studies with non-significant results.</i></p>
<i>Peer Support</i> (4 studies)	<ul style="list-style-type: none"> 4 studies - No significant effects on smoking cessation or relapse prevention among pregnant smokers at longest follow-up.
<i>Feedback about biological measures</i> (3 studies)	<ul style="list-style-type: none"> 3 studies - No significant effect on smoking cessation or relapse prevention among pregnant smokers at longest follow-up.
<i>Facilitation of mother-infant bonding</i> (1 study)	<ul style="list-style-type: none"> 1 study – Significant effect on smoking abstinence from the facilitation of mother-infant bonding in the neonatal intensive care unit at 8 weeks postpartum among postpartum women who had quit smoking (intervention 81% vs. 46%, p<0.001) (good quality).
<i>Delivery of self-help materials</i> (1 study)	<ul style="list-style-type: none"> 1 study – Significant effect on smoking cessation at 6 weeks postpartum (poor quality).

<i>Financial incentives (2 studies)</i>	<ul style="list-style-type: none"> • 1 study – No significant effect on smoking cessation or relapse prevention at 6 months postpartum • 1 study – Did not report a test of statistical significance.
<i>Treatment of depression (1 study)</i>	<ul style="list-style-type: none"> • 1 study – No significant effect on smoking cessation or relapse prevention from a cognitive behavioural intervention at 3 or 6 months postpartum.
<i>Pharmacotherapy (5 studies)</i>	<ul style="list-style-type: none"> • 4 studies - No significant effect of NRT (patch, gum, lozenge) on smoking cessation or relapse prevention during pregnancy or in the postpartum period. • 1 study - Significant effect of NRT on smoking cessation at 38 weeks gestation, but not at 3 months postpartum (poor quality).

Note: Significant results from fair or good quality studies were bolded. Poor quality studies that had significant results were not bolded.

Counselling

Ten studies found counselling to have no effect on smoking cessation or preventing smoking relapse in pregnancy or the postpartum period.

Educational Materials

Eight out of ten studies on print-based, video-based, or technology-based interventions such as text messaging or computer-delivered interventions found no effect on smoking cessation during pregnancy.

- One good quality study from the U.S. examining the effect of a computer-based 5 A's (Ask, Advise, Assess, Assist, Arrange) intervention tailored to the participant's smoking history and attitudes found that after ten weeks, the intervention group had ten times the odds of a cotinine confirmed quit compared to usual care (OR=10.2, 95% CI 1.4-75.0); however, the sample size was small which decreased the precision of the results.
- One study of poor quality found significant effects on smoking cessation using video, advice, and tip sheets during pregnancy at 36 weeks gestation (p=0.02).

Multicomponent Intervention

The Cochrane review of 63 studies by Hajek *et al.* (2013), 15 of which randomized pregnant or

postpartum ex-smokers to interventions, found that there was insufficient evidence to support the use of any specific behavioural interventions to help prevent smoking relapse.

- The meta-analysis of 12/15 studies on behavioural multicomponent interventions for abstinent pregnant or postpartum women found that there was no significant effect on not smoking at longest follow-up after delivery. The multicomponent interventions primarily included individual counselling with additional written material such as letters, pamphlets, and newsletters, or an initial face-to-face session with written materials followed by additional telephone calls.
- However, of the 12 studies, one good quality study found that the intervention had a significant effect on sustaining smoking abstinence at 12 months postpartum (n=1026, RR=1.26, 95% CI 1.03-1.53). This intervention involved an information pack provided by the birth hospitals, including a letter from a pediatrician on the risks of passive smoking, extended counselling support at 2, 4, and 5 month visits, and materials such as a video tape, written material, signs, magnets, and a bib. Control group only received information pack.
- The three studies not included in the meta-analysis were covered in the other systematic review.

The systematic review by Likis *et al.* (2014) found that four 4/14 multicomponent interventions demonstrated significant effects in maintaining smoking cessation among pregnant smokers at longest follow-up and were of fair or good quality.

- Three studies (fair quality) found significant effects on smoking cessation at the end of pregnancy using clinic reinforcement, counselling, information, and quit guides. The

proportion of women remaining abstinent by the end of pregnancy ranged from 6-32% in the intervention arm and from 2-9% in the control group.

- One study (good quality) found that smoking cessation validated by urine cotinine in the treatment group was higher at the end of pregnancy (13% vs. 7%, $p=0.0353$) and at six to twelve weeks postpartum (10% vs. 1%, $p=0.0011$). Intervention consisted of clinic reinforcement, counselling, incentives, information, peer support, personal follow-up and quit guides.

Peer support

Four studies found no significant effect between intervention and control groups at the end of pregnancy or at the latest follow-up in the postpartum period, whether the peer was a trained lay health advisor, a friend or a family member.

Feedback about Biological Measures

Three studies found no significant effects on smoking cessation or relapse prevention from treatments involving ultrasound imaging during pregnancy, urine cotinine testing, or carbon monoxide testing results among pregnant smokers.

Facilitation of mother-infant bonding

One good quality study found a significant effect at eight weeks postpartum using an enhanced bonding approach, involving frequent and prolonged skin-to-skin contact with infants in the neonatal intensive care unit, in addition to weekly encouragement to remain smoke-free and breastfeeding support. The study enrolled 54 postpartum formerly smoking women. The intervention group had an 81% continued cessation rate compared to the 46% in the control group ($p<0.001$).

Delivery of self-help material

One study examined personalized counselling and use of a self-help quit guide among pregnant smokers and found significantly increased incidence of cessation in the intervention group compared to control group with usual care at one month after intervention (14.9% vs. 5%, $p=0.02$), and at six weeks postpartum (13.8% vs. 5.2%, $p=0.04$). Although the results were significant, the study was of poor quality.

Financial incentives

Two studies found no significant effect on smoking cessation and subsequent relapse prevention from receiving contingent vouchers at longest follow-up among pregnant smokers.

Treatment of depression

One study examined a depression-focused cognitive behavioural intervention during pregnancy and found no effect on smoking cessation or relapse prevention at any time point (three or six months post treatment and postpartum).

Pharmacotherapy

Five studies examined the use of nicotine patch, gum, or lozenge among pregnant smokers, and four of these studies found no significant effect. One study of poor quality found significantly higher cessation at 38 weeks gestation but not at three months postpartum for the treatment group where individuals chose between using patches, gum, or lozenges.

Results from the NICE guideline systematic review by Baxter et al. (2009)

Based on the 14 studies examining interventions to establish smoke-free homes:

- Due to limited effectiveness, counselling alone is not recommended, as there are only weak associations between counselling only interventions and smoke-free related outcomes.

- There is mixed evidence in regard to interventions combining counselling with additional interventions such as written material or telephone support.
- There is mixed evidence on interventions using motivational interviewing to promote smoke-free homes.

Recommendations from the NICE guideline (2010) for pregnant and postpartum women:

- Identify pregnant women who smoke and refer them to smoking cessation services.
- Use any appointment as an opportunity to ask women if they smoke and refer them to smoking cessation services.
- Follow-up all women who have been referred to the smoking cessation services using an impartial, non-judgemental, client-centered approach.
- Provide information about risks of smoking and benefits of stopping smoking for both mother and baby.
- Discuss risks and benefits of NRT and only recommend if smoking cessation without fails. Only prescribe two weeks of NRT use from the day they agreed to stop, and advise pregnant women who are using nicotine patches to remove them before going to bed. Do not offer varenicline or bupropion to pregnant or breastfeeding women.
- Ensure services are delivered in an impartial, client-centered manner and are sensitive to the difficult circumstances many women who smoke experience. Services must meet the needs of disadvantaged pregnant women who smoke.
- Ensure all health care providers are trained in the same skills, know how to refer the women, and understand the impact of smoking.

Section II – Partners

The Cochrane Systematic Review (2013) examined behavioural and pharmacological relapse prevention interventions in the general population. These findings may be applicable for partners and are summarized in the table below along with the extracted results from the NICE rapid review by Hemsing *et al.* (2009) addressing partner support and partner cessation (refer to Table 2). Interventions are categorized based on the primary focus of the intervention. Following these findings, the recommendations from the NICE guideline are presented.

Table 2: Summary of effectiveness of interventions for partners

Intervention	Results
<i>Counselling</i> (16 studies)	<ul style="list-style-type: none"> 16 studies - No significant effects on relapse prevention at longest follow-up in the general population.
<i>Educational Materials</i> (9 studies)	<ul style="list-style-type: none"> 8 studies - No significant effect on relapse prevention at longest follow-up. 1 study – Significant effect on partner quit attempts (intervention 30% vs. control 22%, p=0.02), and rate of reduction (39.7% vs. 17.7%, p<0.0001) but not in partner quit rates after 30 days (6.1% vs. 4.2%, p=0.26).
<i>Multicomponent</i> (4 studies)	<ul style="list-style-type: none"> 2 studies - No significant effects of studies including counselling and NRT or bupropion, brief individual counselling with the addition of web-based support at longest follow-up. 1 study – Significant effect of free NRT, telephone counselling, and cessation guide on partner quit rate during pregnancy (intervention 15% vs. control 5%, p=0.02), but not at 2, 6, or 12 months postpartum among a military population. 1 study – Significant effect of free NRT, telephone consultation with a GP, a letter from a GP, and a video on partner quit rate during pregnancy (intervention 16.3% vs. control 9.3%, p=0.011) among a low socioeconomic status male population. No measurements were made in the postpartum period.
<i>Feedback about Biological Measures</i> (1 study)	<ul style="list-style-type: none"> 1 study – Significant effect on partner quit attempts (intervention 34% vs. control 14.9%, p=0.03), but not in partner quit rates during pregnancy (1.8% vs. 2.1%) or in the postpartum period (4.4% vs. 2.8%).
<i>Pharmacotherapy</i> (10 studies)	<ul style="list-style-type: none"> 2 studies – Significant effect of NRT using gum on smoking relapse at 12 months after quit date for smokers who had briefly stopped smoking unaided (RR=1.24, 95% CI 1.04-1.47). 2 studies - No significant effects of pooling 2 studies using gum or inhaler on relapse prevention at longest follow-up for abstainers after cessation therapy. 6 studies - No significant effect of extended therapy with bupropion on smoking relapse for abstainers after cessation therapy. 2 studies – No significant effect of combination therapy of bupropion and NRT versus neither on smoking relapse for abstainers after cessation therapy. 1 study – Significant effect of extended varenicline on smoking relapse for abstainers after cessation therapy (RR=1.18, 95% CI 1.03-1.36). 1 study – Significant effect of rimonabant on smoking relapse for abstainers after cessation therapy.

Note: Significant results from fair or good quality studies were bolded. Poor quality studies that had significant results were not bolded.

Counselling

Sixteen studies on the general population of ex-smokers had no significant effects on relapse prevention from interventions involving group sessions, telephone support, or varying intensity of face-to-face counselling.

Educational Materials

Eight studies on the general population of ex-smokers had no significant effects on smoking relapse prevention from interventions involving booklets, advice letters, mailed self-help relapse program, or computer-delivered interventions.

Hemsing *et al.* (2009) found one study that reported significant differences in partner quit attempts, but not in partner quit rates after an intervention involving advice and educational booklets given to pregnant women on encouraging partners to quit smoking. The intervention group had significantly more quit attempts (30% vs. 22%, $p=0.02$), and also a greater rate of reduction (39.7% vs. 17.7%, $p<0.0001$). However, the 30-day abstinent rate was not significantly different (6.1% vs. 4.2%, $p=0.26$).

Multicomponent

Two studies on the general population of ex-smokers found no significant effects on relapse prevention from interventions involving counselling, NRT, bupropion, brief individual counselling, and web-based support.

Hemsing *et al.* (2009) found two studies that had significant effects on quit rates for male partners during pregnancy.

- One study recruited from a United States military population. The intervention included offering free NRT patches to partners, a cessation guide and six telephone counselling sessions involving motivational counselling and encouragement to develop and write an

agreement on helpful partner support behaviours. The partner quit rate was significantly increased in the intervention group compared to usual care at 28 weeks gestation (15% vs. 5%, $p=0.02$). No significant difference in quit rates at 2, 6, and 12 months postpartum.

- The second study enrolled males with low socioeconomic statuses from Australia.

Intervention involved telephone consultation with a general practitioner (GP), a referral letter from the participant's GP, a video targeted to men, and free NRT patches, followed by two additional mailed support packages including a booklet and motivational newsletter mailed one month later. The intervention group had a greater quit rate compared to usual care (16.5% vs. 9.3%, $p=0.011$) during pregnancy. Quit rates were not measured after birth.

Feedback about Biological Measures

Hemsing *et al.* (2009) found in one intervention, that partners in the intervention group involving biofeedback (demonstration of fetal heart rate due to smoking), with cessation advice and self-help booklets to have significantly more quit attempts (34% vs. 14.9%, $p=0.03$). However, quit rates were not different during pregnancy (1.8% vs. 2.1%) or in the postpartum period (4.4% vs. 2.8%).

Pharmacotherapy

Ten studies examined the use of pharmacotherapy for relapse prevention:

- Two studies looked at nicotine gum among smokers in the general population who had briefly stopped smoking unaided, and found a significant effect at 12 months after quit date ($n=2261$, $RR=1.24$, 95% CI 1.04-1.47).
- Pooling two studies on NRT gum or inhaler did not find a significant effect in the general population.

- Six studies found no significant effect of combination therapy with bupropion on relapse prevention in the general population.
- Two studies found no significant effect of combination therapy of bupropion and NRT versus neither on smoking relapse in the general population.
- One study on extended use of varenicline found a significant effect on relapse prevention in the general population (n=1210, RR=1.18, 95% CI 1.03-1.36).
- One study on rimonabant found a significant effect on relapse prevention; however, rimonabant is not licensed in any country.

Recommendations from the NICE guideline (2010) for partners:

- Encourage partners to stop smoking, and address concerns the mother, partner or family may have about stopping smoking, while offering personalized information, advice and support.
- For partners and others in the household who smoke, provide advice about danger of tobacco smoke poses to pregnant woman and baby before and after birth.
- Recommend not smoking around pregnant women, mother, or baby.
- Offer partners who smoke help to stop smoking using a multicomponent intervention that comprises three or more elements and multiple contacts.
- Discuss and take into account their preferences, contra-indications, and adverse effects of pharmacotherapy, the likelihood they will adhere to treatment, and their previous experience with cessation aids.
- Do not favour one medication over another and choose the option that will most likely succeed.

12 Applicability and Transferability

Members of the *Smoke-Free Homes* workgroup along with the Associate Medical Officer of Health and other Region of Peel staff involved in tobacco-related activities met on July 28th 2014 for a facilitated discussion. The purpose of the meeting was to discuss the feasibility and generalizability of this report, guided by the Applicability and Transferability Tool from the National Collaborating Centre for Methods and Tools. The following points were noted:

- Recommendations on relapse prevention are supported and seem politically acceptable, as Peel Public Health is currently prioritizing Living Tobacco-Free and Nurturing the Next Generation programs.
- Establishing smoke-free homes in the Region of Peel should be a cross-divisional initiative. It is important to leverage with other working groups at Peel within Chronic Disease and Injury Prevention (CDIP) and Family Health (FH), as well as other projects at Peel, including *Smoke-Free Multi-Unit Dwellings*, *Smoke-Free Movies*, *Workplace Tobacco Interventions*, and *Substance Misuse* projects. School health, human services, and primary care are also potential partners.
- There is an issue regarding reach. There are approximately 58,000 smoking parents of children aged 0-18 years. An estimated 37,900 children are potentially exposed to environmental tobacco smoke as a function of living with someone who smokes (1). Individual interventions are not possible. There is a concern on how to effectively target interventions, given that any smoke is harmful to children exposed at home. The *Smoke-Free Homes* workgroup is concerned for not only one cohort of children, but all children exposed at home.

- It is important to consider not only parents, but also other household members when implementing *Smoke-Free Homes* interventions.
- Any *Smoke-Free Homes* messaging should be impartial, positive and non-judgemental. Messages such as “Never around kids” or “Never in the home” were discussed.
- It is essential to consider equity issues when mapping out any tobacco-related interventions. There is a need to ensure that any intervention implemented will benefit all families living in smoking environments, and that disparities are not increased.
- It is also important to be mindful that smoking is an addiction, and that the postpartum time can be a stressful time for parents.

13 Recommendations

Peel Public Health should:

- Include partners and other household members in cessation and relapse prevention interventions.
- Use any appointment as an opportunity to ask pregnant or postpartum women and their partners if they smoke and refer them to smoking cessation services.
- Discuss with parents about the benefits of stopping smoking and about the danger tobacco smoke poses to both parents and their baby, before and after birth.
- Discuss the risks and benefits of pharmacotherapy during pregnancy and in the postpartum period. Recommend using NRT only if smoking cessation without it fails. Do not offer varenicline or bupropion to pregnant or breastfeeding women.
- Include aspects of relapse prevention as part of current smoking cessation interventions.

14 References

- (1) BORN Information System [January 2013 – December 2013], Extracted [May, 2014].
- (2) Statistics Canada, Share File, Ontario Ministry of Health and Long-Term Care. Canadian Community Health Survey. 2007-08 and 2009-10.
- (3) Hajek P, Stead LF, West R, Jarvis M, Hartmann-Boyce J, and Lancaster T. (2013). Relapse prevention interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, 2013(8), Art. No.: CD003999.
- (4) Likis FE, Andrews JC, Fonnesebeck CJ, Hartmann KE, Jerome RN, Potter SA, Surawicz TS, and McPheeters ML. (2014). Smoking cessation interventions in pregnancy and postpartum care. Evidence Report/Technology Assessment Number 214. Vanderbilt Evidence-based Practice Center, Agency for Healthcare Research and Quality
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- (8) Public Health Agency of Canada. What Mothers Say: The Canadian Maternity Experiences Survey. Ottawa, 2009.
- (9) Statistics Canada, Share File, Ontario Ministry of Health and Long-Term Care. Canadian Community Health Survey. 2011/2012.
- (10) World Health Organization. Gender, Women, and the Tobacco Epidemic. Geneva, Switzerland: World Health Organization Press, 2010.
- (11) Statistics Canada, Share File, Ontario Ministry of Health and Long-Term Care. Canadian Community Health Survey. 2007/08, 2009/10, and 2011/12.
- (12) Region of Peel – Peel Public Health. Burden of Tobacco – The Use and Consequences of Tobacco in Peel. 2012.

(13) Kalesan B, Stine J, Alberg AJ. The joint influence of parental modeling and positive parental concern on cigarette smoking in middle and high school students. *Journal of School Health*. 2006 Oct; 76 (8):402.

(14) Bricker JB, Peterson Jr AV, Leroux BG, Andersen MR, Rajan KB, Sarason IG. Prospective prediction of children's smoking transitions: role of parents' and older siblings' smoking. *Addiction*. 2006; 101, 128-136.

Appendices

Appendix A: Conceptual Framework

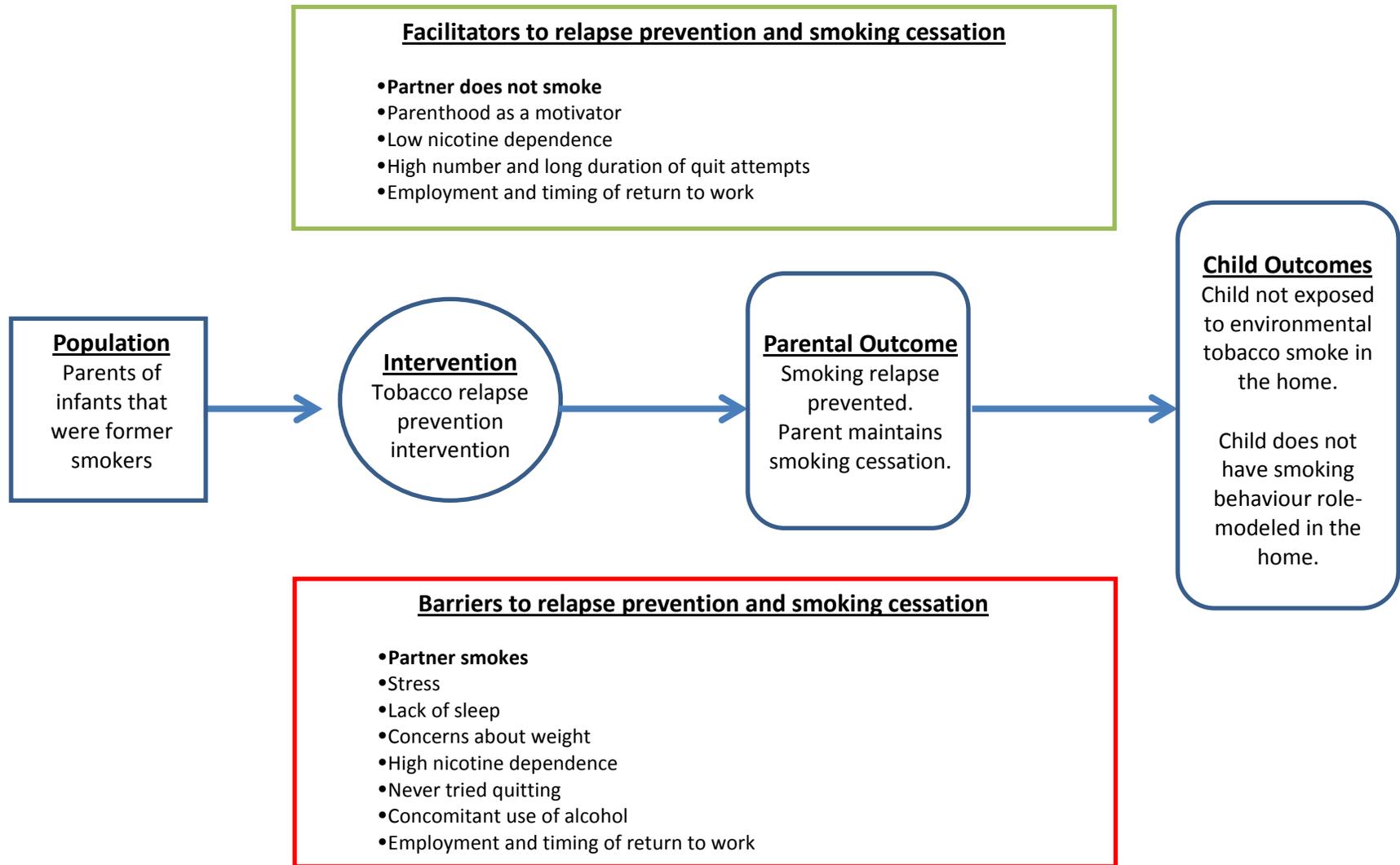
Appendix B: Search Strategy

Appendix C: Literature Search Flowchart

Appendix D: Data Extraction Tables

Appendix A: Conceptual Framework

NORMALIZATION OF SMOKE-FREE HOMES



Appendix B: Search Strategy

<p>Date: 2014-05-23 Source: Health Evidence</p>	<p>Search terms: Tobacco relapse prevention Results: 12 Proceed to relevance assessment of full document: 3</p> <p>Search terms: Smoking relapse postpartum Results: 6 Removal of duplicates: 1 Proceed to relevance assessment of full document: 3</p>
<p>Date: 2014-05-30 Source: National Institute for Health and Care Excellence (NICE)</p>	<p>Search: Guidance, Smoking and Tobacco, Quitting smoking in pregnancy and following childbirth (PH26), Appendix E Supporting Documents Results: 7 Proceed to relevance assessment of full document: 4</p>
<p>Date: 2014-05-23 Source: The Cochrane Database of Systematic Reviews</p>	<p>Search terms: Tobacco relapse prevention Results: 7 Removal of duplicates: 5 Proceed to relevance assessment of full document: 0</p> <p>Search terms: Smoking relapse postpartum Results: 0</p>
<p>Date: 2014-06-02 Source: TRIP Database</p>	<p>Search terms: tobacco relapse prevention postpartum smoking parents Results: 63 Refine results by evidence type: 3 systematic reviews Removal of duplicates: 1 Proceed to relevance assessment of full document: 0</p>
<p>Date: 2014-06-02 Source: PubMed</p>	<p>Search terms: tobacco relapse prevention postpartum Results: 34 Refine results by evidence type and date: 4 systematic reviews in the past 10 years Removal of duplicates: 2 Proceed to relevance assessment of full document: 0</p>

<p>Date: 2014-06-04 Source: Peel Public Health Colleague</p>	<p>Source of document: The Agency for Healthcare Research and Quality (AHRQ) through its Evidence-based Practice Centers (EPCs) Proceed to relevance assessment of full document: 1</p>
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Supplementary search conducted by a Peel Public Health Librarian:

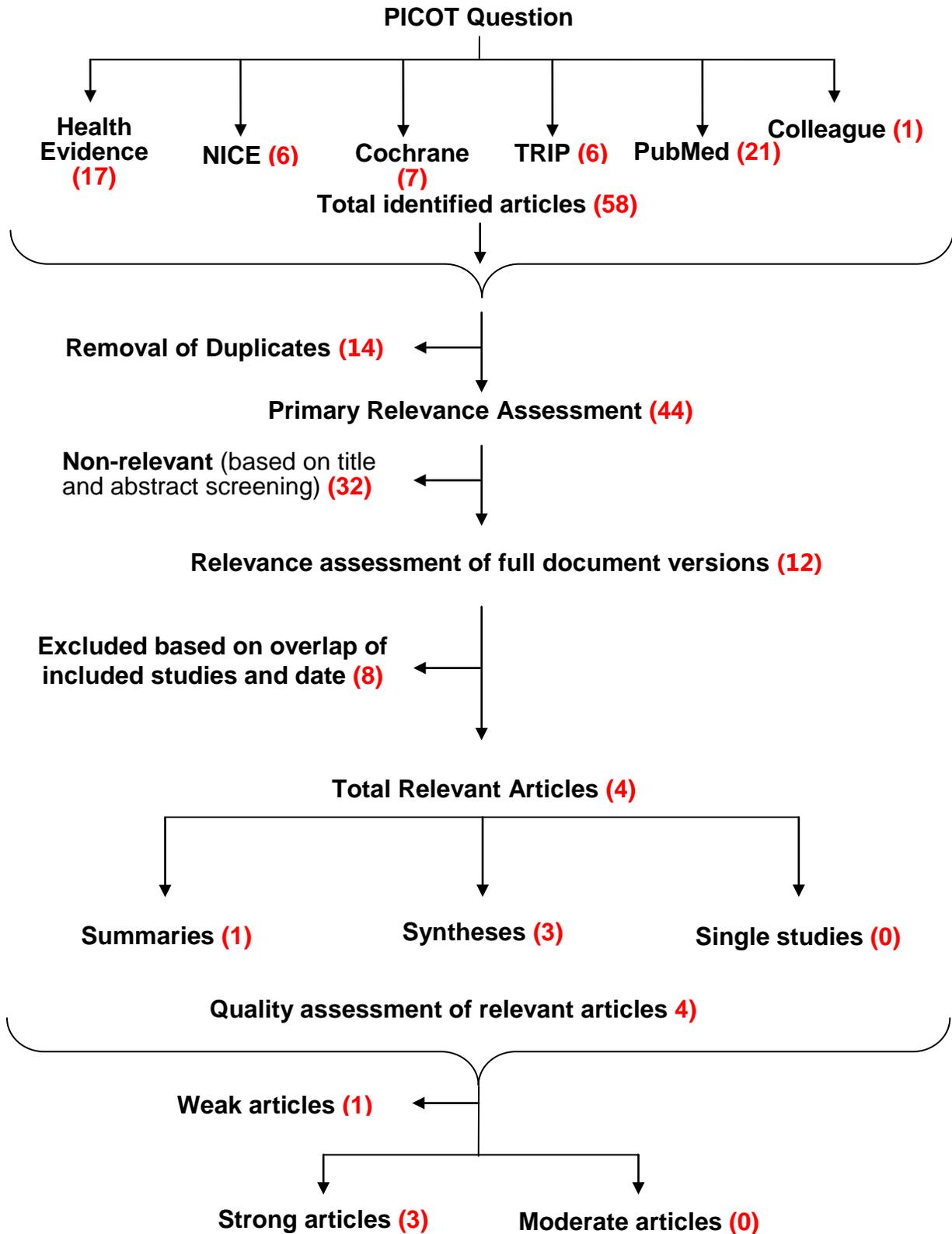
Date: 2014-06-10

Database: Ovid MEDLINE(R) <1946 to May Week 4 2014>

Search Strategy:

-
- 1 Smoking Cessation/ (20086)
 - 2 exp Smoking/pc [Prevention & Control] (15214)
 - 3 tobacco relapse.ab. (6)
 - 4 smoking cessation.ab. (12747)
 - 5 1 or 2 or 3 or 4 (34472)
 - 6 exp Postpartum Period/ (48154)
 - 7 Postnatal Care/ (3847)
 - 8 exp Maternal Behavior/ (9918)
 - 9 exp Parents/ (72341)
 - 10 postnatal.ab. (68247)
 - 11 postpartum.ab. (27651)
 - 12 10 or 11 (94110)
 - 13 9 and 12 (2645)
 - 14 6 or 7 or 8 or 13 (62067)
 - 15 5 and 14 (253)
 - 16 meta-analysis.mp.pt. (71664)
 - 17 systematic review.tw. (40156)
 - 18 cochrane database of systematic reviews.jn. (10474)
 - 19 or/16-18 (100497)
 - 20 exp guideline/ (25263)
 - 21 (practice guideline or guideline).pt. (25263)
 - 22 20 or 21 (25263)
 - 23 19 or 22 (125219)
 - 24 (comment or letter or editorial or note or erratum or short survey or news or newspaper article or patient education handout or case report or historical article).pt. (1703232)
 - 25 23 not 24 (119060)
 - 26 15 and 25 (12)
 - 27 review.ti. (233000)
 - 28 15 and 27 (12)
 - 29 26 or 28 (18)
 - 30 limit 29 to yr="2003 -Current" (18)

Appendix C: Literature Search Flowchart



Appendix D: Data Extraction Tables

<i>Cochrane Systematic Review, Hajek, P. et al. (2013)</i>	33
<i>AHRQ Systematic Review, Likis, F.E. et al. (2014)</i>	41
<i>NICE Guideline (2010)</i>	52

Data Extraction for Systematic Reviews	
Last revised: 2014-06-17	
Systematic Review #1 Hajek, P., Stead, L.F., West, R., Jarvis, M., Hartmann-Boyce, J., and Lancaster, T. (2013). Relapse prevention interventions for smoking cessation. Cochrane Database of Systematic Reviews, 2013(8), Art. No.: CD003999.	
General Information and Quality Rating	
Author and date	Hajek, P., Stead, L.F., West, R., Jarvis, M., Hartmann-Boyce, J., and Lancaster, T. 2013.
Country	United Kingdom. Studies were conducted in Spain, Australia, Germany, United Kingdom, Japan, Belgium, Canada, Netherlands, and the United States.
Health Evidence Quality Tool (Independently rated by 3 reviewers)	Overall rating: 8/10 (High quality)
Generalizability	Authors noted that the rates of abstinence were highly variable across studies due to several factors including the populations studied. Studies were from all over the world; however, the studies focusing on the special sub-population of pregnant and postpartum women were from Canada (1/15), the United Kingdom (1/15), Germany (1/15), and the majority of studies were conducted in the United States (12/15).
Details of the Review	
Objective	To assess whether specific interventions for relapse prevention reduce the proportion of recent quitters who return to smoking.
Evidence used to develop this review	63 studies
Types of studies	Randomized and quasi-randomized controlled trials with a minimum follow-up of six months from quit date.
Search period	Searched all studies up to May 2013. Included studies range from 1981 - 2010.
Number of databases searched	3 databases: Cochrane Tobacco Addiction Group register of trials, which includes electronic bibliographic databases, conference abstracts, and searches of the Cochrane Central Register of Controlled trials (CENTRAL), Issue 12, 2012; MEDLINE (via OVID) to update 20130329 and PsychINFO (via OVID) to update 20130401.
Inclusion/Exclusion Criteria	<u>Inclusion criteria:</u> Randomized or quasi-randomized control trials published in all languages. Included all studies that randomly assigned people already abstaining from smoking and that explicitly identified in their titles or abstracts a focus on relapse prevention or maintenance. Included studies that tested the effect of extended contact by telephone after an initial intervention. <u>Exclusion criteria:</u> Did not include studies of exercise or studies of

	aversive smoking. Excluded most interventions for hospitalized participants.
Quality Appraisal	Authors assessed included studies for risk of bias using the most recent Cochrane Tool. Risk was assessed based on random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, and incomplete outcomes data.
Populations, Interventions, and Outcomes of the Review	
Populations	People - who had quit smoking on their own, underwent enforced abstinence, and smokers who are participating in treatment programs to assist with cessation. One special population consists of pregnant and postpartum women.
Description of interventions	<p>Interventions to prevent relapse, compared with no intervention or a shorter intervention not focused on relapse prevention.</p> <p>Interventions divided into those assessing behavioural interventions and those assessing pharmacotherapy. Behavioural interventions further classified as intensive if they involve repeated face-to-face contact, which usually aimed at teaching participants to identify tempting situations and to apply coping skills and cognitive strategies. Behavioural interventions classified as less intensive were usually those that attempted to teach the coping skills via written material and could have involved one brief face-to-face session and telephone communication.</p> <p>When able, interventions were also analyzed separately if the participant had stopped smoking unaided or if they were assisted meaning they had taken part in a formal treatment program.</p> <p>Special Population – Pregnant and Postpartum Ex-Smokers <u>Behavioural interventions</u>: There were 15 studies that randomized pregnant or postpartum ex-smokers to interventions aimed at assisting the women to remain abstinent during pregnancy and after delivery. Interventions included:</p> <ol style="list-style-type: none"> 1. Six studies evaluated brief interventions comprising an initial face-to-face counselling session with written material handed out during the session, repeatedly mailed over a period of time after, or with a video. 2. One study looked at an initial counselling session for relapse prevention, which would be reinforced at later meetings without pamphlets. 3. Two studies examined the effect of a series of phone calls, or calls paired with letters, booklets, and newsletters. 4. One study assessed a 90-minute psychotherapy session with

additional calls.

5. Two studies evaluated motivational interviewing.
6. One study evaluated an intensive postpartum intervention including eight supportive telephone calls after the initial session with written materials.
7. One study examined six telephone-based counselling calls up to 16 weeks postpartum.
8. One study randomly assigned clinics to implement a provider counselling and office systems interventions.

General Population of Ex-Smokers

Behavioural interventions for unaided abstainers: Five studies randomly assigned participant recruited from local communities. All interventions were of relatively low intensity, involving self-help materials or telephone contact. Interventions included:

1. Eight-week self-guided relapse prevention program based on 16 modules.
2. A two-phase self-help relapse prevention program that included 12 weekly progress reports to be mailed by participants to main office.
3. Single booklet with effects of a partially proactive telephone helpline, eight booklet mailings, and a combination of booklets and helpline.
4. Tailored advice letters based on telephone assessment with the provision of standard materials.
5. Intervention compared eight booklet mailings over 12 months, the booklets at a single mailing, eight supportive letters over 12 months, and a control which received a single booklet.

Behavioural interventions for assisted abstainers: Seven studies randomly assigned abstaining smokers who had taken part in a formal treatment program. Interventions included:

1. A four-week support group, a telephone 'buddy' system, or a no-treatment control.
2. Three weekly skills training group sessions, three weekly discussion group sessions, or a no-treatment control.
3. Monthly group meetings focusing on relapse prevention strategies, monthly group meetings run by former smokers offering support, or a no-treatment control.
4. Two intensive interventions consisted of six 90-minute group sessions spaced over four weeks focusing on developing cessation skills and negative affect, or on intrinsic motivation and resolving participant ambivalence, or no-treatment control.

5. Tailored counselling calls or non-specific calls from a counsellor.
6. Relapse sensitive rapid smoking intervention.
7. Ten sessions of workplace group counselling or ten sessions of proactive telephone counselling over nine months. No control, and therefore author did not include in meta-analysis.

Behavioural interventions – varying intensity of face-to-face treatment:

Seven studies compared longer and shorter interventions

1. Nicotine gum and one-week intensive behavioural treatment, with relapse prevention components, seven further brief visits compared to a group with additional group sessions and optional drop-in visits.
2. Six sessions over two weeks compared to a group with additional relapse prevention sessions.
3. Combined nicotine or placebo gum with 5 or 14 sessions. The treatment group also had a larger relapse prevention component.
4. Addition of three booster six months after the basic nine-session program with relapse prevention components. Both control and intervention group received nicotine patches.
5. Smokers treated for heroin dependence received nicotine patch, 12 weeks of brief visits with an additional behavioural program including relapse prevention, and contingency management where participants were paid for abstinence. Control only received the nicotine patches.
6. Nicotine gum with four educational sessions over three weeks or a behavioural treatment that included relapse prevention components in 14 sessions over eight weeks.
7. Nicotine patches with three supportive sessions with a nurse over nine weeks or with 16 relapse prevention sessions with a behavioural therapist over 16 weeks.

Behavioural interventions – proactive telephone calls:

Two studies examined extended contact via telephone calls.

1. Provided group-based behavioural therapy for eight weeks, then compared a group with no further treatment to a group receiving telephone calls 1, 8, and 11 months later.
2. Callers assigned to the Australia quitline to four to six additional calls designed to prevent smoking relapse.

Behavioural intervention – additional web-based support:

One study examined additional web-based support.

1. Bupropion and brief individual counselling provided to all

participants. Intervention group offered internet access to the Comprehensive Health Enhancement Support System for Smoking Cessation and Relapse Prevention (CHESS SCR) for 12 weeks.

Behavioural interventions – additional computer-delivered interventions:

Three studies examined additional computer-delivered interventions.

1. All participants provided six weeks of nicotine patch therapy, five group counselling sessions and ecological momentary assessment (EMA) procedures for one month post quit date. Intervention group received computer-delivered treatment on palmtop computers for one month post quit date.
2. Participants in the Quit and Win contest received computer-tailored cessation advice and telephone counselling for one month post quit date. Intervention group formulated three coping plans.
3. Quitline callers randomly assigned to standard quitline service or to standard quitline service plus eight printed self-help booklets on relapse prevention.

Behavioural and Pharmacological interventions:

One study examined extended treatment with counselling and nicotine replacement therapy.

1. All participants provided with NRT and five telephone calls over four weeks. Intervention group received extended telephone counselling and NRT for a further 48 weeks. Control group received one additional telephone call at eight weeks, and no additional NRT.

Pharmacological interventions for short-term unaided abstainers:

Two studies looked at nicotine gum randomly assigned.

Interventions included:

1. Participants that stopped smoking for 48 hours were randomly assigned to nicotine gum, with a no gum control.
2. Participants that stopped smoking for 24 hours were randomly assigned to nicotine chewing gum or no medication control.

Pharmacological interventions for abstainers following cessation pharmacotherapy: Eight studies enrolled people to use pharmacotherapy to aid initial cessation before randomly assigning successful quitters to pharmacotherapy for maintenance.

	<p>Interventions included:</p> <ol style="list-style-type: none"> 1. Bupropion and nicotine patch combination and then after eight weeks, double placebo-controlled maintenance testing bupropion and nicotine gum in a factorial design. 2. Bupropion, nicotine inhaler, or combination for three months and then randomly assigned same therapy or placebo for nine months. 3. Bupropion used to aid cessation, and then after they had quit for at least seven weeks, bupropion or placebo was used for the rest of the year. 4. Nicotine patch for cessation, and then abstainers randomly assigned bupropion or placebo used for six months 5. Combination therapy of nicotine patch, bupropion and individual counselling for three months, and then either bupropion or placebo for 14 weeks. 6. Randomly assigned to 5mg or 20mg rimonabant for ten weeks, then abstainers assigned same dose or placebo for 42 weeks. 7. Varenicline used for 12 weeks and then abstainers randomly assigned to varenicline or placebo for another 12 weeks, and follow up at six months. 8. Weekly counselling and nicotine patches for cessation in a group of recovering alcoholics for eight weeks, and then abstainers randomly assigned either bupropion or placebo for 44 weeks.
Outcomes	The number of quitters at the longest follow-up. Authors used biochemically validated cessation in preference to self-report if available and continuous abstinence in preference to point prevalence abstinence.
Results of the Review	
Main results	<p>There is insufficient evidence to support the use of any specific behavioural intervention to help smokers who have quit for a short time to avoid relapse. The results of both special population studies and studies of smokers seeking treatment suggest that brief behavioural interventions and interventions based on written materials, mailings and telephone contact are ineffective for relapse prevention. As for pharmacotherapy, the extended use of varenicline may help prevent relapse in the general population. More studies are required on the use of nicotine replacement therapy.</p> <p>Special Population – Pregnant and Postpartum Ex-Smokers</p> <p><u>Behavioural interventions</u>: Pooled results of eight studies of interventions during pregnancy did not demonstrate a significant effect at the end of pregnancy (n=1523, RR=1.04, 95% CI 0.98-</p>

1.11, $I^2 = 0\%$). Twelve studies on behavioural interventions included follow-up in the postpartum period. The meta-analysis did not detect any significant benefit for not smoking at longest follow-up after delivery (ranging from 6 to 54 months) among postpartum women ($n=3524$, $RR=1.08$, $95\% CI 0.99-1.19$, $I^2 = 0\%$).

Of the twelve interventions included in the meta-analysis, one study found that the intervention had a significant effect on sustaining smoking abstinence at 12 months postpartum ($n=1026$, $RR=1.26$, $95\% CI 1.03-1.53$). This intervention involved an information pack provided by birth hospital, including a letter from a pediatrician on the risks of passive smoking, extended counselling support at 2, 4, and 5 month visits, and materials such as a video tape, written material, signs, magnets, and a bib. Control group only received information pack.

General Population of Ex-Smokers

Behavioural interventions for unaided abstainers: Five studies found no evidence of a benefit of interventions ($n=3561$, $RR=1.08$, $95\% CI 0.98-1.19$, $I^2 = 1\%$).

Behavioural interventions for assisted abstainers: Five studies found no long-term benefit of skills-based interventions ($n=1462$, $RR=1.00$, $95\% CI 0.87-1.15$, $I^2 = 56\%$). Meta-analysis compared most intensive intervention to least intensive control. One study on rapid smoking found no evidence treatment was effective. One study on workplace group counselling did not detect a significant effect at 12 months ($RR=1.07$, $95\% CI 0.88-1.31$).

Behavioural interventions – varying intensity of face-to-face treatment: No significant effect of relapse prevention in seven trials that looked at extended face-to-face contact ($n=699$, $RR=1.01$, $95\% CI 0.80-1.27$, $I^2 = 4\%$).

Behavioural interventions – proactive telephone calls: Two trials did not detect a significant effect of providing extended contact by telephone ($RR=1.06$, $95\% CI 0.90- 1.23$, $I^2 = 0\%$).

Behavioural intervention – additional web-based support: One trial did not detect a significant effect of providing support via the Internet as an adjunct to bupropion and brief counselling ($RR=1.27$, $95\% CI 0.70- 2.31$).

Behavioural interventions – additional computer-delivered interventions: One trial did not detect significant effect of adding

	<p>computer-delivered treatment on palmtop computers to Ecological Momentary Assessment (EMA) for one month post-cessation (n=1566, RR=0.93, 95% CI 0.64-1.35). One trial did not find a significant effect of asking participants of Quit and Win contests to generate coping strategies (RR=1.27, 95% CI 0.97-1.67). A quasi-randomized trial did not find a significant effect on abstinence at six months after adjusting for age, amount of treatment content, number of patches dispensed, and stress level (n=892, OR=1.15, 95% CI 0.78-1.67).</p> <p><u>Behavioural and Pharmacological interventions:</u> One study on extended therapy with both NRT and proactive telephone counselling did not detect an effect at 18 months (n=433, RR=1.28, 95% CI 0.94-1.75).</p> <p><u>Pharmacological interventions for short-term unaided abstainers:</u> Pooled results of two large trials of NRT using gum detected a significant effect at 12 months after quit date (n=2261, RR=1.24, 95% CI 1.04-1.47, I²= 56%).</p> <p><u>Pharmacological interventions for abstainers after cessation therapy:</u> Pooling two studies of NRT (one using nicotine gum, and the other an inhaler) did not suggest a significantly long-term beneficial effect (n=553, RR=1.04, 95% CI 0.77-1.40, I²= 0%). Six studies found no effect of extended therapy with bupropion (n=1697, RR=1.15, 95% CI 0.98-1.35, I²= 0%). Two studies found no significant benefit of combination therapy of bupropion and NRT versus neither (n=243, RR=1.18, 95% CI 0.75-1.87, I²= 66%). One study on extended varenicline found a significant effect (n=1210, RR=1.18, 95% CI 1.03-1.36). One study on extended rimonabant found a significant effect (n=1017, RR=1.29, 95% CI 1.08-1.55); however, rimonabant is not licensed in any country.</p>
Comments/limitations	<p>Review did not detect a statistically significant effect for existing behavioural relapse prevention interventions. Authors noted that the included studies had methodological and content limitations. The overall quality rating of the included studies was generally low. Most reported only point prevalence abstinence and only a small number of studies had adequate sample sizes to detect expected effects. Most interventions were brief and less intensive.</p>

Data Extraction for Systematic Reviews	
Last revised: 2014-06-23	
Systematic Review #2 Likis, F.E., Andrews, J.C., Fonnesebeck, C.J., Hartmann, K.E., Jerome, R.N., Potter, S.A., Surawicz, T.S., and McPheeters, M.L. (2014). Smoking cessation interventions in pregnancy and postpartum care. Evidence Report/Technology Assessment Number 214. Rockville, Maryland: Vanderbilt Evidence-based Practice Center (EPC), Agency for Healthcare Research and Quality	
General Information and Quality Rating	
Author and date	Likis, F.E., Andrews, J.C., Fonnesebeck, C.J., Hartmann, K.E., Jerome, R.N., Potter, S.A., Surawicz, T.S., and McPheeters, M.L. 2014.
Country	Studies were conducted in the United States, Canada, United Kingdom, Australia, Scotland, Spain, Sweden, and England.
Health Evidence Quality Tool (Independently rated by 3 reviewers)	Overall rating: 10/10 (High quality)
Generalizability	Authors assessed applicability of results according to Evidence-based Practice Center (EPC) methods guidance. They looked at what factors would affect the ability to apply intervention in a real-world setting. From this assessment they identified that the population and intervention were such factors.
Details of the Review	
Objective	To evaluate the effectiveness of smoking cessation interventions in pregnant and postpartum women. <u>Key Question #1</u> : 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?
Evidence used to develop this guideline	59 unique studies in 72 publications
Types of studies	56 randomized controlled trials and 3 prospective cohort studies
Search period	Search was not limited to studies conducted in any specific time period. Searched from database inception to present (2014)
Number of databases searched	3 databases: MEDLINE, CINAHL, and PsycINFO. Authors also searched the reference lists of included publications and recent systematic reviews related to smoking cessation interventions for pregnant women.

<p>Inclusion/Exclusion Criteria</p>	<p><u>Inclusion criteria:</u> Included studies published in English of pregnant or postpartum women within six months post-birth who currently smoked or who had quit during the index pregnancy. Studies had to have a minimum of 20 participants with data in each study arm. For Key Question #1, only randomized controlled trials were included. Original research studies that provided sufficient detail for methodology and results. Included studies must address treatment modality aimed at smoking cessation and/or outcomes related to interventions, such as smoking cessation, continuous abstinence, smoking relapse, harms of intervention to the mother or fetus, gestational age, NICU admission, birth weight, and preterm birth.</p> <p><u>Exclusion criteria:</u> Excluded studies that did not provide extractable data presented in text or tables on relevant outcomes. Did not include interventions targeting the behaviour of smokers' partners or providers exclusively. The review also did not include public health initiatives or system-level smoking cessation research. Did not include outcome data that relied exclusively on self-reporting.</p>
<p>Quality Appraisal</p>	<p>Two senior members independently assessed risk of bias using the Cochrane Risk of Bias Tool for RCTs and the Newcastle-Ottawa Assessment Scale for nonrandomized studies. The Cochrane tool assesses quality based on sequence generation, allocation concealment, blinding, outcome data, and selective reporting.</p>
<p>Populations, Interventions, and Outcomes of the Review</p>	
<p>Populations</p>	<p>Pregnant and postpartum (within six months post-birth) women who smoke or have quit smoking in the index pregnancy.</p>
<p>Description of Interventions</p>	<p>Any smoking cessation intervention, including pharmacological and non-pharmacological interventions.</p> <p>Studies on smoking cessation and relapse prevention interventions were multi-faceted. Multiple components were used and compared with usual care or an alternate level of standard care. Studies were grouped together into six categories.</p> <p>Categories based on primary focus of RCT interventions:</p> <ul style="list-style-type: none"> • Counselling (14 studies) • Educational materials (10 studies) • Multicomponent interventions (14 studies) • Nicotine replacement therapy (NRT) (5 studies) • Peer support (4 studies) • Other interventions (9 studies)

	<p>Counselling (14 studies)</p> <ul style="list-style-type: none"> • 14 studies: two good, three fair, and nine of poor quality • Ten studies conducted in the U.S., and one in each Canada, Scotland, Spain, and Australia. • Interventions included motivational interviewing (seven studies), cognitive behavioural therapy (two studies), psychotherapy (one study), and individualized smoking behaviour change counselling for cessation or relapse prevention (four studies). • Counselling conducted in-person at a clinic or at the patient’s home, or delivered via telephone. • Sessions ranged from one to six. • Two studies (one good quality and one poor) enrolled women during postpartum hospitalization who had quit smoking during pregnancy. The good quality study conducted in Canadian hospitals randomized women to in-person counselling session from a nurse and up to eight weeks of telephone follow-up during the first three months postpartum. Smoking status was verified by a carbon monoxide exhalation level of less than 10 parts per million (ppm). <p>Educational Materials (10 studies)</p> <ul style="list-style-type: none"> • 10 studies: three good, three fair, and four of poor quality • Six studies conducted in the U.S., three in the U.K., and one in Sweden. • Five studies on print-based interventions, two on video-based interventions, and three on technology-based such as text messaging and computer-delivered interventions. Materials included quit guides that provided advice for quitting smoking and preventing relapse. • All studies conducted during the prenatal period, and two report outcomes in the postpartum period. <p>Multicomponent (14 studies)</p> <ul style="list-style-type: none"> • 14 studies: three good, five fair, and six of poor quality. • Ten studies conducted in the U.S., two in Europe, and two in Australia. • Smoking cessation outcomes reported at end of pregnancy (12 studies), at four to 12 weeks postpartum (five studies), and at six months postpartum (two studies). • Most common intervention components were counselling, information, quit guides, clinic reinforcement, peer support, and personal follow-up.
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	<p>NRT (5 studies)</p> <ul style="list-style-type: none"> • 5 studies on pregnant women who were current smokers: two good, one fair, and two of poor quality. • Three studies conducted in the U.S., one in each England and Australia. • Three studies examined nicotine patches, one used gum, and one allowed participants to choose nicotine patches, gum, or lozenges. • All studies reported outcomes at end of pregnancy and two reported postpartum cessation. <p>Peer Support (4 studies)</p> <ul style="list-style-type: none"> • 4 studies on pregnant women who were current smokers all conducted in the U.S.: two good, one fair, and one of poor quality. • Two studies used specially-trained peer counselors that were non-smokers in the community, and two studies used female friends or family members as peer supporters. • Peer supporters provided advice and support in person during visits, by telephone referrals, or in smoking cessation sessions. • All studies reported outcomes at birth and two studies reported postpartum outcomes, with the latest follow-up at one year postpartum. <p>Other Interventions (9 studies)</p> <ul style="list-style-type: none"> • 9 studies: two good, two fair, and five of poor quality. • Seven studies conducted in the U.S., one in each Canada and the U.K. • Interventions included various forms of biological feedback intended to motivate pregnant women to quit smoking, facilitation of mother-infant bonding, modified delivery of self-help materials, financial incentives, counselling for depression, and clinic reinforcement. • <u>Feedback about biological measures (3 studies – 1 fair, 2 poor)</u>: ultrasound imaging, urine cotinine testing with visual and quantitative representation of results, and carbon monoxide testing results. • <u>Facilitation of mother-infant bonding (1 study - good)</u>: Treatment included enhanced support for maternal-infant bonding such as frequent and prolonged skin-to-skin contact with their infants, plus weekly encouragement to remain smoke-free and breast feeding support for women with infants in neonatal intensive care unit who have quit smoking. Treatment involved videos, pamphlets, books,
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	<p>and DVDs). Control group were only provided with encouragement to remain smoke-free and routine breastfeeding support.</p> <ul style="list-style-type: none"> • <u>Delivery method of self-help material (1 study – poor):</u> Personalized counselling and use of a quit guide compared to usual care. • <u>Financial incentives (2 studies – 1 fair, 1 poor):</u> Fair study examined providing one group with vouchers redeemable for retail items (15\$/ visit antepartum, and 20\$/ visit postpartum) independent of smoking status, and the other group with vouchers depending on the current smoking status. • <u>Treatment for depression (1 study – good):</u> Depression-focused cognitive behavioural intervention consisted of ten individualized sessions before birth for women with a lifetime history of major depressive disorder or partial remission at time of study enrollment. • <u>Clinic reinforcement (1 study – poor):</u> Cluster-randomized trial assessed six clinics and their use of a health-center based intervention compared to usual care. Intervention consists of providing training in delivery of a cessation intervention, a management system, and a process for sharing documents among prenatal clinics.
Outcomes	<ul style="list-style-type: none"> • Smoking cessation had to be confirmed by one or more biochemical measurements (e.g. urine, salivary, or serum cotinine, expired carbon monoxide, serum thiocyanate). • Continuous abstinence (biochemically validated) • Smoking Relapse
Results of the Review	
Main results	<p>Counselling</p> <ul style="list-style-type: none"> • No significant effect of interventions at longest follow-up time in all 14 studies. <p><u>Initial Smoking Cessation - Pregnant Women:</u></p> <ul style="list-style-type: none"> • 9 studies enrolled pregnant women who were current smokers (1 good, 3 fair, 5 of poor quality). • One good quality study examined motivational interviewing and cognitive-behavioural counselling intervention delivered by trained counselors via telephone. Intervention group had 10% cotinine validated quit rate vs. 7.5% in control (OR=1.37, 95%CI 0.69-2.70). At 3 months postpartum, rate declined to 6.7% vs. 7% (OR=0.93, 95%CI 0.44-1.99). • Three fair quality studies were examined. One study

compared motivational interviewing telephone counselling plus a quit guide booklet, or a computerized cessation program plus booklet, to a control group receiving only the booklet. Cotinine validated quit rate in late pregnancy were similar (20.8%, 16.7%, and 22.5%). The second study examined a 90-minute in-person psychotherapy session and found significantly higher cessation verified by carbon monoxide in intervention group compared to control at the end of pregnancy (28.3% vs. 9.6%, $p=0.015$), but not at 6 months postpartum (9.4% vs. 3.8%, $p=0.251$). The third study looked at providing structured physician advice and referral to individualized relapse prevention counselling at their 1st, 2nd, and 5th prenatal visits compared to usual care and found that at the 36-week prenatal visit, 14.1% of intervention and 9.9% of control group were not smoking (OR=1.49, 95%CI 0.71-3.10).

- The five studies of poorer quality did not report statistically significant results.

Relapse Prevention – Pregnant Women

- Four studies, all of poor quality, enrolled pregnant women who had quit smoking, and one study included current smokers, in individualized smoking relapse prevention, a combination of problem-solving skills and motivational interviewing, or individually tailored motivational interventions; however, they did not find statistically significant differences between intervention and control groups.

Relapse Prevention - Postpartum Women:

- Two studies enrolled women during postpartum hospitalization who had quit smoking during pregnancy. The good quality study looked at women who had quit at least 6 weeks prior to birth. The intervention including an in-person counselling session from a nurse and up to 8 telephone follow-up phone calls during the first 3 months found no significant difference between the intervention and usual care groups in maintaining smoking cessation at six months postpartum (37.6% vs 27.0%, OR=1.63, 95%CI 0.96-2.78). The poor quality study found no difference in smoking cessation at 3 months postpartum.

Educational Materials (10 studies)

- All studies conducted in the prenatal period.
- Eight studies enrolled women who were current smokers,

	<p>one study included both current and former smokers, and one study enrolled only women who had quit smoking.</p> <ul style="list-style-type: none"> • Eight studies did not detect a significant effect between interventions and control groups. The two studies that detected significant effects only enrolled current smokers. • One good quality study from the U.S. examining the effect of computer-based 5A's (Ask, Advise, Assess, Assist, Arrange) intervention tailored to the participant's smoking history and attitudes found that after ten weeks, the intervention group had ten times the odds of a cotinine confirmed quit (OR=10.2, 95% CI 1.4-75.0) compared to usual care. Note the sample size was small which decreased the precision (n=110). • One study of poor quality found greater cessation during pregnancy at 36 weeks in group shown a video, and given advice and a tip sheet (p=0.02). • The study enrolling pregnant women who were current or former smokers was of good quality and compared midwives providing usual care to usual care plus distribution five self-help booklets (quit guides). No significant difference in urine cotinine validated smoking cessation at 26 weeks gestation (intervention 18.8% vs control 20.7%). • The study enrolling pregnant quitters found that self-help booklets compared to usual care found that at 26 weeks gestation, there was no significant difference between groups (intervention 78.9% vs. control 84.7%, adjusted for parity, length of abstinence, smoking belief, and quitting self-efficacy). <p>Multicomponent (14 studies):</p> <ul style="list-style-type: none"> • 14 studies examined multicomponent interventions, of which nine enrolled only current smokers, two enrolled only recent quitters, and three enrolled both current and former smokers. <p><u>Initial Smoking Cessation - Pregnant Women:</u></p> <ul style="list-style-type: none"> • 12 studies on pregnant current smokers • One good quality study examined an intervention where a group of pregnant women received advice from a physician, counselling from a midwife, watched a smoking cessation video, were given a quit guide, were entered into a lottery with monetary rewards when they stopped smoking, identified a support person who was given educational
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	<p>materials and were given educational materials, had a sticker placed in their medical records, and were sent a letter from the midwife every week. Smoking cessation validated by urine cotinine in the treatment group was higher at end of pregnancy (13% vs. 7%, p=0.0353) and six to twelve weeks postpartum (10% vs. 1%, p=0.0011).</p> <ul style="list-style-type: none"> • The other two good quality studies did not find significant effects. One study involving clinic reinforcement, counselling, feedback about biologic measures, peer support, quit contract, quit guides compared to usual care found for current smokers at six months postpartum both groups had a 3% quit rate. The other study involving clinic reinforcement, counselling, biologic feedback, personal follow-up, prescription to quit, and quit guide found at last prenatal visit cessation was 20% in intervention and 10% in control (p=0.052, OR=2.20, 95% CI 0.98-4.94). • Four studies were of fair quality, of which three found significant effects. The first intervention consisted of clinic reinforcement, counselling, information, peer support, personal follow-up, and quit guide and found at the end of pregnancy cessation was significantly higher for the intervention group (14.3% vs. 8.5%, p=0.01). The second intervention consisting of counselling, information, and quit guides compared to a different counselling found that the intervention group had 6% cessation compared to 2%. The third fair quality study found verbal and written information about smoking cessation along with a quit guide and a preferably female non-smoker social supporter with whom there was regular contact to be effective. Cessation validated with saliva thiocyanate was higher in intervention group compared to control at end of pregnancy (32% vs. 9%, p<0.0001) and two months postpartum (21% vs. 6%, p<0.0009). The fourth study on clinic reinforcement, counselling, information, personal follow-up, prescription to quit, and quit guide found no significant difference in cessation in the third trimester (6.2% vs. 5.6%). • Five studies were of poor quality, of which one found significant differences in cessation. This study involved women receiving midwifery care, individual and group counselling, written information about risks of smoking and NRT. Cessation at 37 weeks gestation was significantly higher in intervention group (7.0% vs. 2.2%, p=0.004). <p><u>Relapse Prevention – Pregnant Women</u></p> <ul style="list-style-type: none"> • Four studies on relapse prevention for pregnant women
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	<ul style="list-style-type: none"> • One good quality study focused on pregnant women who had quit smoking recently. In the good-quality study, midwives were randomized to provide intervention or routine care to 1120 women. Intervention consisted of midwives providing counselling, information on their carbon monoxide reading, a quit guide, a quit contract, pairing with another pregnant smoker for peer support, and clinic reinforcement notes in their medical charts. At the end of pregnancy, cessation was 65% in treatment group and 53% in control group ($p < 0.05$). At six months postpartum, there was no significant difference between groups (23% vs. 25%, $p = \text{not significant}$). • Three poor quality studies found no significant effect of intervention at end of pregnancy. First study examined clinic reinforcement, counselling, information, peer support, personal follow-up versus control group which had different counselling (intervention 29% vs. control 44%, $p = 0.1$). Second study on current smokers and recent quitters smoking cessation looked at using counselling and information versus usual care (intervention 6.1% vs. control 5.9%, $OR = 1.0$, 95% CI 0.69-1.6). Third study looked at counselling, information, NRT, partner/household/social support, peer support, and quit contracts for recent quitters at end of pregnancy (intervention 42% vs. control 25%, $p = 0.39$). <p><u>Relapse Prevention - Postpartum women:</u></p> <ul style="list-style-type: none"> • One study examined interventions given in the postpartum period • One fair quality study found no significant difference in cessation at four to eight weeks postpartum comparing multicomponent intervention involving counselling and educational materials given in the postpartum period (37% in intervention and 25% in control, $p = 0.319$). Outcome was biochemically validated. <p>NRT (5 studies)</p> <ul style="list-style-type: none"> • All five studies enrolled pregnant current smokers. • One good quality study in England, found no significant difference in cessation at birth between NRT (patch) and placebo groups ($OR = 1.26$, 95% CI 0.82-1.96). • One fair quality study in the U.S. found no significant difference in cessation between NRT (gum) and placebo groups at 32 to 34 weeks' gestation (18.0% vs. 14.9%) or at 6-12 weeks postpartum (11.0% vs. 9.6%).
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	<ul style="list-style-type: none"> • One poor study in the U.S. found significantly higher cessation in NRT (patch, gum, or lozenge) group compared to control at 38 weeks' gestation, but not at three months postpartum. • Two poor studies of NRT (patch) found no significant effect. <p>Peer Support (4 studies)</p> <ul style="list-style-type: none"> • All four studies examined pregnant current smokers. • Three of the four were underpowered for their primary outcome. • The one study with sufficient power was of good quality and examined adding peer cessation counselors to a clinic-based brief intervention program involving quit guide and clinic reinforcement designed for pregnant women. At 36 weeks gestation, there was no significant difference (24% vs. 21%, p=0.84). • Four studies found no significant effect of peer support on smoking cessation at longest follow-up (28-36 weeks gestation, 3 months or 1 year postpartum) • One fair quality study found friends were more effective supporters than family members and authors stated trends suggested that ex-smokers were also more effective supporters than never or current smokers. <p>Other Interventions (9 studies)</p> <ul style="list-style-type: none"> • <u>Feedback on biological measures</u>: Three studies (one fair, and two of poor quality) found no significant differences in cessation among pregnant smokers between treatment and control group for feedback about biological measures. The fair quality study found that the three groups consisting of ultrasound feedback and motivational interviewing, ultrasound feedback and best practice counselling per AHRQ guidelines, and best practice counselling had no significant difference in cessation at the end of pregnancy (18.3%, 14.2%, 10.8%, p=0.30). • <u>Facilitation of mother-infant bonding</u>: One good quality study found a significant effect for the enhanced bonding approach in remaining abstinent among postpartum women who had quit smoking in the intervention group compared to usual care at eight weeks postpartum (81% vs. 46%, p<0.001). • <u>Delivery of self-help material</u>: One poor quality study found significantly increased incidence of cessation among pregnant smokers in the intervention group compared to
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	<p>control group with usual care at one month after intervention (14.9% vs. 5%, p=0.02), and at six weeks postpartum (13.8% vs. 5.2%, p=0.04).</p> <ul style="list-style-type: none"> • <u>Financial incentives</u>: In the fair quality study, cessation among pregnant smokers was higher for group receiving contingent vouchers at end of pregnancy (41% vs. 10%, p=0.003) and at 12 weeks postpartum (24% vs. 3%, p=0.006), but no difference at six months postpartum (8% vs. 3%, p=not significant). Poor quality study did not report a test of statistical significance. • <u>Treatment of depression</u>: No significant effect on smoking cessation at any time point (three and six months post treatment, 3 and six months postpartum) among pregnant smokers. • <u>Clinic reinforcement</u>: No significant effect on smoking status between treatment and control group among pregnant smokers and recent quitters.
Comments/limitations	<p>Authors noted that almost half of the included studies were of poor quality (n= 28). Studies were rated this way, as there was an unclear risk of bias.</p>

Data Extraction for Systematic Reviews	
Last revised: 2014-06-24	
Guideline #1 National Institute for Health and Care Excellence (2010) Quitting smoking in pregnancy and following childbirth (PH26). London: National Institute for Health and Care Excellence.	
General Information and Quality Rating	
Author and date	National Institute for Health and Care Excellence, 2010
Country	United Kingdom
AGREE II Quality Rating Tool (Independently rated by 3 reviewers)	Overall rating: 6/7 (High quality, meaning guideline is recommended for use)
Generalizability	Similar population
Details of the Review	
Objective	The Department of Health asked the National Institute for Health and Clinical Excellence to produce public health guidance on interventions aimed at stopping smoking in pregnancy and following childbirth.
Evidence used to develop this guideline	<p><u>3 reviews of the evidence:</u></p> <ol style="list-style-type: none"> 1. 'Which interventions are effective and cost effective in encouraging the establishment of smoke-free homes?' 2. 'Factors aiding delivery of effective interventions' 3. 'The health consequences of pregnant women cutting down as opposed to quitting' <p><u>3 expert reports:</u></p> <ol style="list-style-type: none"> 1. 'The effectiveness of smoking cessation interventions during pregnancy: a briefing paper' 2. 'Interventions to improve partner support and partner cessation during pregnancy' 3. 'Rapid review of interventions to prevent relapse in pregnant ex-smokers' <p><u>Economic modelling:</u> 'The economic analysis of interventions for smoking cessation aimed at pregnant women'</p> <p><u>Fieldwork report:</u> 'Consultation on NICE draft recommendations on quitting smoking in pregnancy and after childbirth: Report to the National institute for Health and Clinical Excellence' Expert advice, comments from stakeholder and the Public Health Interventions Advisory Committee (PHIAC).</p>
Types of studies	Fieldwork report, systematic review, economic analysis review, a briefing paper, and two rapid reviews
Search period	1990 - 2009
Number of databases	9 databases searched for the effectiveness reviews: Applied Social

searched	Sciences Index and Abstracts (ASSIA), British Nursing Index, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Embase, Maternity and Infant Care, MEDLINE, PsycINFO, Science Citation Index, Social Science Citation Index. Web of Science Cited Reference and Google Scholar were also used to search for citations and internal topic experts were consulted. Reference lists of papers and reviews identified through the search process were examined as well.
Inclusion/Exclusion Criteria	<p><u>Inclusion criteria:</u> Studies were included in reviews if they included women who smoked who were planning a pregnancy, were pregnant, or had an infant less than 12 months. Studies included anyone who smoked and lived in the same dwelling as a pregnant woman or one who was planning a pregnancy, or where an infant less than 12 months old lived. Studies were included if they covered interventions aimed at making a home smoke-free or addressed factors that aided in the delivery of effective interventions. Lastly, studies were included if they looked at the health consequences of pregnant women cutting down compared to quitting smoking.</p> <p><u>Exclusion criteria:</u> Excluded if the study focused on women who did not smoke or who lived in a smoke-free home. Studies excluded if they focused on women who smoked but were not planning a pregnancy, were not pregnant, or did not have a child aged less than 12 months.</p>
Quality Appraisal	Papers were assessed using the NICE methodology checklist, as per NICE technical manual 'Methods for the development of NICE public health guidance'. Studies were graded (++, +, -) based on the risk of potential bias due to design and execution.
Populations and Interventions of the Guideline	
Populations	<p>The recommendations should benefit women who smoke and are planning a pregnancy, are already pregnant, have an infant under twelve months of age, as well as the unborn child, any other infants or children the women may already have, and her partner in the household.</p> <p>The guidance is for the National Health Service (NHS), United Kingdom, and other commissioners, managers and practitioners who have a direct or indirect role in helping women to stop smoking in pregnancy and following childbirth. This includes local authorities, education and the wider public, private, voluntary, and community sectors. Women who are planning a pregnancy, who are pregnant or who already have children, and their partners or other members of the public may find the guidance of interest.</p>

Description of Interventions	<p>This guidance presents effective smoking cessation strategies. Interventions include identifying and referring the women to cessation services, initial and ongoing support via telephone, face-to-face meetings, pharmacotherapy, or self-help materials. Interventions also include providing appropriate training to various health care professionals.</p>
Recommendations	
1	<p>Identifying pregnant women who smoke and referring them to NHS Stop Smoking Services – action for midwives.</p> <p><u>Provider:</u> Midwives at first maternity booking and then at subsequent appointments</p> <p><u>Description:</u></p> <ul style="list-style-type: none"> • Assess woman’s exposure to tobacco smoke through discussion and use of a carbon monoxide (CO) test. • Provide information about risks of smoking during pregnancy and of exposure to second hand smoke to unborn child and mother, as well as explain health benefits of stopping. • Refer all women who smoke, women who have recently stopped smoking, or women with a CO reading of 7 ppm or above to NHS Stop Smoking Services. • Make appointment and provide Pregnancy Smoking Helpline number. • If partner smokes, suggest they contact the NHS Stop Smoking Services as well. • At next appointment, check if referral was taken up.
2	<p>Identifying pregnant women who smoke and referring them to NHS Stop Smoking Services – action for others in the public, community and voluntary sectors.</p> <p><u>Provider:</u> GPs, practice nurses, health visitors and family nurses. Obstetricians, pediatricians, sonographers and other members of the maternity team (not including midwives). Those working in youth and teenage pregnancy services, children’s centers, social services, fertility clinics, dental practices, community pharmacies, and voluntary and community organizations.</p> <p><u>Description:</u></p> <ul style="list-style-type: none"> • Use any appointment as an opportunity to ask women if they smoke, and if they do, explain how NHS Stop Smoking Services can help people quit. • Offer a referral to NHS Stop Smoking Services. • Give the NHS Pregnancy Smoking Helpline number in case

	<p>they want to talk to someone in the meantime.</p> <ul style="list-style-type: none"> • Those with training should provide pregnant women who smoke with information about risks. Information should be available in a variety of formats.
3	<p>NHS Stop Smoking Services – contacting referrals.</p> <p><u>Provider:</u> NHS Stop Smoking Services specialist advisers</p> <p><u>Description:</u></p> <ul style="list-style-type: none"> • Telephone all women who have been referred and discuss the issues they are facing, using an impartial, client-centered approach. • Attempt to see those who cannot be contacted via telephone • Address factors that prevent the women from using the services (e.g. lack of confidence in ability to quit, lack of knowledge about services, etc.). • If women are reluctant to attend clinic, consider providing structured self-help materials, support via telephone helpline, or offering a visit at home. • Send info to those who opted out during the initial telephone call information on smoking and pregnancy
4	<p>NHS Stop Smoking Services – initial and ongoing support.</p> <p><u>Provider:</u> NHS Stop Smoking Specialist advisers</p> <p><u>Description:</u></p> <ul style="list-style-type: none"> • During first face-to-face meeting, discuss how many cigarettes the woman smokes, how frequently, and if anyone else in the household smokes. • Provide information about risks of smoking and benefits of stopping for both mother and baby. • Address concerns she, her partner, or her family may have about stopping smoking and offer personalized information, advice, and support. • If partner or other family members are present at face-to-face meeting, encourage them to stop smoking if they do. • Provide woman with intensive and ongoing support throughout pregnancy and beyond, including regular monitoring of her smoking status using CO tests. • Biochemically validate that the woman has quit on the date she set and 4 weeks after. This can also be a useful way of providing positive feedback. If possible use urine or saliva cotinine tests over CO tests, as they are more accurate. • Establish links with contraceptive services, fertility clinics

	and ante- and postpartum services to ensure organizations are aware of NHS Stop Smoking Services.
5	<p>Use of NRT and other pharmacological support.</p> <p><u>Provider:</u> NHS Stop Smoking Services</p> <p><u>Description:</u></p> <ul style="list-style-type: none"> • Discuss risks and benefits of NRT, especially with those who do not accept other help from NHS Stop Smoking Services. Use only if smoking cessation without NRT fails. • Only prescribe NRT for use once they have stopped smoking, and only prescribe 2 weeks of NRT for use from the day they agreed to stop. • Advise pregnant women who are using nicotine patches to remove them before going to bed. • Do not offer varenicline or bupropion to pregnant or breastfeeding women.
6	<p>NHS Stop Smoking Services – meeting the needs of disadvantaged pregnant women who smoke.</p> <p><u>Provide:</u> NHS Stop Smoking Services</p> <p><u>Description:</u></p> <ul style="list-style-type: none"> • Ensure services are delivered in an impartial, client-centered manner and are sensitive to the difficult circumstances many women who smoke find themselves in. Need to take into account sociodemographic factors such as age, ethnicity, and ensure provision is culturally relevant. • Involve these women in planning and development of services. • Ensure services are flexible, coordinated, take place in locations and at times that make them easily accessible and tailored to meet individual needs. • Identify additional opportunities for providing intensive and ongoing support. E.g. collaborate with the family nurses that make frequent home visits. • Work in partnerships with agencies that support women who have complex social and emotional needs. These include substance misuse services, youth and teenage pregnancy support and mental health services.

7	<p>Partners and others in the household who smoke.</p> <p><u>Provider:</u> NHS Stop Smoking Services</p> <p><u>Description:</u></p> <ul style="list-style-type: none"> • Provide advice about danger of tobacco smoke poses to pregnant woman and baby (before and after birth). • Recommend not smoking around pregnant woman, mother, or baby. • Offer partners who smoke help to stop smoking using a multi-component intervention that comprises three or more elements and multiple contacts. Discuss and take into account: their preferences, contra-indications and adverse effects of pharmacotherapy, likelihood they will adhere to treatment, and previous experience with cessation aids. • Do not favour one medication over another. Choose the option that will most likely succeed.
8	<p>Training to deliver interventions.</p> <p><u>Provider:</u> Commissioners of NHS Stop Smoking Services, maternity services, professional bodies and organizations, NHS Centre for Smoking Cessation and Training, and other providers of smoking cessation training which meets the national standard</p> <p><u>Description:</u></p> <ul style="list-style-type: none"> • Ensure all midwives are trained to the same standard as NHS Stop Smoking advisers, and that they receive additional specialized training, and are offered support and training updates. • Ensure all midwives and NHS advisers who work with pregnant women know how to ask questions that will encourage them to be open, know to always recommend quitting rather than cutting down, and have received accredited training in the use of CO monitors. • Ensure all health professionals are trained in the same skills, know how to refer the women, understand the impact of smoking. • Ensure training addresses barriers to confronting smoking with a pregnant woman (e.g. they may feel broaching the subject may damage their relationship).

Extracted results from effectiveness reviews	
<p>Baxter S, Blank L, Guillaume L, Messina J, Everson-Hock E, and Burrows J. (2009). Systematic review of how to stop smoking in pregnancy and following childbirth. School of Health and Related Research</p>	<p>Review 1 – Which interventions are effective and cost effective in encouraging the establishment of smoke-free homes?</p> <ul style="list-style-type: none"> • 14 studies on effectiveness of interventions • Most common outcome in the papers related to self-reported cigarette consumption, mostly of parents but sometimes also of other family members or household visitors. • Interventions categorized based on whether they consisted of counselling, counselling plus additional aspects, individually adapted smoke-free home policies, motivational interviewing, and also staff training. • Data from six studies suggest weak associations between counselling interventions and smoke-free related outcomes. • There is mixed evidence in regard to interventions combining counselling with additional interventions such as written materials or telephone support. • There is mixed evidence on interventions using motivational interviewing promoting smoke-free homes and individually adapted smoke-free home plans. • Evidence statement: Due to limited effectiveness, counselling alone is not recommended.
<p>Myers K, West O, and Hajek P. (2010). Rapid review of interventions to prevent relapse in pregnant ex-smokers. Queen Mary University London. Report to National Institute of Health and Care Excellence</p>	<ul style="list-style-type: none"> • 17 RCTs found that there are two types of methods evaluated so far: efforts to strengthen women’s determination to remain abstinent by education, motivational interviewing, and persuasion; and teaching them to identify relapse situations and put in place coping strategies. • Interventions examined so far had no effect on relapse • Authors state incentives seem like a promising approach, not tested in context of relapse prevention • Results of Cochrane systematic review (2009) meta-analysis of 14 studies on pregnant and postpartum women showed no benefit of motivational and ‘skills-based’ interventions (RR=1.04 [0.98, 1.11])
<p>Hemsing, N., O’Leary, R., Chan, K., Okoli, C., and Greaves, L. (2009). Interventions to improve partner support and partner cessation during pregnancy. British Columbia Centre of</p>	<ul style="list-style-type: none"> • Limited evidence on which interventions are effective in encouraging partners to support smoking cessation during pregnancy and postpartum. • 7 studies addressed partner support of women’s cessation. Studies reporting non-significant outcomes used workbooks, counselling, and a media education campaign, or biofeedback methods.

<p>Excellence for Women's Health. NICE Rapid Review.</p>	<ul style="list-style-type: none"> • One study found significant outcomes (Dutch RCT). Intervention included pregnant women receiving health counselling along with video and print resources on smoking cessation, while partners received a booklet, explaining that quitting together is important for the health of the baby. Important to note, only 76.2% of women reported delivering booklet to partner and only 48.5% of partners reported reading the booklet. • 8 studies examined whether interventions encouraging partners who smoke to stop smoking were effective. • 2 studies reported significant differences in partner quit attempts, but not in partner quit rates. One intervention included advice and educational booklets to pregnant women on encouraging partners to quit smoking. Intervention group had significantly more quit attempts compared to control (30% vs. 22%, $p=0.02$), and also a greater rate of reduction (39.7% vs. 17.7%, $p<0.0001$). However, 30-day abstinent rate was not significantly different (6.1% vs. 4.2%, $p=0.26$). The second intervention included biofeedback (demonstration of fetal heart rate due to smoking), along with cessation advice and self-help booklet. Partners in intervention group made more quit attempts compared to the control group (34% vs. 14.9%, $p=0.03$), however, quit rates were not different between groups during pregnancy (1.8% vs. 2.1%) or postpartum (4.4% vs. 2.8%). • 2 studies had significant effects in quit rates for male partners during pregnancy. One study found the effect was not sustained in the postpartum period (2, 6, and 12 months postpartum) and the other study did not examine the postpartum period. • The first intervention enrolled a U.S. military population. Intervention included offering free NRT patches to partners, a cessation guide and 6 telephone counselling sessions involving motivational counselling and encouragement to develop and write an agreement on helpful partner support behaviours. The partner quit rate was significantly increased in the intervention group compared to usual care at 28 weeks gestation (15% vs. 5%, $p=0.02$). No significant difference in quit rates at 2, 6, and 12 months postpartum. • The second intervention enrolled 505 low socioeconomic status males in Australia and involved telephone
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	<p>consultation with a general practitioner (GP), a referral letter from the participant’s GP, a video targeted to men, and free NRT patches, followed by two additional mailed support packages including a booklet and motivational newsletter mailed one month later. The intervention group had a greater quit rate compared to usual care (16.5% vs. 9.3%, p=0.011) during pregnancy. Quit rates were not measured after birth.</p> <ul style="list-style-type: none"> • Based on 9 studies, there is moderate evidence that multicomponent interventions including free NRT are effective in encouraging partners who smoke to stop smoking. • No studies specifically examined whether status of the person delivering an intervention influences effectiveness. However, the three studies that demonstrated significant effects were delivered by highly trained medical personnel.
Results of the Review	
Comments/limitations	<p>The Public Health Interventions Advisory Committee noted that there are several gaps in the evidence. These gaps include the limited evidence on how to prevent pregnant women who have given up smoking from relapsing after giving birth. Limited evidence on effectiveness and cost effectiveness of interventions aimed at encouraging partners to help pregnant woman stop smoking, establishing smoke-free homes, helping women in certain demographic groups quit smoking. They noted there is also limited evidence on how and why some women spontaneously quit smoking when they become pregnant.</p> <p>The guideline was reviewed in October 2013 and it remains current with no updates. The next review will occur in July 2015.</p>