The Effectiveness of Smoking Cessation Interventions during Pregnancy: A Briefing Paper

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Update information

November 2021: NICE guideline PH26 (June 2010) has been updated and replaced by NG209.

This guideline contains the evidence and committee discussion for recommendations from PH26 dated [2010] and [2010, amended 2021].

See www.nice.org.uk/guidance/NG209 for all the current recommendations and the evidence behind them.

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EXECUTIVE SUMMARY

This report summarises key evidence from recent systematic reviews of the effectiveness of smoking cessation interventions in pregnancy, provides a new meta-analysis of the effectiveness and safety of NRT in pregnancy and updates a 2006 NICE review on the effectiveness of NHS intensive smoking cessation interventions in pregnancy.

Review Evidence

The 2009 Cochrane review includes 72 trials. Pooling results from these trials, the review authors conclude that cessation interventions reduce smoking in late pregnancy and also reduce incidence of low birthweight and preterm births. Interventions used in early pregnancy can reduce smoking in later pregnancy by around 6% (or 3% using studies least prone to bias).

The same review found that interventions which employ cognitive behavioural approaches to cessation are effective. Those using a „stages of change" approach showed borderline effectiveness and there was no evidence that using the results of feedback tests (such as reports of urinary cotinine levels) increased cessation.

Financial incentives for smoking cessation during pregnancy were found to be the single most effective intervention based on the results of four trials conducted in the USA. A further meta-analysis included in this report focuses on three of these four trials and confirms that incentives are effective but that further research is required to explore their applicability in the UK.

The Cochrane review found that NRT in pregnancy was effective. However it included a large trial from which the independent effect of NRT for cessation cannot be isolated. It did not include one large negative trial published in 2009. This report provides a new meta-analysis of those trials in the review which provide evidence on the efficacy of NRT and the new trial. This analysis concludes that there is still insufficient evidence for the effectiveness of NRT for smoking cessation in pregnancy.

We also provide a meta-analysis of the same trials focusing on the safety of NRT but this analysis must be viewed with extreme caution because heterogeneity present indicates that trials are better considered individually. There is no evidence that NRT either increases or decreases low birthweight. There areinsufficient data to form judgements about any impact of NRT on stillbirth or special care admissions

A recent review of self-help interventions for cessation during pregnancy suggests these types of interventions are effective, although the same review failed to find evidence that more intensive (i.e. longer or more frequently used) self-help materials had a greater impact than less intensive ones.

Individual Studies

Ten UK studies of NHS interventions for smoking cessation in pregnancy were included in a review updating previous work completed for NICE in 2006. These

studies were of mixed quality and research design, with all but one limited to observational and/or qualitative data.

Four studies suggest that NHS stop smoking services are effective in supporting women to stop smoking. However, the reach and effectiveness of services varies.

There was limited evidence on whether the way the intervention is delivered influences effectiveness. One UK trial found that stage-matched interventions, based on the transtheoretical model of behaviour change, were more effective than stage mismatched interventions but concluded that this finding was difficult to interpret as the stage-based interventions were also more intensive. One qualitative study described the characteristics of NHS stop smoking services for pregnant women that were perceived to be linked to effectiveness and these included systematic training for midwives, offering NRT to all clients, having an efficient prescribing system, offering home visits and providing multi-session behavioural support delivered by specialist staff.

There was also limited evidence on whether the site or setting of the intervention influences effectiveness. One study that reviewed routine data from all NHS stop smoking services for pregnant women in Scotland concluded that interventions offered in the home engaged a higher proportion of pregnant smokers than clinic-based services, but more research is required to explore this further.

A number of facilitators and barriers to implementation were identified. For example, good evidence from two studies in Scotland suggests that around one infour women who smoke during pregnancy do not accurately disclose their smoking status at maternity booking. The introduction of routine CO monitoring to identify smokers can help address this problem and facilitate referral to NHS stop smoking services.

However, the nature of the referral pathway can then affect how many women do receive support and try and quit. There is very preliminary evidence that opt-out referral pathways result in a higher proportion of women setting a quit date. However further research is needed to test the merits of different referral methods for smoking cessation in pregnancy in the NHS.

Women who took part in one survey and one qualitative study reported barriers to accessing support to stop smoking. These included, among others, feeling unable to quit, lack of knowledge about services, difficulty accessing services, fear of failing and concerns about being stigmatized.

Conclusion

Research is underway and planned that will help to address some of the current gaps in evidence outlined in this report. A large trial of the effectiveness of NRT for smoking cessation in pregnancy is underway in the UK, as is a trial examining exercise with behavioural support for smoking cessation in pregnancy. Proposals are currently being prepared for research to test the efficacy of financial incentives, to explore service delivery issues (such as referral pathways) in the NHS and to refine and test self-help cessation methods for pregnant smokers in the UK.

EVIDENCE STATEMENTS

Evidence statement ER1.1
There is good evidence from one recently updated systematic review on the effectiveness of interventions for promoting smoking cessation in pregnancy.

Lumley et al 2009 (International) Review ++

The review included 72 trials. Pooled results show that cessation interventions reduce smoking in late pregnancy [IR 0.94, 95% CI 0.93 to 0.96] and reduce incidences of low birth weight [RR 0.83, 95% CI 0.73 to 0.95] and pre-term births [RR 0.86, 95% CI 0.74 to 0.98] while increasing birth weight by a mean of 53.91g [95% CI 10.44g to 95.38g] .

The overall finding of the updated review is that smoking cessation interventions used in early pregnancy can reduce smoking in later pregnancy by around 6% (or 3% using studies least prone to bias).

Evidence statement ER1.2
There is good evidence from one recently updated systematic review on the effectiveness of financial incentives for promoting smoking cessation in pregnancy.

Lumley et al 2009 (International) Review ++

Four trials in the review examined financial incentives. A meta-analysis found that financial incentives paid to pregnant women to promote smoking cessation were found to be significantly more effective than other intervention strategies [RR 0.76, 95% CI 0.71 to 0.81]

Evidence statement ER1.3
There is mixed evidence from one recently updated systematic review and one recent trial (not included in the review) on the effectiveness of nicotine replacement therapy (NRT) for promoting smoking cessation in pregnancy

Lumley et al 2009 (International) Review ++
Oncken et al 2008 (USA) RCT ++

In the review, meta analysis of data from five trials found NRT to be effective [RR 0.95 CI 0.92 to 0.98]. However, a large double blind placebo controlled trial was published after the review searches were completed that found [RR 0.96, 95% CI 0.85-1.09] found no evidence that NRT was effective for smoking cessation in pregnancy.

Evidence statement ER1.4
There is no evidence that NRT either increases or decreases low birthweight. There are insufficient data to form judgements about any impact of NRT on stillbirth or special care admissions

Lumley et al 2009 (International) Review ++
Oncken et al 2008 (USA) RCT ++

Evidence statement ER1.5
There is good evidence from one recent systematic review on the effectiveness of self-help interventions for smoking cessation in pregnancy, although the extent of UK evidence is limited.

Naughton et al 2008 (International) Review ++

Fifteen trials were included in the review and 12 in the primary meta-analysis which found that self-help interventions were effective [OR 1.83, 95% CI 1.23- 2.73]. A further meta analysis failed to find evidence that more intensive self-help interventions had greater impact than less intensive ones.

Evidence statement ER1.6
There is evidence from four UK studies that NHS stop smoking services are effective in supporting pregnant women to stop smoking.

Bryce et al 2007 (UK) + mixed methods
McGowan et al 2008 (UK) + mixed methods
Macaskill et al 2008 (UK) + mixed methods
Lee et al 2006 (UK) + qualitative

The NHS stop smoking service interventions for pregnant women described in these articles consist of a combination of behavioural support (delivered in a range of settings and formats) and NRT (for most but not all women). They report varied outcomes but those that included four week post quit date outcomes reported quit rates of between 32 -48%. However, evidence from a national study of smoking cessation services for pregnant women in Scotland found that the reach and effectiveness of services varied significantly between health boards and that some areas offered no tailored (specialist) smoking cessation interventions for pregnant women.

Evidence statement ER1.7
There is very preliminary evidence from two pilot studies, reported in one article, that combining exercise with behavioural support for smoking cessation in pregnancy is feasible and can be effective.

Ussher et al 2008 (UK) + cross sectional

Evidence statement ER1.8
There is limited evidence about whether the form of delivery can affect the effectiveness of smoking cessation interventions for pregnant women.

Aveyard et al 2008 (UK) ++ RCT
Lee et al 2006 (UK) + qualitative

One trial found some evidence that stage-matched interventions for smoking cessation in pregnancy were more effective, particularly in improving women‟s readiness to quit but concluded that it was difficult to interpret this finding as the stage-based interventions were also more intensive. Another qualitative study summarised the delivery characteristics of stop smoking services for pregnant women that were perceived to be successful by key stakeholders. These characteristics included training of midwives in how to refer pregnant smokers to specialist services, offering NRT to almost all clients, having an efficient system of providing prescriptions, offering home visits, and providing intensive multi-session behavioural support delivered by specialist staff.

Evidence statement ER1.9
There is limited evidence that the site or setting of the intervention influences the effectiveness of smoking cessation interventions for pregnant women in the UK

Macaskill et al 2008 (UK) + mixed methods

One study found that most stop smoking services in Scotland offered home visits by trained advisers to pregnant women. An analysis of routine service data, suggested that for those home based services for which data on engagement (whether a woman attended the first appointment with a specialist advisor) were available, about 50% of those referred engaged compared with 20% for clinic-based services.

Evidence statement ER1.10
There is good evidence that women in the UK underreport smoking during pregnancy and that CO monitoring can aid in the identification of pregnant smokers.

Shipton et al in press (UK) ++ cross sectional
Usmani et al 2008 (UK) + cross sectional

Two studies found that around one in four pregnant women in the west of Scotland do not accurately disclose their smoking status when asked during the booking visit with a midwife. One of these studies described how routine CO monitoring in ante-natal clinics, if implemented consistently, can improve theaccurate identification of pregnant smokers and facilitate referral to smoking cessation services.

Evidence statement ER 1.11
There is very preliminary evidence from two observational studies that opt-out referral pathways can increase the number of women who engage with NHS stop smoking services and result in larger numbers of women quitting smoking, when compared with opt-in referral pathways.

Macaskill et al 2008 (UK) + mixed methods
McGowan et al 2008 (UK) + mixed methods

Evidence statement ER1.12
There is some evidence about the barriers to accessing stop smoking support by pregnant women in the UK.

Ussher et al 2006 (UK) + cross sectional
Taylor et al 2008 (UK) – qualitative
Two studies explored pregnant women"s views about smoking cessation services. Barriers to accessing services included, among others, feeing unable to quit, lack of knowledge about services, difficulty of accessing services, fear of failing and concerns about being stigmatized.

INTRODUCTION

Smoking during pregnancy harms women and children, yet at least 17% of mothers in the UK continued to smoke throughout their pregnancy in 2005, and only a fifth of women who smoked during pregnancy believed that they would actually quit smoking after birth (The Information Centre, 2007). Smoking ratesare particularly high in some groups of women. Pregnant mothers aged 20 or under are three times as likely to smoke before or during pregnancy as mothers aged 35 or over, and are also less likely to quit. In addition, mothers in routine andmanual occupations were over four times as likely as those in managerial and professional occupations to have reported that they smoked throughout pregnancy - 29% and 7% respectively (Information Centre, 2007).

The adverse effects of smoking during pregnancy include up to 4,000 deaths per year in the UK from miscarriage and stillbirth, more preterm and low birth weight babies (Royal College of Physicians, 1992, Charlton, 1996) and an increase in sudden infant death, asthma and attention deficit hyperactivity disorder (Charlton, 1996, Bastra et al, 2003). Reducing smoking in pregnancy is, therefore, an important policy priority for improving population health and reducing health inequalities.

In 2008, the National Institute of Health and Clinical Excellence (NICE) published public health guidance (PH10) on smoking cessation interventions and one element of this included guidance for the NHS on addressing smoking during pregnancy (NICE, 2008). This guidance was informed by a number of systematic reviews of the evidence, including a review that explored the effectiveness of National Health Service intensive treatments for smoking cessation in England (Bell et al, 2007, Bauld et al, 2009). This briefing paper was commissioned to provide an update of the smoking cessation in pregnancy elements of the 2006 review, and to summarise the findings of key systematic reviews on the topic of smoking cessation during pregnancy.

This paper consists of four main sections. First, we outline the methods used to update the NHS intensive interventions for smoking cessation review and toobtain and summarise two key systematic reviews. Secondly, we highlight the main findings of the recently updated Cochrane review of interventions for smoking cessation during pregnancy (obtained prior to publication for the purposes of this paper) and a relevant review on self-help interventions for smoking cessation during pregnancy. Thirdly, we assess the extent to which papers published since the 2006 NICE review can help to address the questions posed in the guidance scope. We then briefly highlight ongoing and future research that may help to address the questions that remain about how best to intervene to support pregnant women to stop smoking during pregnancy.

METHODS

This briefing paper includes a number of different components. It focuses on summarizing key international and UK evidence on the effectiveness of smoking cessation interventions in pregnancy. In order to produce this summary an update of a systematic review conducted in 2006 for NICE (Bell et al, 2007, Bauld et al, 2009) was conducted. In addition, a detailed synthesis of key findings from the recently updated Cochrane review of smoking cessation interventions inpregnancy was undertaken. This methods section describes the main stages in the updated review. Further information on the approach used to summarise the Cochrane review (and conduct a meta analyses of relevant studies) is included in the next section of this report.

Literature search

To address the question "Which interventions are effective in encouraging women who are planning a pregnancy, women who are pregnant and women who have an infant less than 12 months to quit smoking?" the following types of literature were targeted:

- Primary studies located via searches of bibliographic databases
- Studies suggested by experts.

The search aimed to be as comprehensive as possible but was more limited in scope that previous NICE reviews as it was intended to feed into a briefing paper rather than a comprehensive review. It was also conducted by one reviewer rather than a team of reviewers. Thus, for example, it was not possible for time and resource reasons to do a comprehensive search of websites. However, the reviewer‟s knowledge of the field and detailed consultation with experts aimed to identify all possible UK sources that were relevant to the terms of the briefing paper.

Search process

A search strategy was developed which mirrored the strategy used in the 2006 review *The Effectiveness of National Health Service Intensive Treatments for Smoking Cessation in England* (Bell et al, 2007). However, the 2006 review was not limited to interventions for pregnant women but included a range of other groups, so a refined strategy was developed to identify *only* studies that included pregnant women. The search strategy also aimed to limit results to UK studies and focused on interventions delivered in the NHS. As it intended to mirror the 2006 review, it focused on cessation *during pregnancy* rather than followingpregnancy. The strategy used the keywords pregn*, smok*, cessation or stop* or quit* for studies published between 2006 and the search date (June 2009). A second search employed the same strategy but included a filter for studies conducted in the UK.

The 2006 review did not search all electronic databases but limited its search to Medline. This was the approach taken for this review, with the caveat that Medline is now hosted by the Web of Science database and thus the search was

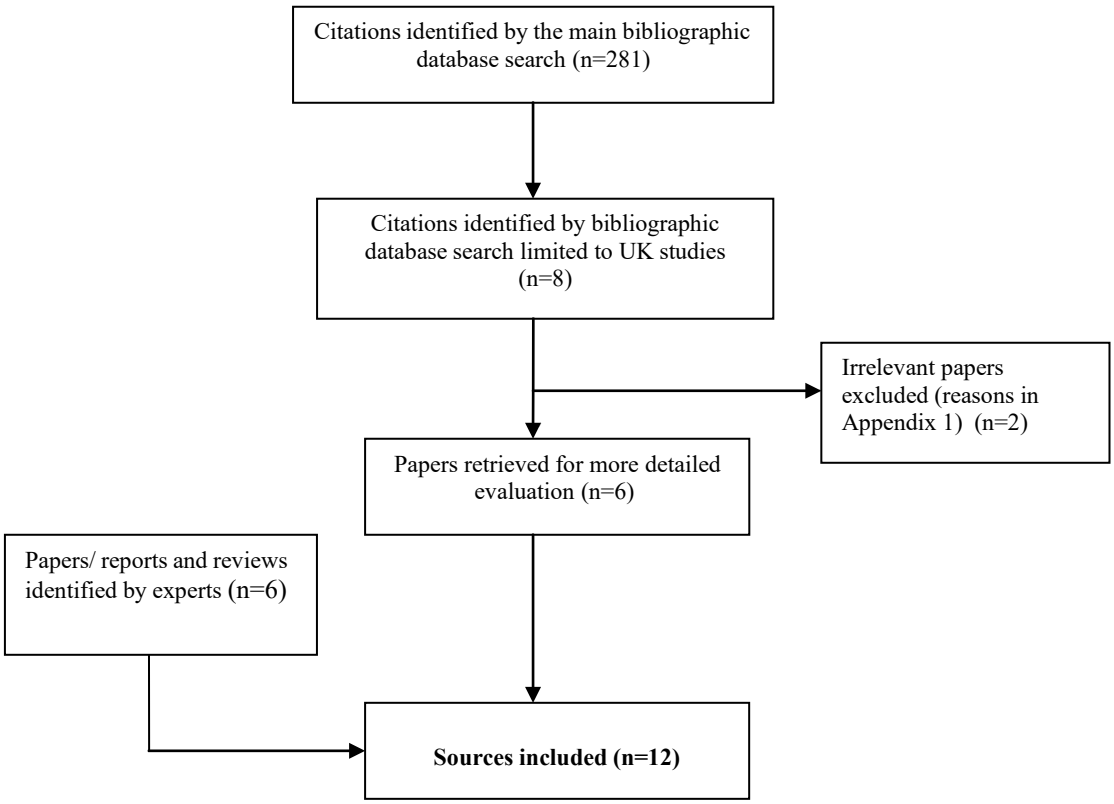
conducted using the full Web of Science. The search was conducted in June 2009 and used the following limits: English language only and a date range of 2006-2009, in order to identify those studies not included in the 2006 review.

The database search was supplemented by consulting with smoking cessation and tobacco control experts to identify sources. An email was sent in June 2009to seven colleagues in the UK who have conducted research or reviews onsmoking cessation during pregnancy. This email contained a list of the studies identified by the preliminary search and asked if there were any further papers in press or reports that could inform the review. In addition to this enquiry, a specificrequest for early access to the updated Cochrane review of interventions for promoting smoking cessation during pregnancy was sent to Professor Sandy Oliver. After consulting with her co-authors, Professor Oliver agreed to share this review in confidence to inform the briefing paper. Since then the review has been published on the Cochrane website and is now in the public domain.

Screening

Records retrieved from the bibliographic database search were imported into a Reference Manager database. A total of 281 sources were initially included in the database. However the vast majority of these sources were international studies and the search was rerun to limit results to UK studies. Just 8 UK studies on smoking cessation interventions in pregnancy delivered in the NHS and published between January 2006 and June 2009 were identified. The title and abstract of these records was screened by one reviewer to identify whether the studies were relevant or not. 6 studies were considered potentially relevant and full papers for these records were ordered for review. In addition, 3 other in-press or web-access pre-publication papers, one research report and one review (this review had emerged in the original search without the UK filter) were suggested by tobacco control research experts and early access to the updated Cochrane review, as explained above, was also obtained. Overall, therefore, 10 articles/reports and 2 systematic reviews were included. The 2 excluded UK papers, and the reason for exclusion, are listed in Appendix 1. The selection process is shown in Figure 1

Figure 1 Flow chart (QUOROM diagram): study selection process



Critical Appraisal

All of the studies that met the inclusion criteria were rated by one reviewer in order to determine the strength of the evidence. Critical appraisal was guided by the approach set out “Methods for the development of NICE public health guidance” (NICE, 2006, p85).

Based on the outcomes from the critical appraisal assessment, each study was graded using a code „++", „+" or „–", based on the extent to which the quality criteria had been fulfilled. These grading codes, as set out in the methods manual,are included in Box 1. As this is a briefing paper, rather than a full review, it was not possible for more than one reviewer to undertake the critical appraisal. Studies included in the Cochrane review and self-help review were not graded individually – instead a critical appraisal assessment of the review as a whole wasconducted.

Box 1: Evidence Grading

Grading the evidence	
++	**All or most of the quality criteria have been fulfilled** Where they have been fulfilled the conclusions of the study or review are thought *very unlikely* to alter
+	**Some of the criteria have been fulfilled** Where they have been fulfilled the conclusions of the study or review are thought *unlikely* to alter
-	**Few or no criteria fulfilled** The conclusions of the study are thought *likely or very likely* to alter

Synthesis

Data was extracted from all of the included articles in the form of main themes and issues emerging from the studies and used to inform the development of evidence tables which are included later in this report. A narrative synthesis of the main findings from each paper was then provided. The exception is for the updated Cochrane review, where data extraction was followed by a meta-analysis of findings relating to NRT use in pregnancy and incentives for smoking cessation. Further detail on the meta-analyses is included in the next section of this report.

REVIEW EVIDENCE

Commentary on the 2009 Cochrane review

This section of the report provides an appraisal of the updated Cochrane review"s findings, with an assessment of how these relate to the UK context. The updated review (Lumley et al, 2009) includes 72 trials, with eight new studies includedsince the previous iteration in 2004 (Lumley et al, 2004). Compared to the 2004 version, principal review findings remain unchanged: cessation interventions are found to reduce smoking in late pregnancy [risk ratio (IR) 0.94, 95% confidence interval (CI) 0.93 to 0.96] and also to reduce incidences of low birth weight (LBW) [RR 0.83, 95% CI 0.73 to 0.95] and pre-term births [RR 0.86, 95% CI 0.74 to 0.98]whilst increasing birth weight by a mean of 53.91g [95% CI 10.44 g to 95.38 g]. Treatment effects derived from the updated and previous reviews are broadly similar.

The review pools all available trials which include any type of smoking cessation-orientated intervention for pregnant women and to obtain an overall treatment effect for all interventions, but report significant heterogeneity across studies. This probably arises because trials with very different treatment strategies are combined; for example, data from trials investigating financial rewards and nicotine replacement therapy are synthesised together. The updated review[1] alsoassesses whether or not methodological quality of included trials affects estimatesfor the size of interventions" treatment effects, finding that trials with the lowest risks of bias showed lower, more acceptable levels of heterogeneity but also gave a lower estimate for cessation interventions" treatment effects [RR 0.97, 95% CI 0.94 to 0.99]. This lower figure probably gives the most accurate estimate of the efficacy of cessation interventions in pregnancy because it is based on the most robust available evidence.

Effectiveness of different intervention strategies

The overall finding of the 2004 and updated Cochrane reviews is that smoking cessation interventions used in early pregnancy can reduce smoking in later pregnancy by around 6% (or 3% using studies least prone to bias). However, this finding is achieved by pooling data from trials of *any* intervention strategy and provides no information about which kinds of intervention might be effective. Sub-group analyses within reviews provide these data, which are most likely to be useful to clinicians and policy makers, and the principal findings of such analyses from the updated review[1] are described below.

Intervention strategies which employed *cognitive-behavioural approaches* to cessation were most frequently used (31 trials) and meta-analysis of these produced a similar treatment effect to the impact found by pooling trials of all intervention strategies (Wisborg et al, 2000). 11 trials using psychological interventions based around the *"Stages of Change"* theory showed borderline effectiveness (no effect in 2004) and there was no evidence for the effectiveness of using the results *feedback* tests, such as reports of urinary cotinine levels for cessation (four trials).

Updated review findings relating to use of financial incentives and nicotine replacement therapy (NRT), are worth describing in more detail (Lumley et al, 2009). Financial incentives paid to pregnant women to promote smoking cessation are found to be significantly more effective than other interventionstrategies. In 2004, two trials, were identified as using financial incentives or reward strategies (Sexton et al, 1984, Donatelle et al, 2000) and, in 2009, a meta- analysis of four trials employing such strategies indicated that these are more effective than other cessation interventions in pregnancy [RR 0.76, 95% CI 0.71 to0.81] (Sexton et al, 1984, Donatelle et al, 2000, Higgins et al, 2004, Heil et al, 2008). In 2004, using NRT for cessation in pregnancy showed borderline effectiveness - three trials (Wisborg et al, 2000, Hegaard et al, 2003, Kapur et al, 2001) but in the update, meta-analysis of data from five studies found NRT to be effective [RR 0.95, 95% CI 0.92 to 0.98] (Wisborg et al, 2000, Hegaard et al, 2003, Kapur et al, 2001, Hotman et al, 2006, Pollak et al, 2007).

NRT is already widely used in pregnancy in the UK and although financial incentives are not these could, in theory, be incorporated into standard clinical practice. Consequently, in the next sections, the design and setting of trialsemploying each intervention strategy and how these might relate to the UK context are considered. Data synthesis and meta-analysis of data from NRT trialsis repeated using new data which was not available for the 2009 Cochraneupdate, providing more up to date estimates for the effectiveness and safety of NRT used for smoking cessation in pregnancy. Additionally, a meta-analysis ofthe three trials which unequivocally provide information on the efficacy of financial incentives for cessation is conducted.

All re-analyses involving data from the 2009 Cochrane review were conducted with substantial help and support from Ms Catherine Chamberlain one of the authors of the updated Cochrane review.

Evidence statement ER1.1
There is good evidence from one recently updated systematic review on the effectiveness of interventions for promoting smoking cessation in pregnancy.

Lumley et al 2009 (International) Review ++

The review included 72 trials. Pooled results show that cessation interventions reduce smoking in late pregnancy [IR 0.94, 95% CI 0.93 to 0.96] and reduce incidences of low birth weight [RR 0.83, 95% CI 0.73 to 0.95] and pre-term births [RR 0.86, 95% CI 0.74 to 0.98] while increasing birth weight by a mean of 53.91g [95% CI 10.44g to 95.38g] .

The overall finding of the updated review is that smoking cessation interventions used in early pregnancy can reduce smoking in later pregnancy by around 6% (or 3% using studies least prone to bias).

Effectiveness of financial incentives

Although the 2009 updated Cochrane review found that interventions which employ financial incentives to encourage smoking cessation in pregnancy mightbe more effective than other intervention strategies, this is based on data fromonly four trials (n = 1285) (Sexton, et al, 1984, Donatelle et al, 2000, Higgins et al, 2004, Heil et al, 2008). These four studies are briefly summarised below with conclusions about their relevance to provision of smoking cessation support in pregnancy via the UK NHS. This is followed by meta analysis of the three trials (n
= 350) (Donatelle et al, 2000, Higgins et al, 2004, Heil et al, 2008) which are designed in a manner to test the effectiveness of incentives alone and not as part of a multi-component intervention.

Sexton 1984[4]
This large, positive trial included a relatively small financial incentive for trial participants in addition to comprehensive behavioural intervention. The incentive took the form of a monthly lottery conducted amongst abstinent participants in the intervention group. The principal trial publication does not mention the reward components of the intervention, but a detailed description of intervention strategies employed is available in a secondary publication[12] and the primary intervention strategy used is a cognitive-behavioural one. The trial design is such that the impact of the whole intervention only is assessed and it is not possible to isolate the impact of the reward strategy employed on women‟s smoking cessation.Consequently, it is probably best to omit this trial from meta-analyses which assess the impact that financial incentives may have on pregnant women‟s smoking cessation.

Donatelle 2000[5]
This trial enrolled 220 participants, all of whom were paid $5 each time they attended an assessment appointment. Both trial groups received verbal and written information on the importance of smoking cessation and a pregnancy- specific „self-help‟ smoking cessation kit. Additionally women were telephoned monthly to encourage their quit attempt and also to ascertain their smoking status.Intervention group smokers designated a friend as a “social supporter” and both received financial gift vouchers for biochemically-confirmed smoking cessation by trial participants. This study, therefore, investigates the efficacy of financial incentives paid for smoking cessation in the context of a „significant other person‟ (i.e. significant to the participant) being aware of the cessation attempt and also being rewarded for abstinence from smoking by the participant. This intervention could, if desired, be incorporated into NHS routine care.

Higgins 2004[6]
53 participants were recruited to this trial, with the first 37 taking part in a pilot with non-random allocation of interventions. Control and intervention groups received identical levels of smoking cessation support and both also received financial vouchers which were intended to be of similar total value in both trial arms. The only difference between trial arms was that vouchers given to intervention group smokers were dependent upon cessation being demonstrated by exhaled CO monitoring. Again, if desired, this intervention could easily augment current UK clinical practice, as could Heil, below (uses same intervention).

Heil 2008[7]

This trial randomised 82 women to the same intervention strategy as Higgins (above). In this study, however, biochemical validation of smoking cessation was via urinary cotinine estimation because this method validates approximately seven days abstinence from smoking cessation as opposed to the 24 hr period of abstinence that exhaled carbon monoxide readings do. As with the Higgins trial, this study investigated the impact of providing financial incentives which are specifically contingent upon smoking cessation being achieved.

The three trials which investigate the impact of financial incentives (i.e. excluding Sexton) were conducted in the US and a total of only 350 participants were enrolled. Table 1 presents a meta-analysis of these studies using Cochranemethods and shows that the trials indicate financial incentives are effective at promoting smoking cessation by pregnant women, giving an OR (95% CI) for smoking in later pregnancy of 0.73 [0.66, 0.82]. However, it would probably be unwise to accept changes in clinical practice based on these data alone as it is possible that for cultural reasons, financial incentives might have a different impact in the UK and UK-based research is required prior to any recommendations being made.

It should also be noted that all studies used 7-day point prevalence of smoking abstinence as a primary outcome. This relatively-volatile measure is prone to fluctuations because it only requires that participants agree they have not smoked for 7 days. Continuous or prolonged reports of smoking cessation are preferable as outcome measures and any further research should adopt such measures for trial primary outcomes.

Table 1 Impact of financial incentives for smoking cessation in pregnancy

	Intervention		**Control**			
	Events	Total	Events	Total	Weight	
Donatelle 2000	78	112	99	108	0.9%	0.76 [0.66, 0.87]
Heil 2008	22	37	36	40	0.3%	0.66 [0.50, 0.88]
Higgins 2004	19	30	21	23	0.2%	0.69 [0.51, 0.94]
Subtotal (95% CI)		**179**		**171**	**1.4%**	**0.73 [0.66, 0.82]**
Total events	119		156			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.93$, df = 2 (P = 0.63); $I^2 = 0\%$

Test for overall effect: Z = 5.37 (P < 0.00001)

Evidence statement ER1.2
There is good evidence from one recently updated systematic review on the effectiveness of financial incentives for promoting smoking cessation in pregnancy.

Lumley et al 2009 (International) Review ++

Four trials in the review examined financial incentives. A meta-analysis found that financial incentives paid to pregnant women to promote smoking cessation were found to be significantly more effective than other intervention strategies [RR 0.76, 95% CI 0.71 to 0.81]

Effectiveness of Nicotine Replacement Therapy in Pregnancy

The recently updated Cochrane review (Lumley et al, 2009) does not provide the most accurate possible estimate for the safety and effectiveness of NRT in pregnancy because:

- A double blind, placebo-controlled large trial has been published since searches for the update were completed (Onken et al, 2008) and findings should be included in considerations[1].
- The Cochrane reviews synthesises data from trials with multi-modal intervention strategies which often involve a number of different interventions being delivered. Whilst this permits maximum use of available research data, it is not necessarily an appropriate strategy for determining the effectiveness of the individual interventions.
- To assess the effectiveness of NRT, trials would, ideally have no differences between study arms other than the provision of NRT but this is not the case with the Cochrane reviews[1;2] which include in meta analyses all studies employing NRT whether or not this is provided as part of multi- modal intervention strategy. Consequently, Cochrane analyses (Lumley et al, 2004, Lumley et al, 2009) include one trial in which NRT was offered to women as part of a multi-modal treatment strategy and in which the level ofbehavioural support for smoking cessation offered in addition to NRT in the intervention group was substantially higher than the amount offered in the „routine care" control group (Hegaard et al, 2003). As behavioural support is an effective treatment for smoking cessation in pregnancy, the inclusion of this trial has probably resulted in an over-estimate of the effectiveness of NRT in both the current and previous Cochrane.

Consequently, we present a meta analysis of data from current trials (published prior to August 2009) with designs which are appropriate for determining the effectiveness of NRT, providing contemporary estimates for the effectiveness of NRT for smoking cessation in pregnancy.

Methods

For the period prior to April 2008, we considered including all trials from the later Cochrane review (Lumley et al, 2009), categorised as having an intervention strategy which involved offering NRT to participants. We knew of one trial published since Cochrane searches had been completed (Onken et al, 2008) and,to find any other papers describing trials and published prior to August 2009 we used an „auto alert" for the databases CINAHL, Embase, MedLine, and PsychLit which flagged any publications (not conference presentations or abstracts) citing "smoking or tobacco" in the title or abstract. We also searched the Cochrane Pregnancy and Childbirth Group Trial Register by contacting the Trials Search Co-ordinator (August 2009). Methods for maintaining this register are included in the 2009 Cochrane review. Where titles were thought to indicate an appropriate study (see below) or this was unclear, papers were obtained. Trials were included

[1] Please note this trial was not identified in the main search for this briefing paper as that focused on UK studies. It is not, therefore, one of the ten studies and two reviews included in the evidence tables at the end of this report. Instead, the trial was known to the authors and therefore included in this meta-analysis as a key new piece of evidence.

for analyses if their design permitted any independent effect of NRT for smoking cessation to be isolated. Trials were excluded if the level of behavioural support differed substantially between trial arms. This exclusion criteria was used because behavioural support is an effective treatment for smoking cessation in pregnancy and the provision of this intervention unequally to trial arms would be expected to have an impact on trial outcomes. The following randomised controlled trial designs were acceptable:

- NRT with behavioural support / cognitive behaviour therapy or brief advice compared to behavioural support / cognitive behaviour therapy or brief advice alone (non-placebo controlled trials)
- NRT plus behavioural support plus/ cognitive behaviour therapy or brief advice compared with placebo NRT and behavioural support/ cognitive behaviour therapy or brief advice (placebo randomised controlled trials).

For any new trials identified, data extraction was conducted by Tim Coleman (TC) and Catherine Chamberlain (CC), using the data extraction forms employed in Cochrane reviews, with differences of opinion being clarified by discussion. TC also checked and discussed with CC previously extracted data from trials includedin Cochrane reviews and, where necessary, trialists were contacted to clarify outcome data. Meta analyses used the same methods as the Cochrane review and we present the following principal analyses:

- All trials included versus control conditions
- NRT versus placebo (i.e. from NRT versus placebo in trials with equal behavioural support in each arm)
- NRT versus NRT plus behavioural support / cognitive behaviour therapy or brief advice (i.e. from all included non-placebo controlled trials)

For comparison with the Cochrane review, sensitivity analyses were undertaken adding to the appropriate comparison group, data from any trials included in the Cochrane review, but excluded from principal analyses in this manuscript.

Results

The five NRT trials included in the 2009 Cochrane review were considered for inclusion in analyses (Wisborg et al, 2000, Hegaard et al, 2003, Kapur et al, 2001, Hotman et al, 2006, Pollak et al, 2007) as was the one new trial that we were already aware of (a double-blind placebo RCT investigating the use of nicotine gum for cessation – Onken et al, 2008) but we identified no further trials that had reported (and are not aware of any from non-search methods). Wisborg was contacted to clarify smoking cessation data for her trial and, consequently, different numbers of events in her trial appear here (compared to Cochranereviews), but data presented here should be regarded as definitive, because no clarification was sought previously.

One trial, Hegaard et al, 2003, included in Cochrane reviews, was excluded from principal analyses here because this included a substantial imbalance in the behavioural support allocated to trial groups. This trial has also been excluded from other previous analyses examining the effectiveness of NRT (Fry-Smith et al,2006). The control condition for the Hegaard trial was normal clinical antenatal care delivered by usual health service staff, but the intervention group received a cessation intervention delivered by specially trained staff who were only present in ante natal care settings at times when recruitment to the intervention group

occurred. The intervention comprised an initial intensive behavioural support session, followed by an invitation to join further programme of behavioural support for smoking cessation comprising up to nine further support sessions. NRT was offered as only one part of this intensive programme of behavioural support and not all women in the intervention group accepted the offer. It should be noted thatthis trial was also quasi-randomised with different days of the week being allocated to the delivery of control and intervention interventions but this was not the grounds used to exclude the trial from principal analyses.

Results are summarised in tables on the next page. Table 1 shows that, taken together, findings of all trials suggest that NRT is effective for reducing smoking in later pregnancy [RR, 95% CI = 0.92 (0.87, 0.98)], but that all of the evidence for NRT being effective comes exclusively from the trials which are at highest risk of bias (non-placebo randomised studies, Table 3, [RR, 95% CI = 0.87 (0.81, 0.94)]). *The most robustly designed trials (placebo randomised,) provide no evidence that NRT is effective for smoking cessation in pregnancy* [RR, 95% CI = 0.94 (0.87, 1.02)].

For the sensitivity analysis, the excluded, Hegaard trial was included in the „all trials" and „non placebo controlled trials analyses and resulted in the following riskratios and 95% confidence intervals: „all trials" 0.94 (0.90, 0.97) and „non placebo controlled" 0.93 (0.90, 0.96).

Table **2** **Nicotine replacement therapy for smoking cessation in pregnancy: all trials**

	Intervention		**Control**			Risk Ratio
	Events	Total	Events	Total	Weight	MH, Fixed 95% CI
Kapur 2001	13	17	13	13	5.0%	0.78 [0.58, 1.03]
Hotham 2005	17	20	20	20	6.7%	0.85 [0.70, 1.05]
Pollak 2007	105	122	58	59	25.7%	0.88 [0.81, 0.95]
Wisborg 2000	102	124	109	126	35.5%	0.95 [0.85, 1.06]
Oncken 2008	82	100	80	94	27.1%	0.96 [0.85, 1.09]
Total (95% CI)		**383**		**312**	**100.0%**	**0.92 [0.87, 0.98]**
Total events	319		280			
Heterogeneity: Chi² = 4.26, df = 4 (P = 0.37); I² = 6%						
Test for overall effect: Z = 2.80 (P = 0.005)						

Table 3 **Nicotine replacement therapy for smoking cessation in pregnancy: placebo controlled trials**

	Intervention		**Control**			Risk Ratio
	Events	Total	Events	Total	Weight	MH, Fixed 95% CI
Kapur 2001	13	17	13	13	2.5%	0.78 [0.58, 1.03]
Oncken 2008	82	100	80	94	13.3%	0.96 [0.85, 1.09]
Wisborg 2000	102	124	109	126	17.4%	0.95 [0.85, 1.06]
Total (95% CI)		**241**		**233**	**33.1%**	**0.94 [0.87, 1.02]**
Total events	198		201			
Heterogeneity: Chi² = 1.89, df = 2 (P = 0.39); I² = 0%						
Test for overall effect: Z = 1.47 (P = 0.14)						

Table 4 Nicotine replacement therapy in pregnancy for smoking cessation: non-placebo controlled trials

	Intervention		**Control**			Risk Ratio
	Events	Total	Events	Total	Weight	MH, Fixed 95% CI
Hotham 2005	17	20	20	20	6.7%	0.85 [0.70, 1.05]
Pollak 2007	105	122	58	59	25.7%	0.88 [0.81, 0.95]
Subtotal (95% CI)		**142**		**79**	**32.4%**	**0.87 [0.81, 0.94]**
Total events	122		78			
Heterogeneity: $Chi^2 = 0.05$, df = 1 (P = 0.82); $I^2 = 0\%$						
Test for overall effect: Z = 3.60 (P = 0.0003)						

Evidence statement ER1.3

There is mixed evidence from one recently updated systematic review and one recent trial (not included in the review) on the effectiveness of nicotine replacement therapy (NRT) for promoting smoking cessation in pregnancy

Lumley et al 2009 (International) Review ++
Oncken et al 2008 (USA) RCT ++

In the review, meta analysis of data from five trials found NRT to be effective [RR 0.95 CI 0.92 to 0.98]. However, a large double blind placebo controlled trial was published after the review searches were completed that found [RR 0.96, 95% CI 0.85-1.09] found no evidence that NRT was effective for smoking cessation in pregnancy.

Safety of Nicotine Replacement Therapy in Pregnancy

The updated Cochrane review (Lumley et al, 2009) did not present any meta-analysis of safety data from NRT trials as limited data were available. As one new trial has since reported substantial information on safety outcomes (Onken et al, 2008), we present below a contemporary analysis of all data published to date.

Method

We used the same methods to identify papers as for the NRT effectiveness review (above). Tim Coleman and Catherine Chamberlain extracted all data on compliance with treatment regimens and birth outcomes from newly identified papers, using data extraction forms employed in original Cochrane reviews and resolved differences of opinion by discussion. There was no, „a priori", view as to how compliance data would to be taken into account, rather the extracted compliance data was collated and considered together to determine how thismight best be synthesised.

Trials were included if they had information on any of the following outcomes: mean birth weight, low birth weight, preterm birth, still birth and special care admissions. Trials providing substantially unequal amounts of behavioural supportin different trial arms were excluded from principal analyses because behavioural support for smoking cessation in pregnancy is known to improve birth outcomes (this is a major finding of the Cochrane review). Therefore, the provision of greater behavioural support to either trial group would render attribution of any effects observed difficult, making the findings of any safety analysis difficult to interpret.

After principal analyses for the four birth outcomes above were conducted, sensitivity analyses were intended which involved:

- Including any trials with imbalances in behavioural support offered in trial arms
- Excluding any trials with very low compliance

Results

The six trials identified for the effectiveness review were potentially available for inclusion in safety analyses, but, as noted earlier, the Hegaard trial (Hegaard et al, 2003) provided substantially different levels of behavioural support to participants in different trial arms and so was only included in insensitivity analyses. Different trials reported compliance with treatment protocols in different ways and could not be easily be categorised and, hence compliance data could not easily be collated together. Participants in all trials used NRT for much shorter periods than trial protocols dictated, so compliance was generally low and no trials provided a „per protocol" analysis reporting outcomes in only those participants who had fully completed the trial protocol. Consequently, a meaningful sensitivity analysisrelating to compliance was not considered possible and one is not presented.

Tables 5-8 present the findings of meta-analyses for the four safety outcomes. Substantial heterogeneity exists for analyses relating to mean and low birth weights (Tables 5 and 6) – i.e. there are two studies that show positive impacts on birthweight (both placebo controlled) and two which show negative impacts, both not placebo controlled. Thus even though pooled findings are presented using a random effects model for these outcomes, the most appropriate use of data would

be to consider trials findings individually. Including Hegaard"s trial in a sensitivity analysis does not change overall findings with respect to these two outcomes; OR 95% CI become 103.72g [-72.85, 280.29] for mean difference in birth weight and 0.59 [0.20, 1.72] for low birth weight, respectively. *Overall, therefore, there is no evidence that NRT either increases or decreases birthweight*. There are insufficient data to form judgements about any impact of NRT on stillbirth or special care admissions (Tables 7 and 8).

Table 5 Impact of Nicotine replacement therapy: mean birth weight

	Intervention			**Control**				Mean difference
	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Oncken 2008	3287.0	566.0	93	2950.0	653.0	90	26.7%	337.00 [159.71, 514.29]
Pollak 2007	3061.0	661.0	122	3132.0	688.0	59	18.8%	-71.00 [-282.13, 140.13]
Wisborg 2000	3457.0	500.0	124	3271.0	500.0	126	54.5%	186.00 [62.04, 309.96]
Total (95% CI)			**339**			**275**	**100.0 %**	**159.47 [-40.46, 359.41]**

Heterogeneity: Tau² = 26579.20; Chi² = 20.27, df = 3 (P = 0.0001); I² = 85%

Test for overall effect: Z = 1.15 (P = 0.25)

Table 6 Impact of nicotine replacement therapy in pregnancy: low birth weight

	Intervention		**Control**			Risk Ratio
	Events	Total	Events	Total	Weight	MH, Random, 95% CI
Oncken 2008	2	97	16	87	48.9%	0.11 [0.03, 0.47]
Pollak 2007	17	122	5	59	19.5%	1.64 [0.64, 4.24]
Wisborg 2000	4	120	11	122	31.6%	0.37 [0.12, 1.13]
Total events	23		32			
Total (95% CI)		**339**		**268**	**100.0%**	**0.44 [0.10, 2.02]**

Heterogeneity: Chi² = 10.52, df = 2 (P = 0.005); I² = 81%

Test for overall effect: Z = 2.45 (P = 0.01)

Table 7 Impact of nicotine replacement therapy in pregnancy: stillbirths

	Intervention		**Control**			Risk Ratio
	Events	Total	Events	Total	Weight	MH, Fixed 95% CI
Oncken 2008	2	97	2	87	43.9%	0.90 [0.13, 6.23]
Pollak 2007	2	122	2	59	56.1%	0.48 [0.07, 3.35]
Total (95% CI)		**219**		**146**	**100.0%**	**0.66 [0.17, 2.58]**
Total events	4		4			

Heterogeneity: Chi² = 0.20, df = 1 (P = 0.66); I² = 0%

Test for overall effect: Z = 0.59 (P = 0.55)

Table 8 Impact of nicotine replacement therapy in pregnancy: infant special care admissions

	Intervention		Control			Risk Ratio
	Events	Total	Events	Total	Weight	MH, Fixed 95% CI
Oncken 2008	7	97	11	0		Not estimable
Pollak 2007	13	122	4	59	100.0%	1.57 [0.54, 4.61]
Total (95% CI)		**219**		**59**	**100.0%**	**1.57 [0.54, 4.61]**
Total events	20		15			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.82 (P = 0.41)

Evidence statement ER1.4
There is no evidence that NRT either increases or decreases low birthweight. There are insufficient data to form judgements about any impact of NRT on stillbirth or special care admissions

Lumley et al 2009 (International) Review ++
Oncken et al 2008 (USA) RCT ++

Self-help Smoking Cessation Interventions in Pregnancy

A systematic review, published in 2008, investigated the effectiveness of self-help interventions for smoking cessation in pregnancy (referred to as the „self-help review") (Naughton et al, 2008). Most of research papers included within this analysis also appear in previously described Cochrane reviews, but the categorising of interventions as „self-help" or not is a significant, novel addition to the literature and the self-help review is the first systematic synthesis of empirical data relating to the effectiveness of self-help interventions for pregnant women.

Methods
Randomised and quasi-randomised trials involving pregnant smokers aged over 16 years, were included if at least one trial arm included a self-help intervention. Self-help was defined as „the provision of structured materials to assist an individual in making a quit attempt without significant assistance from a health professional or group". Trials were excluded if, in addition to self-help interventions, experimental arms received more cessation counselling than controlarms (i.e. they investigated the impact of counselling or advice combined with self-help interventions). Trials included were permitted to allow up to 15 minutes of total contact time with health professionals to facilitate introduction of self-help materials to participants.

Findings
Fifteen trials met with review inclusion criteria having data extracted and the primary meta-analysis comprised 12 trials comparing usual care (median quit rate 4.9%) with self-help (median quit rate 13.2%), yielding a pooled odds ratio of (0R) 1.83 [95% confidence intervals (CI) 1.23-2.73]. A further meta-analysis failed to find evidence that more intensive (i.e. longer or more frequently used) self-help materials had a greater impact than less intensive ones, (pooled OR= 1.25, 95%

CI 0.81-1.94) but this could be due to a lack of available trial evidence. The review authors conclude that self-help interventions are more effective than standard care for smoking cessation in pregnancy.

Commentary on Self-Help Review
There is strong evidence that structured self-help materials provided to pregnant smokers could help a substantial number achieve cessation. However, there is little, if any, published data on use of self-help interventions for smoking cessationby pregnant women within the UK and the extent to which NHS Stop Smoking Services recommend pregnant women to use self-help materials is not known.Self help materials which are appropriate for use by UK women could be, however, easily incorporated into standard NHS Stop Smoking Service care. As most women who stop smoking in pregnancy do so without obtaining any help from NHS Stop Smoking Services or other health professionals, there is potential for self-help interventions to be used by and have a large impact on the smokingof this very large group of women. Below the nature of interventions provided within review trials and how these might relate to the NHS context are considered.

The trials included varied contact time with women receiving the intervention. Of the 12 trials included in the review"s primary meta-analysis, 6 involved interventions which took 5 minutes or less to introduce to patients, whilst the remainder took more than 5 but no more than 15 minutes. Such interventions could readily be integrated into specialised NHS cessation support consultations which are relatively long. However, incorporating interventions into routine NHS (e.g. midwife) care consultations could be more difficult as finding to allocate 5 minutes solely to discuss smoking within these may be a challenge.

Of the 12 trialled interventions, all involved dissemination of written materials to participants (e.g. pamphlets, advise sheets or booklets), 3 also used video or audio cassettes, 2 letters of encouragement and 1 a self-help programme accessible via a computer available on ante-natal care visits (i.e. not accessed by women from their own computers over the internet). Most trials were implemented before widespread adoption of mobile internet / telephone technology and, therefore, the potential for using the internet, mobile phone, SMS messaging and quit lines to deliver self-help interventions to women has not been fully explored. With current technology it would be entirely possible to design self-help interventions utilising such techniques, minimising the time needed for these to be introduced by health professionals and facilitating their adoption into routine care. Below details are given of the two trials of self help interventions whichhave been conducted in the UK.

Moore 2002
1527 women were randomised into this pragmatic, cluster randomised controlled trial which used community midwives employed within 3 English NHS hospital trusts as units for randomisation (Moore et al, 2002). The trial tested the effect of providing a series of five self-help booklets to pregnant women. These booklets comprised a step by step programme aimed at increasing women"s motivation for stopping smoking and providing strategies to help them with this. The first bookletwas given to women at a midwife appointment with subsequent booklets being mailed directly to them. No evidence was found for the effectiveness of the intervention and self-reported quit rates were higher in the control group, despite

women reporting high levels of intervention delivery. However, women could join this trial if they had smoked prior to pregnancy, whether or not they were smoking the point of trial enrolment, so non-smokers were included in both trial treatment groups and this complicates interpretation trial findings. It is unlikely that smoking cessation-orientated interventions would be delivered to non-smokers in routine clinical practice. Additionally, this trial monitored the effectiveness of providing self help materials to all women, whether or not they had any interest in stopping smoking and, hence, the trial population will have included a proportion of women who would be highly unlikely to make use of self help intervention materials.

Lawrence 2003
This cluster randomised trial recruited 918 pregnant smokers in the West Midlands (Lawrence et al, 2003). General practices formed study clusters and midwives working from different practices delivered one of three interventions, with only one type of intervention being delivered in any one practice. Routine antenatal care was compared with the dissemination of written self-help manuals supported by a computer programme which participants had to work through at their point of antenatal care (i.e. the programme could not be accessed from women‟s homes). Again, in this trial the self help intervention was offered to all women, whether or not they were motivated to try stopping smoking, so the trial population will have included women with no intention of stopping smoking. The self-help intervention groups within the trial achieved modest (3%) levels of sustained cessation throughout pregnancy and for up to 10 days postnatally. The authors comment that their intervention was relatively resource-intensive and, therefore, question whether it might be viable for adoption for within the NHS.

There is, therefore, good evidence from the international literature that self-help interventions are effective for smoking cessation when used by pregnant women. However, there is very little evidence available from UK trials and, currently, there are no “off the shelf” self-help interventions available which have been designed specifically for UK smokers. Previous trials have provided self help interventions to all smokers, irrespective of their motivation to stop smoking. Such interventions could, potentially, provide a means of engaging women in cessation attempts who would not otherwise do so and research should investigate the potential of modern means of communication to deliver self-help cessation support in pregnancy (e.g. SMS text messaging and internet technologies). Research to develop self-help interventions for UK smokers is required and trials should focus on delivering these interventions to smokers who are motivated to quit and who are most likely to use them, rather than as part of routine antenatal care.

Evidence statement ER1.5
There is good evidence from one recent systematic review on the effectiveness of self-help interventions for smoking cessation in pregnancy, although the extent of UK evidence is limited.

Naughton et al (2008) Review ++

Fifteen trials were included in the review and 12 in the primary meta-analysis which found that self-help interventions were effective [OR 1.83, 95% CI 1.23- 2.73]. A further meta analysis failed to find evidence that more intensive self-help interventions had greater impact than less intensive ones.

INDIVIDUAL STUDIES

This part of our report outlines findings from an update to the 2006 review of the effectiveness of intensive NHS interventions for smoking cessation, with specific reference to interventions for pregnant women. We identified ten new UK studies relating to interventions for pregnant women (in addition to the Cochrane and self-help reviews summarised above). These studies were of mixed quality and design (one ++ RCT and one ++ cross-sectional study, three + mixed method studies, three + cross sectional studies, one + qualitative study and one – qualitative study). The majority were largely descriptive studies of service delivery with some analysis of outcomes using routinely available monitoring data. Thus while they provide a useful description of how smoking cessation interventions for pregnant women are being delivered in the NHS, they do not provide the same quality of evidence as the trials included in the Cochrane and self-help reviews summarised in the previous section.

Findings from the ten UK studies are used to attempt to address the key review question and sub-questions posed by the NICE scope.

Which interventions are effective in encouraging women who are planning a pregnancy, women who are pregnant and women who have an infant aged less than 12 months to quit smoking?

Evidence from the Cochrane review is most helpful in answering this question and it has been outlined in a previous section of this report. We focus here on recent evidence of effectiveness of interventions in the UK.

Three (+) mixed method studies and one (+) qualitative study suggest that NHS stop smoking services are effective in supporting pregnant women to stop smoking. The NHS stop smoking service interventions for pregnant women described in these articles consist of a combination of behavioural support (delivered in a range of settings and formats) and NRT (for most but not all women). However, the four recent UK studies report a range of outcomes, suggesting that the way in which interventions are delivered and the characteristics of women accessing services may affect outcomes.

Bryce et al 2007 (mixed methods+) describe a service for younger pregnant smokers delivered in a deprived area of the west of Scotland consisting of behavioural support using motivational interviewing (i.e. a tailored intervention delivered largely in the client‟s home) and NRT. The study reports CO validated quit rates of 20% at 3 months and 12.7% at one year. McGowan et al (2008) (mixed methods +) found a self-reported quit rate of 32% at four weeks following delivery of behavioural support (again involving motivational interviewing) largelyin a clinic setting in Glasgow and provision of NRT. Lee et al (2006) (Qualitative semi-structured interviews and some reporting of service data +) describe four week self-report quit rates of between 37-48% achieved by three „beacon‟ stop smoking services for pregnant women in England.

Macaskill et al (mixed methods +) aimed to describe delivery and to report quit rates for all stop smoking services for pregnant women in Scotland. In reviewing service data they found considerable variation in service provision in at least threerespects. First, not all health board areas in Scotland had tailored interventions available for pregnant women within their stop smoking services. At the time ofthe study (2006/07) at least five of Scotland"s 12 health board areas had no smoking cessation in pregnancy advisors in post and pregnant women who wanted support to stop smoking either accessed this through their midwife or GP (usually limited support) or through „generic" stop smoking services – ie stop smoking services for the general population[2]. Secondly, the „reach" (the extent to which NHS stop smoking services were being accessed by pregnant smokers) of services varied. The proportion of all pregnant smokers setting a quit date in Scotland with NHS stop smoking services ranged from 1% in some areas to 7% inothers. Finally, the effectiveness of services varied. The proportion of pregnant smokers who quit at four weeks ranged from 0.4% to 5.4%. Poorer outcomes were achieved by areas that did not have specialist services for pregnant women but instead relied on „generic" stop smoking services to support pregnant women to quit (generic services being those for the general population, rather than those delivered by a specialist adviser trained to support pregnant women to quit). Even in areas with specialist services (of the kind described by Bryce et al and McGowan et al above) four week quit rates varied.

Evidence statement ER1.6
There is evidence from four UK studies that NHS stop smoking services are effective in supporting pregnant women to stop smoking.

Bryce et al 2007 (UK) + mixed methods
McGowan et al 2008 (UK) + mixed methods
Macaskill et al 2008 (UK) + mixed methods
Lee et al 2006 (UK) + qualitative

The NHS stop smoking service interventions for pregnant women described in these articles consist of a combination of behavioural support (delivered in a range of settings and formats) and NRT (for most but not all women). They report varied outcomes but those that included four week post quit date outcomes reported quit rates of between 32 -48%. However, evidence from a national study of smoking cessation services for pregnant women in Scotland found that the reach and effectiveness of services varied significantly between health boards and that some areas offered no tailored (specialist) smoking cessation interventions for pregnant women.

There is very preliminary evidence from two small pilot studies (reported in a single article) that combining exercise with behavioural support to stop smoking may be effective in the NHS (Ussher et al, 2008, cross-sectional +). Pregnant smokers were provided with sessions of supervised exercise combined with behavioural support from a trained smoking in pregnancy specialist and self-help smoking cessation materials. Of the 32 women recruited into the pilots, 25%

[2] A recent survey in the south west of England (unpublished and not included in this review) also found that some PCTs did not have specialist support for pregnant women in place as part of their stop smoking services. In the south west in 2007/08, 3 out of 14 PCTs had no tailored support for pregnant women to stop smoking (Bauld et al, 2008).

(8/32) had quit at eight months gestation (approximately 4-5 months post quit date) and most (75%) of these had achieved the target level of 110 minutes of physical activity at the end of treatment. This combination of exercise and support to stop smoking is now being tested in a definitive trial (the LEAP trial, led by Michael Ussher).

Evidence statement ER1.7
There is very preliminary evidence from two pilot studies, reported in one article, that combining exercise with behavioural support for smoking cessation in pregnancy is feasible and can be effective.

Ussher et al 2008 (UK) + cross sectional

Does the way the intervention is delivered influence effectiveness?

One ++ trial and one + qualitative study provide some insight into how particular forms of delivery can influence the effectiveness of smoking cessation interventions for pregnant women in the UK. Aveyard et al (2006) (++ RCT) aimedto examine whether stage matched interventions (based on the transtheoretical model of behaviour change) were more effective than stage mismatched interventions in supporting pregnant women to quit smoking. They found some evidence that stage-matched interventions were more effective, particularly in improving women"s readiness to quit but concluded that it was difficult to interpret this finding as the stage-based interventions were also more intensive. This study,while useful as it took place in the UK, forms part of a wider body of literature on stage based interventions for smoking cessation in pregnancy covered in the Cochrane review and summarised in the previous section of this report.

Lee et al (2006) (semi-structured interviews and reporting of service data +) explored how six stop smoking services in the UK delivered support to pregnant women. They focused in particular on the characteristics of three beacon services that were perceived to be examples of good practice. They concluded that the following delivery mechanisms contributed to the effectiveness of these services:

- Systematic training of midwives in how to refer pregnant smokers to specialist services
- Offering NRT to almost all clients
- Having an efficient system of providing prescriptions
- Offering flexible home visits
- Providing intensive multi-session behavioural support delivered by specialist staff.

Evidence statement ER1.8
There is limited evidence about whether the form of delivery can affect the effectiveness of smoking cessation interventions for pregnant women.

Aveyard et al 2008 (UK) ++ RCT
Lee et al 2006 (UK) + qualitative

One trial found some evidence that stage-matched interventions for smoking cessation in pregnancy were more effective, particularly in improving women‟s readiness to quit but concluded that it was difficult to interpret this finding as the stage-based interventions were also more intensive. Another qualitative study summarised the delivery characteristics of stop smoking services for pregnant women that were perceived to be successful by key stakeholders. These characteristics included training of midwives in how to refer pregnant smokers to specialist services, offering NRT to almost all clients, having an efficient system of providing prescriptions, offering home visits, and providing intensive multi-session behavioural support delivered by specialist staff.

Does effectiveness depend on the status of the person delivering it?

There were insufficient data to answer this question in the studies identified in this review.

Does the site/setting influence effectiveness?

One mixed methods study (Macaskill et al, 2008 +) identified differences in the way in which stop smoking services for pregnant women were delivered in Scotland, including whether interventions were delivered in the client‟s home or in a clinic setting. They found that most stop smoking services in Scotland offered home visits by trained advisers to pregnant women, with some providing most support in the home. Two areas did not provide home visits – one where interventions were delivered by pharmacists and another where the intervention setting was the ante-natal clinic followed by telephone support. In their analysis of routine service data, Macaskill and colleagues found that, for those home based services for which data on engagement (whether a woman attended the first appointment with a specialist advisor) were available, about 50% of those referredwere engaged compared with 20% for clinic-based services. This provides some evidence that home-based interventions may be more convenient and appealingto women, however, this study was limited to a description of routine service data. This type of observational data means that differences in outcomes could be explained by other factors than the type of service delivery. Further research is required to test whether delivering smoking cessation interventions to pregnant women in the home can increase service uptake.

Evidence statement ER1.9
There is limited evidence that the site or setting of the intervention influences the effectiveness of smoking cessation interventions for pregnant women in the UK

Macaskill et al 2008 (UK) + mixed methods

One study found that most stop smoking services in Scotland offered home visits by trained advisers to pregnant women. An analysis of routine service data, suggested that for those home based services for which data on engagement (whether a woman attended the first appointment with a specialist advisor) were available, about 50% of those referred engaged compared with 20% for clinic-based services.

Does the intensity of the intervention influence effectiveness or duration of effect?

There were insufficient data to answer this question in the studies identified in this review.

How does effectiveness vary according to the age, sex, socio-economic status or ethnicity of the target audience?

There were insufficient data to answer this question in the studies identified in this review. However, at the time this review was commissioned one of the authors (LBauld) identified another relevant review commissioned by the Department of Health (examining outcomes by subgroup, including disadvantaged women, from the trials included in the updated Cochrane review) that could feed into the NICE guidance development process. Key findings from this review, conducted by colleagues from the EPPI centre, will be provided to PHIAC in a separate briefing paper and should help to address this question.

What are the facilitators and barriers to implementation?

Four papers and one research report provide some evidence of the facilitators and barriers to the delivery of smoking cessation interventions for pregnant women in the UK. Three key issues emerge:

- The identification of pregnant smokers
- Referral pathways
- Women"s views on facilitators and barriers

Two cross-sectional studies (Shipton et al, in press ++) (Usmani et al, 2008 +) examine the extent to which relying on self report to identify smoking during pregnant under-estimates the prevalence of smoking and removes opportunities to refer women to stop smoking services. These studies build on earlier evidence about discrepancies between self-report and validated smoking status amongst pregnant women in the UK.

Shipton and colleagues compared the obstetric records (which contain self- reports of smoking status) of a random sample of pregnant women in the west of Scotland with validated smoking status obtained from stored blood samples for these women (which allowed for serum cotinine testing). They found that self- reported smoking records underestimated true smoking rates by 25% (1046/3475 by cotinine validated vs. 839/3575 by selfreport, $z=8.27$, $p<0.001$). They concluded that in Scotland at the time of the research 2,400 pregnant smokers went undetected each year, representing a missed opportunity for referral to smoking cessation services to maximize quit rates.

Usmani et al, in a study conducted at one maternity hospital in Glasgow, compared self-report smoking status with CO validated smoking amongst 2,584

pregnant women. They found that 206 women who self-reported as non smokers had CO levels of >2p.p.m, suggesting they may in fact be smokers. They concluded that 27% of women provided false answers to a question on smoking status at maternity booking. The study described how routine CO monitoring in ante-natal clinics, if implemented consistently, can improve the accurate identification of pregnant smokers and facilitate referral to smoking cessation services.

Evidence statement ER1.10
There is good evidence that women in the UK underreport smoking during pregnancy and that CO monitoring can aid in the identification of pregnant smokers.

Shipton et al in press (UK) ++ cross sectional
Usmani et al 2008 (UK) + cross sectional

Two studies found that around one in four pregnant women in the west of Scotland do not accurately disclose their smoking status when asked during the booking visit with a midwife. One of these studies described how routine CO monitoring in ante-natal clinics, if implemented consistently, can improve theaccurate identification of pregnant smokers and facilitate referral to smoking cessation services.

One mixed method study (Macaskill et al, 2008 +) described how different forms of referral pathways can influence the number of women who set a quit date with stop smoking services and go on to stop smoking. They outlined how two main forms of pathway were in place in smoking cessation services in Scotland. In one health board area, an opt-out referral pathway was in place (as is the case in some areas of England). In that area in the study, almost all women identified as smokers at maternity booking (following routine CO monitoring) were referred on to a smoking cessation in pregnancy specialist. In other areas (the report highlights one particular example) the more common opt-in referral pathway (where women are asked if they would like to be referred) was in place. Again based only on an audit of routine service data, a higher proportion of pregnant smokers were referred to services in areas operating an opt-out referral pathway. This higher rate of referral resulted in a higher proportion of women setting a quit date than in areas with opt-in referral pathways. A similar finding is outlined in McGowan et al (2008 +) However, as noted above, the limitations of these descriptive studies must be noted and further research is required to test the merits of opt-in vs. opt-out referral pathways for smoking cessation in pregnancy.

Evidence statement ER 1.11
There is very preliminary evidence from two observational studies that opt-out referral pathways can increase the number of women who engage with NHS stop smoking services and result in larger numbers of women quitting smoking, when compared with opt-in referral pathways.

Macaskill et al 2008 (UK) + mixed methods
McGowan et al 2008 (UK) + mixed methods

Finally, one cross-sectional survey (Ussher et al, 2006, +) and one qualitative study (Taylor et al, 2007, -) explored pregnant women‟s views of the barriers and facilitators to accessing smoking cessation services in the UK.

Ussher and colleagues conducted an online survey with 443 smokers and recent ex-smokers. They found that the most frequently endorsed barriers (from stated options) to attending a smoking cessation course were “I am afraid I would disappoint myself if I failed”, “I do not tend to seek help for this sort of thing” and “I do not have access to such a course”. Around half of respondents agreed with all the benefits of attending a course, with the most frequent benefits being help with dealing with cravings and praise and encouragement to quit.

Reports of greater interest in receiving help were associated with: the smoker being less likely to believe they could quit without help, a doctor or partner advising cessation, being older and having a lower household income.

Taylor and colleagues, in a small qualitative study conducted as part of PhD research and presented in a conference poster and published abstract only, aimed to explore pregnant women‟s views about stopping smoking and accessing services using the theory of planned behaviour as a framework. They found that women‟s beliefs about control appeared to inhibit use of services. These beliefs related to feeing unable to quit, lack of knowledge about services, difficulty of accessing services, fear of failing and concerns about being stigmatized. The authors concluded that health professionals could improve service uptake by routinely offering services in a sensitive manner, stressing the non-judgmental approach of the services, and highlighting the flexible appointment structure of many NHS stop smoking services for pregnant women, such as home visits.

Evidence statement ER1.12
There is some evidence about the barriers to accessing stop smoking support by pregnant women in the UK.

Ussher et al 2006 (UK) + cross sectional
Taylor et al 2008 (UK) – qualitative

Two studies explored pregnant women‟s views about smoking cessation services. Barriers to accessing services included, among others, feeing unable to quit, lack of knowledge about services, difficulty of accessing services, fear of failing and concerns about being stigmatized.

CONCLUSION

This briefing paper has attempted to summarise the most recent evidence on the effectiveness of smoking cessation interventions during pregnancy. It provides a critical assessment of available international evidence (as outlined in the Cochrane and self-help reviews) and considers how this can be applied to the UK.It has also identified the most recent evidence on the effectiveness of intensive smoking cessation interventions for pregnant women delivered in the NHS.

What this paper suggests is that smoking cessation interventions for pregnant women are effective but important questions remain about the strength of some aspects of this evidence and its applicability to the UK. Questions also remain about how best to deliver evidence-based smoking cessation interventions for pregnant women in the NHS and the extent to which these interventions are already in place throughout the UK.

In concluding this paper we highlight current and planned research that could help to address some of the remaining research questions about the effectiveness of interventions for smoking cessation during pregnancy.

First, we briefly describe two trials that are underway. The first of these is the SNAP (Smoking, Nicotine and Pregnancy) trial led by Tim Coleman from the University of Nottingham (Coleman et al, 2007). This placebo-randomised, controlled trial is comparing the effectiveness of nicotine patches when used for smoking cessation by pregnant women with that of placebo. The double-blind study design is robust and would be considered as “at low risk of bias” according to Cochrane Collaboration criteria. The primary outcome of the study is self- reported, prolonged smoking cessation between a quit date (set between 12 and 24 weeks gestation) and delivery, validated by expired air CO and / or saliva cotinine estimation. The principal secondary outcomes are infants‟ cognitive and behavioural development at 2 years, but a range of other outcomes will also be reported upon, including birth outcomes. Trial findings should be available by autumn 2010 and the target sample size is 1050. Over 950 participants have been enrolled to date and follow up rates are high with 95% primary outcomes being ascertained. Consequently, the findings of this trial should contribute substantially to the body of the evidence on the use of NRT in pregnancy.

A second trial is testing the efficacy of combining behavioural support for smoking cessation with exercise during pregnancy. The LEAP (London Exercise and Pregnant Smokers) trial, led by Michael Ussher from St. Georges University of London. It involves 1,100 pregnant smokers and aims to compare quit rates at the end of pregnancy for individual behavioural support plus a physical activity intervention vs. individual behavioural support alone.

In addition, outline proposals have been submitted to funders in England and Scotland in the past year that have now progressed to the full proposal stage. A full proposal is currently being prepared for a trial of financial incentives forsmoking cessation during pregnancy. If funded this study will help address the question of whether promising evidence from the USA that incentives are an effective intervention for smoking cessation during pregnancy is applicable to the

UK. In addition, an NIHR programme proposal for applied research will be submitted shortly for research that aims to increase the uptake and effectiveness of NHS stop smoking services for pregnant women by determining how and when cessation support is best offered in pregnancy and testing self-help cessation methods. These and other future studies should contribute to knowledge about how best to intervene to support women to stop smoking during pregnancy.

ACKNOWLEGEMENTS

This briefing paper was funded by the National Institute of Health and Clinical Excellence. The views expressed are those of the authors and not necessarily those of NICE. Linda Bauld and Tim Coleman are members of the UK Centre for Tobacco Control Studies, a UKCRC Centre of Public Health Research Excellence. Funding from the British Heart Foundation, Cancer Research UK, the Economic and Social Research Council, the Medical Research Council and the Department of Health, under the auspices of the UK Clinical Research Collaboration, is gratefully acknowledged.

The authors would like to thank Professor Sandy Oliver and the other authors of the 2009 Cochrane review of smoking cessation interventions in pregnancy for providing early access to their manuscript prior to publication on the Cochrane website. Particular thanks is due to Ms. Catherine Chamberlain who provided access to data from the trials in the review and assisted with the new meta-analyses included in this report.

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EVIDENCE TABLES

Individual Studies

Reference	Aims of Research	Sample	Country	Design	Findings	Quality score
Aveyard et al 2006 RCT	To examine whether, as predicted by the Transtheoretical Model of behaviour change (TTM) stage matched interventions are more effective than stage-mismatched interventions in smoking cessation interventions with pregnant women.	Participants were 918 pregnant smokers drawn from 16 of 19 midwifery antenatal services in the West Midlands. Arm one: n= 289 Arm two: n=305 Arm three: n=324	England	RCT – pragmatic three armed trial. Arm one: standard midwifery advice to stop smoking and a self-help leaflet appropriate for women in the preparation stage. Midwives received no additional training except in study protocol. Arm two: TTM based arm. Women seen by midwives wit 2.5 days specialist training, 2 of these days on TTM. Women received a TTM based self-help booklet and received four sessions of behavioural counseling from the midwives (three during pregnancy and one 10 days post partum) Arm three: TTM based arm. Women seen by midwives with 2.5 days training as in arm one. Intervention was the same as arm two, with	Pregnant women in arms two and three (TTM-based) were significantly more likely to move forward in stage of change than women in the control arm. Greater benefit was seen for women in the „preparation" stage at baseline rather than women in the „precontemplation" or „contemplation" stages. This is contrary to the TTM derived hypothesis used in the study. Overall, the TTM-based intervention produced some movement in women"s readiness to quit but it was difficult to interpret this finding as the TTM interventions were also more intensive. The authors concluded that TTM had little validity in explaining smoking cessation behaviour during pregnancy.	++

				the addition of a computer based cessation intervention (TTM related info and feedback) used on the four occasions of the midwive"s visit. Outcomes were movement in stage of change (measured at 30 weeks gestation and 10 days post-partum).		
Bryce et al 2007 Mixed methods	To develop, implement and evaluate a smoking cessation programme („CATCH") for young pregnant smokers delivered by midwives.	79 pregnant women aged 25 and under attending a single hospital maternity unit in a deprived area of the west of Scotland between November 2002 and February 2004.	Scotland	Process and outcome evaluation using mixed methods. Intervention was part of NHS stop smoking services in the area. Intervention involved behavioural support using motivational interviewing by specialist smoking cessation midwives. This was delivered initially in the maternity unit and then in the participants" own homes. Counseling aimed to address wider life circumstances not just smoking. NRT was also provided directly to clients using a patient group directive. However it is not clear from the paper if all 79 participants used NRT.	There were 152 eligible clients within the study period and 79 (52%) joined CATCH. Of these, 18 (23%) were self-reported quitters at 3 months of whom 16 (20%) were CO validated as quitters. At one year, 13 (16%) of clients self-reported quitting and 10 of these (12.7%) were CO validated as quitters. Clients reported a positive experience of the service. In particular, one to one face to face support was described as important as was continuity of care with the same midwife.	+

				Outcome data included self-reported and CO validated quit rates at 3 months and 12 months from quit date. Participants views of the service were collected using semi-structured interviews.		
Lee et al, 2006 Qualitative	To identify examples of good practice in NHS stop smoking services for pregnant women in England	Six NHS stop smoking services that provided specialist support to pregnant women to quit. Three of these services had the highest number of successful four week quitters in 2003/2004 and another three that were nominated by smoking cessation professionals as examples of best practice („beacon" services).	England	Qualitative study involving in-depth interviews with professionals in each service, combined with a review of service documentation and monitoring returns.	Features of the successful „beacon" services included: • Systematic training of midwives in how to refer pregnant smokers to specialist services • Offering NRT to almost all clients • Having an efficient system of providing prescriptions • Offering flexible home visits • Providing intensive multi-session behavioural support delivered by specialist staff. The beacon services all appeared to be monitoring outcomes genuinely and achieved CO-validated quit rates of between 37-48% at four weeks. The other three services, those that had reported the highest monitoring returns, were found to have included unaided quitters in their returns identified from hospital wards. One of the findings of the study was therefore that clearer monitoring guidance was required.	+
Macaskill et al, 2008 Mixed	To describe the nature and extent of smoking	13266 women who reported being current smokers at	Scotland	A descriptive epidemiological study using routinely collected data. This was supplemented by	25% (13266 of 52370) of pregnant women reported being current smokers and 24% (3133/13266) were referred to smoking cessation services in 2005/06. In centres with CO monitoring	+

methods	cessation services for pregnant women in Scotland, and to conduct an audit of service data including establishing a denominator for pregnant smokers and describe the proportion who are: referred to specialist services; engage in one to one counseling; set a quit date and quit four weeks later.	maternity booking in 2005. 16 tobacco control leads in Scotland"s 14 health board areas who participated in telephone interviews, 20 specialist smoking cessation staff and midwives who completed a structured questionnaire and 28 professionals who were interviewed during visits to six case study services,		a qualitative study involving a survey and semi-structured interviews with specialist smoking cessation services. An additional case study element involved in-depth face to face interviews with service providers.	and opt out referral, 58% (1936/3352) were referred to services (clinic based support), 11% (370/3352) set a quit date and 3.5% (116/3352) quit. In areas without CO monitoring and opt-in referral, 43% (1195/2776) were referred to services (home-based support), 15% (409/2776) set a quit date and 4.3% (119/2776) quit by four weeks. Cost of home-based support was greater. Overall in Scotland the proportion of pregnant smokers who set a quit date ranged from 1% in some areas to 7% in others. The proportion of all identified pregnant smokers who quit at four weeks ranged from 0.4% to 5.4%. Nationally, only 3.2% of pregnant smokers identified at maternity booking, living in areas with recognized specialist smoking in pregnancy services or good generic services quit smoking during 2006.	
McGowan et al, 2008 Mixed methods	To develop and evaluate a specialist stop smoking service (known as „Breathe") for pregnant	1936 pregnant smokers referred to Breathe from three maternity hospitals in Glasgow from January to	Scotland	Secondary analysis of routine data on smoking in pregnancy in Scotland and service monitoring data. Description of service structure and intervention content.	The study examined the pathway from pregnant women attending a booking visit through to possible cessation at four weeks. Booking midwives found it difficult to ask all pregnant women about smoking.	+

	smokers	December 2006		Intervention involved routine CO monitoring of all pregnant women and opt out referral of all women with a CO reading of > 7 parts per million. Women were then contacted by telephone by a specialist smoking cessation midwife and invited to attend a clinic-based visit. At the clinic visit they received behavioural support using motivational interviewing and were offered NRT. Subsequent behavioural support was delivered by telephone. Quit rates were recorded at 4 weeks.	Use of routine CO monitoring varied between the three hospitals, with the hospital that used auxiliary nurses to perform this task reporting that 89% of women were tested. • Of the 1936 smokers referred to specialist smoking cessation midwives, 386 (20%) attended for a face to face appointment, 370 (19%) set a quit date and 117 of these (6%, or *32% of those who set a quit date*) had quit at 4 weeks. The study highlights in particular the difficulties of identifying pregnant smokers even when CO monitoring is used and low uptake of face to face clinic based support even with opt-out referral. The authors discuss how more consistent use of CO monitoring could be applied and whether home visits would increase uptake.	
Shipton et al, 2008 Cross sectional	To determine what impact reliance on self-report of smoking during pregnancy has on the accuracy of prevalence figures and access to smoking cessation services for pregnant women	A random sample of (n=3475) of the 21029 pregnant women who opted for second trimester prenatal screening in the west of Scotland between May 2003 and July 2004.	Scotland	Retrospective, cross sectional study. The obstetric records (SMR02) of the sample, which include self-reported smoking status at booking, were matched with stored blood samples for these women, which allow for serum cotinine testing.	Self-reported smoking records underestimated true smoking (as measured by serum cotinine levels) by 25% (1046/3475 by cotinine validated v. 839/3475 by selfreport, $Z=8.27$, $p<0.001$). This suggests that in Scotland 2,400 pregnant smokers go undetected each year, representing a missed opportunity for referral to specialist smoking cessation services to maximize quit rates. Although underreporting was slightly more common in more affluent women, the concentration of smokers in deprived areas meant that twice as many pregnant smokers in the bottom 40% of areas in Scotland (SIMD 4&5) were undetected compared to pregnant smokers in	++

					more affluent areas.	
Taylor et al, 2007 (conference poster only) Qualitative	To identify those beliefs pregnant smokers have about NHS stop smoking services which influence their use of thse services (using a theory of planned behaviour).	14 pregnant smokers or recent quitters recruited at maternity booking 4 mothers who had smoked during their most recent pregnancy recruited through a Sure Start programme 18 health professionals wo deliver smoking cessation support to pregnant women (although poster does not report findings from interviews with health professionals)	England	Qualitative study using semi-structured interviews Topic guide aimed to identify salient beliefs based on the theory of planned behaviour.	Study identified behavioural, normative and control beliefs about using stop smoking services. Found that the theory of planned behaviour is a pertinent model for investigating pregnant smokers use of stop smoking services. Beliefs about control appear to be the most influential in inhibiting use of services. These relate to feeing unable to quit, lack of knowledge about services, difficulty of accessing services, fear of failing and concerns about being stigmatized. Study concluded that health professionals could improve service uptake by: Routinely offering services in a sensitive manner Stressing the non-judgmental approach of the services Highlighting the flexible appointment structure of services such as home visits.	-
Usmani et al, 2008 Cross sectional	To explore the use of CO validation to identify women who are smoking during pregnancy and to assess the validity of a cut	2548 women attending antenatal booking from June 2005 to June 2006 in one maternity hospital in Glasgow	Scotland	Retrospective, cross sectional study. Obstetric records, which include self-reported smoking, were compared with breath CO levels using a cut off of 8 p.p.m.	Just over one fifth (21.4%, 546/2584) self-reported as current smokers. A cut off of 8p.p.m identified only 325 of these 546 individuals as smokers. Sensitivity and specificity analysis found that CO cut off levels of 2 or 3 p.p.m were best for identifying smokers and non smokers. A cut off of 2 p.p.m would have identified 86% (468/546) of current smokers.	+

	off of >8 p.p.m in identifying pregnant smokers				In addition, 206/2002 women who self-reported as non-smokers had CO levels of >2 p.p.m. If all these women were „true" smokers, the real prevalence of smoking in pregnancy would have been 26.5% (752/2548). In other words, 27% of true smokers provided false answers to a question on smoking status at maternity booking.	
Ussher et al, 2006 Cross sectional	To assess perceived barriers to and benefits of attending a smoking cessation course during pregnancy	443 pregnant smokers and recent ex-smokers who took part in an online survey between October 2003 and August 2004	England (although some survey respondents were from other countries, in particular the USA)	Cross-sectional survey Survey was posted on a smoking cessation website and linked to other websites addressing smoking cessation and/or pregnancy. Participants completed the questionnaire on a single occasion. Demographic and smoking related questions were included as well as a 20 item decisional balance measure relating to barriers and benefits of attending a stop smoking course.	491 women responded and 48 were excluded because they had not smoked for one month or more. The most frequently endorsed barriers (from stated options) to attending a smoking cessation course were “I am afraid I would disappoint myself if I failed”, “I do not tend to seek help for this sort of thing” and “I do not have access to such a course”. Around half of respondents agreed with all the benefits of attending a course, with the most frequent benefits being help with dealing with cravings and praise and encouragement to quit. Reports of greater interest in receiving help were associated with: the smoker being less likely to believe they could quit without help, a doctor or partner advising cessation, being older and having a lower household income. There are a number of limitations to the study primarily the fact that respondents were a self-selected group not representative of pregnant smokers and were from countries other than the UK where cessation services for pregnant women may not be as available.	+
Ussher et al, 2008	To assess the feasibility of	32 pregnant smokers who	England	Two cross-sectional pilot studies	Between the two studies, 11.6% (32/277) women who self-reported as smokers at their booking visit	+

Cross sectional	recruiting pregnant women to a trial of physical activity for smoking cessation and to explore adherence to physical activity and women"s perceptions of the intervention	took part on one of two pilot studies combining physical activity with smoking cessation in London. Timing of studies not clear from the article.		Study 1: six weekly sessions of supervised exercise combined with behavioural smoking cessation support from a trained smoking cessation therapist and self-help guides for smoking cessation. Study 2: twelve sessions of supervised exercise for six weeks followed by one supervised session for a further three weeks. combined with behavioural smoking cessation support from a trained smoking cessation therapist and self-help guides for smoking cessation. The exercise component in study 2 was more intensive following feedback from study 1 participants.	were recruited. At eight months gestation, 25% (8/32) had achieved continuous abstinence. These women attended at least 85% of treatment sessions and 75% (6/8) achieved the target level of 110 minutes a week of physical activity at the end of treatment. Women reported that the intervention helped weight management and increased their confidence for quitting along with reducing cigarette cravings. The pilot studies demonstrated that women could be recruited into a future trial of smoking cessation and physical activity in pregnancy (women indicated they would be willing to be randomized to intervention or control groups), and that study is currently underway.	

Reviews

Lumley et al, 2009 Systematic Review	To assess the effects of smoking cessation interventions	Over 20,000 pregnant women who took part in 56 randomised controlled trials	International	A number of bibliographic databases were searched to identify randomized controlled	72 trials were included. There was a significant reduction in smoking in late pregnancy following interventions (RR 0.94, 95%CI 0.93-0.96). However there was significant heterogeneity in the combined data (I^2 > 60%). In the trials with the lowest risk of bias,	++

	during pregnancy as smoking behaviour and perinatal health outcomes	and an additional more than 5000 pregnant women who took part in nine cluster-randomised trials		trials where smoking cessation during pregnancy was the primary aim of the intervention. Trial authors were also contacted to locate additional unpublished data.	the interventions had less effect (RR 0.97, 95%CI 0.94 to 0.99) and lower heterogeneity (I^2 =36%). Eight trials of relapse prevention showed no statistically significant reduction in relapse. Smoking cessation interventions reduced low birthweight (RR 0.83, 95%CI 0.73 to 0.95) and preterm birth (RR 0.86, 95%CI o.74 to 0.98) and there was a 53.1g (95% CI 10.44g to 95.38 g) increase in mean birtweight. No significant differences were found in neonatal intensive care admissions, very low birthweight, stillbirths, perinatal or neonatal mortality (but analyses had limited power).	
Naughton et al, 2008 Systematic Review	To provide a systematic assessment of the efficacy of self-help smoking cessation interventions for pregnant women	Over 6,000 pregnant women who took part in 12 randomised controlled trials of self-help smoking cessation interventions in pregnancy.	International	A number of bibliographic databases were searched to identify randomized controlled trials of self-help smoking cessation interventions for pregnant women..	12 trials were included. These compared usual care (median quit rate 4.9%) with self-help (median quit rate 13.2%) with a pooled OR of 1.83 (95%CI 1.23-2.72). A further meta-analysis examined whether greater intensity intervention materials improved outcomes compared with lower intensity materials but found no significant effect (pooled OR 1.25, 95%CI 0.84-1.94). There was also insufficient evidence to determine whether the tailoring of materials or levels of one to one contact were related to efficacy.	++

APPENDIX 1: EXCLUDED STUDIES

1. Coleman,T.; Thornton,J.; Britton,J.; Lewis,S.; Watts,K.; Coughtrie,M.W.H.; Mannion,C.; Marlow,N.; Godfrey,C. (2007) *Protocol for the Smoking, Nicotine and Pregnancy (SNAP) trial: double-blind, placebo-randomised, controlled trial of nicotine replacement therapy in pregnancy*. BMC Health Services Research, 7, WOS:000243417500001

Reason for exclusion: This is a published protocol for an RCT that is currently underway. The trial is mentioned in the conclusion of this report but the protocol was not suitable for inclusion in the review as it contained no data that could answer any of the review questions.

2. Percival, J (2007) Smoking: tackling the silent epidemic, *Journal of Family Healthcare*, 17, 4, 109-110.

Reasons for exclusion: this is a commentary article. It contained no data that could answer any of the review questions.

APPENDIX 2: EXTRACT OF PREVIOUS NICE REVIEW

The text that follows is a section of:
Bell K, Bauld L, McCullough L, Greaves L, and Jategaonkar K, (2007). *The Effectiveness of National Health Service Intensive Treatments for Smoking Cessation in England: A systematic review.* NICE, London.
http://www.nice.org.uk/page.aspx?o=404427

This section relates to the effectiveness of NHS intensive interventions for smoking cessation for pregnant women. This text formed only one part of the 2006 review.

4.6 How effective have the NHS stop smoking services been in reaching pregnant smokers?

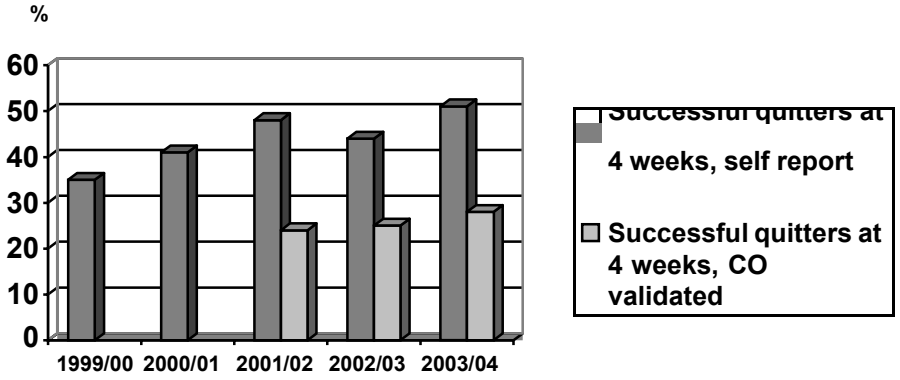
4.6.1 How successful are pregnant women in quitting smoking?

Five annual statistical bulletins (DH 2004; DH 2003; DH 2002; DH 2001a; DH 2001b) (rating 3-) have been published by the Department of Health that evaluate how successful pregnant women have been in quitting smoking through the services. The findings of these statistical bulletins are graphically represented in figure 8. According to the DH statistical bulletins, it appears that the percentage of pregnant women who self-reported as successful quitters at 4 weeks between 1999 and 2004 was between 35-51% (see figure 8). This is significantly lower than the self-reported quit rate at 4 weeks for England as a whole during the same period[3] (see section 4.1). Moreover, the percentage confirmed by CO validation is much smaller[4] – between 24 and 28%. Given that it has been established that self report is not a reliable way of ascertaining current smoking status – especially where pregnant women are concerned (see 4.6.2) – it is likely that overall quit rates at 4 weeks are reasonably low.

[3] Although the proportion of pregnant women who successfully quit smoking at 4 weeks is lower than average, there is evidence that many of these „failed quitters" do cut down on the amount that they smoke even though they do not necessarily give up altogether. This would indicate that although the effectiveness of interventions for pregnant women may be limited in terms of their ability to facilitate smoking cessation, they may, in conjunction with wider social pressures, encourage smoking reduction. Although there is currently no established position on whether smoking reduction in pregnancy reduces the risks to the foetus (Lumley et al. 2004), there is review evidence that limiting or interrupting exposure to smoking and nicotine (especially when considering heavy smokers) has the potential to reduce harm to *both* the woman and the foetus (Greaves et al. 2003). It is therefore probable that despite the low rates of cessation amongst pregnant smokers, their involvement in the NHS stop smoking services has some positive health benefits. Indeed, a more accurate way of measuring the success of interventions might be to measure the level of CO in the system, rather than merely its presence or absence.

[4] A number of the pregnant quitters were not CO validated, so this should not be taken as an accurate reflection of how many pregnant women actually quit smoking at 4 weeks.

Figure 8. Percentage of successful pregnant quitters at 4 weeks, based on self report and CO validation



The evaluation of the NHS stop smoking services by Judge and co-workers (2005) (rating 2++) sheds further light on the actual quitting success of pregnant smokers at 4 weeks. They found a self-reported quit rate of 40.5% - which is in line with the DH statistical bulletins. However, the clients taking part in their study were more consistently CO-validated and the CO-validated success rate for pregnant women was 37.2%.

Although pregnant women are less successful at quitting at 4 weeks through the NHS stop smoking services than other members of the English population, given the unique barriers that pregnant women face in trying to quit (see section 4.6.2), questions can be raised about the utility of using the 4 week benchmark to measure the success of the services. A recent „best practice" review of smoking cessation services for pregnant smokers (Lee et al. 2006) highlights that pregnant smokers require intensive and ongoing support for their cessation attempts and the three „beacon" services discussed all provide between 8-12 weeks of intensive support for pregnant smokers, often with ongoing support as needed throughout the pregnancy and post-partum. Interestingly, although these services were found to offer exemplary support to pregnant smokers, they did not achieve the highest quit rates at 4 weeks. This study therefore demonstrates the problems with using the 4 week quit rates for pregnant women to measure service success.

Findings from local evaluations of NHS stop smoking services for pregnant women are now beginning to be published. A recent study by Bryce and colleagues describes a home-based cessation intervention targeted at pregnant women under the age of 25 in Paisley, Scotland (Bryce et al, 2007, quality rating 2+). The study reports that, during the 16 month period of the evaluation between November 2002 and February 2004, 52% of eligible women set a quit date through the service and CO validated quit rates were 20.3% and 12.7% at 4 and 52 weeks respectively. These rose to 22.8% at four weeks and16.5% at 52 weeks when self-report cases were included.

No. 22

Strength and applicability of evidence

Five 3- bulletins, one 2+ and one 2++ study provide a body of evidence that between 23-51% of pregnant women self-report as successful quitters at 4 weeks through the NHS stop smoking services. However, given the unique challenges that pregnant smokers face, the utility of 4 week quit rates as a measure of service effectiveness is questionable.

As all seven studies took place within smoking cessation services in the UK, they are directly applicable to the target population.

4.6.2 What barriers do women face when trying to quit smoking during pregnancy?

Barriers to quitting

The last fifteen years have witnessed an emphasis on the status of the foetus in medical and legal matters (Greaves et al. 2003). This „supersubjectivity" of the foetus (Bordo 1993) has led to increased recognition of the effects of behaviours such as smoking, drinking and drug taking on the foetus, but has also solidified negative social and legal attitudes towards pregnant smokers (Greaves et al. 2003). Therefore, pregnant smokers are under immense pressure to quit smoking during pregnancy for the sake of their foetus.

The majority of pregnant women who quit smoking (between 9-45%) do so „spontaneously", without any formal intervention (Lawrence et al. 2005; Greaves et al. 2003). These spontaneous quitters tend to be older, less addicted, more highly educated, and less likely to have a partner who smokes (Greaves et al. 2003). Indeed, spontaneous quitters are likely to differ in important (but often un-investigated[5]) ways from those pregnant smokers who take part in smoking cessation programmes, with the former less likely to return to smoking following the birth of their baby (Lawrence et al. 2005).

On the other hand, pregnant smokers who enrol in smoking cessation programmes are likely to wish to merely suspend their smoking behaviour for the duration of their pregnancy as opposed to quit altogether (Lawrence et al. 2005). They are also more likely to be from routine and manual groups and may experience multiple barriers that make long-term smoking cessation difficult.[6] For example, Butler and Bryce (Butler and Bryce 2005) in their study on young pregnant smokers in Renfrewshire, Scotland, found that for some clients, life was a struggle on a daily basis. Many of the pregnant smokers in the study had problems with housing, financial difficulties, relationships and mental health and emotional issues.

[5] An important exception is a series of HEA surveys commissioned between 1992 and 1999 that explore the changes in smoking behaviour of women over the course of their pregnancy (Owen and Penn 1999).

[6] See also Owen and Penn for a discussion of this issue.

No. 23

Background Evidence

Background evidence shows that pregnant smokers face numerous barriers when trying to quit. They are more likely to be from routine and manual groups and may experience more pressing issues such as financial and relationship difficulties, and may also fear being judged for their smoking behaviour.

Barriers to recruitment

Given the stigma that pregnant smokers experience and the broader barriers to quitting that they experience, attracting pregnant women into smoking cessation programmes poses significant challenges for the NHS services. One of the most fundamental barriers to recruitment is the problem of misreport amongst pregnant smokers. Smoking rates amongst pregnant women have usually been measured by self reports through questionnaires or interviews. However, when more objective measures of smoking status have been used, considerable discrepancies emerged (Ford et al. 1997). While rates of misclassification appear to be in the order of 5-10% in the general population, misreport is significantly higher amongst pregnant smokers – one international study has reported a „deception" rate of 38% (Ford et al. 1997).

In the UK context, researchers (Owen and McNeill 2001) have also discussed the problems with using self-report to assess smoking in pregnant women and the findings of their study suggest that smoking in pregnancy may be significantly higher (perhaps more than double the target) than previous government estimates – although there were no significant differences in rates of reporting in pregnancy by occupational class, education or tenure (Graham and Owen 2003). The authors stress that because smoking may be perceived to be particularly undesirable among pregnant women, it is important to validate smoking status within this group using biochemical measures.

Aside from this basic barrier to recruitment, there are also many other challenges that the services face in attracting pregnant smokers. One cessation specialist (Marr 2005) reports that in the Northeast, the largest barriers to recruitment into smoking cessation programmes are poor engagement and the transient nature of the population. Many of the pregnant smokers are teenagers and are unfamiliar with the concept of behaviour change, and boredom seems to be a key factor in continued smoking. Moreover, this population of smokers frequently move or change their phone number which compromises the ability of specialist advisors to recruit them into the programmes.

One qualitative study in Northeast Scotland on the attitudes of primary healthcare professionals" (HCPs) towards smoking cessation provides further information about barriers to recruitment into smoking cessation interventions (Cleland et al. 2006). Pregnant smokers from low SES groups were thought to lack motivation to quit and HCPs did not feel that they had the skills to address these motivational issues – many voicing the concern that they would be seen as „preaching" to the women. HCPs expressed the fear that attempts to provide smoking cessation advice would jeopardise the professional-patient relationship and that ensuring women attended ante- and post-natal care was more important than providing such advice. Interviewees also indicated a preference for referring pregnant smokers on to special cessation services as opposed to tackling this issue themselves. The concerns HCPs voiced in this study seem borne out by other studies that have been conducted with pregnant smokers themselves.

Another study (Lowry et al. 2004) focusing on Sunderland PCT also identified a number of other barriers that pregnant women face when trying to quit smoking during pregnancy, such as unsatisfactory information, lack of enthusiasm or empathy from healthcare professionals and short-term support, all showing as a reluctance to be recruited. To overcome these barriers they engaged in proactive recruiting, with a dedicated worker undertaking home visits, as well as conducting role plays to enhance the ability of health professionals to empathise with their clients.

Other studies also exist that provide useful information about how smoking cessation interventions might be tailored for pregnant smokers. Therefore, although a discussion of „best practice" in smoking cessation services for pregnant smokers was not part of the remit of this review, a summary has been provided of approaches that appear to be working successfully (see table 8). Given that these studies did not directly relate to the key research questions, they have not been evaluated. However, the conclusions they draw seem to offer valuable insights into what interventions are most effective.

No. 24

Background Evidence

Background evidence indicates that there are numerous barriers to recruiting pregnant women into smoking cessation programmes. One of the most fundamental barriers to recruitment is the problem of misreport amongst pregnant smokers – which indicates the importance of biochemically validating smoking status. Health care professionals are also often unwilling to address smoking with their pregnant clients in the fear that it will jeopardise their relationship with the clients.

Table 8. Studies taking place within the NHS stop smoking services that point to innovative and potentially effective interventions for pregnant smokers

Reference	Study population	Content of the intervention	Job title/position of the deliverer	Significant features of an effective deliverer	Site or setting of the intervention	Does the intensity of the intervention influence its effectiveness?	Comments
(Lee 2006)	Pregnant women in 3 beacon NHS smoking cessation services	Provide intensive multi-session treatment delivered by a small number of full time staff and offer NRT to almost all pregnant smokers	Less relevant than whether they provide smoking cessation advice as part of routine or dedicated service	Information not provided.	Flexible home visits	Not explicitly stated but it is implied that more intensive interventions are more effective.	This paper provides a discussion of best practice in smoking cessation services for pregnant smokers.
(O'Gorman 2005) powerpoint presentation	Pregnant smokers in North Birmingham PCT	Multi-session, intensive, one-on-one behavioural support (group sessions do not work) with offer of NRT	Specially trained, dedicated midwives	non-judgemental; full, frank information; individualised attention; encouraging; supportive; builds confidence; works as team; provides positive feedback; empowering; empathetic	Home-based; involving partners and family	Information not directly provided; but the importance of sustained support and follow up is emphasised	Result: Set quit date: 61% of referrals Successfully quit at 4 weeks: 39% CO validated quits: 25%
(Tappin et al. 2005)	Pregnant smokers at two antenatal clinics in Glasgow	Home-based motivational interviewing	Specially trained midwives	Information not provided	Home-based	Not assessed	Results: home-based motivational interviewing did not significantly increase smoking cessation amongst pregnant women. Authors

							conclude that NRT may increase effectiveness of this type of intervention.
(Marr 2005) powerpoint presentation	Pregnant smokers in Sedgefield Durham Dales and Darlington PCTs	Intensive one-on-one behavioural counselling accompanied by intensive telephone contact and offer of NRT	Midwife employed in a dedicated position as a smoking cessation specialist	1) Non-judgemental attitude 2) Engaging 3) Solution-oriented 4) Works in partnership with pregnant woman	Clinic services close to women"s homes and where appropriate, home visits.	Increasing # of phone follow up calls in first week led to significant increase in # of clients staying in their quit programmes & # of 4 week quits.	Paper recommends the benefits of harm reduction as even „failed" quitters experienced a substantial reduction in CO levels.
(Butler and Bryce 2005)	Pregnant smokers, 25 years and under	Intensive one-on-one behavioural counselling with offer of NRT	Midwife employed specifically in a dedicated position as smoking cessation specialist	1) ability to make clients feel positively about ability to give up 2)supportive, friendly & understanding 3) not pressuring clients to quit 4) offering flexible service	Flexible service at time & location of client"s choice but most clients preferred home visits	N/A: intensive intervention took place	Results: 20% quit rate at 3 months 16% quit rate at 12 months
(Lowry et al. 2004)	Health workers delivering Interventions to pregnant women	Role play with actor to increase empathy for pregnant smokers	Health professionals (largely midwives) – although study stresses the importance of training	Support, empathy & enthusiasm rather than a nagging & judgemental attitude	N/A	N/A	Recruitment of pregnant smokers into interventions significantly increased following role play sessions with midwives
(Taylor and Hajek 2001)	All PCTS with smoking cessation services for pregnant women	Maudsley model or the Prochaska and DiClemente Cycle of Change	Intervenors do not have to have a background in midwifery.	Information not provided	Home visits are labour intensive but achieve the best results	More intensive treatments yield better results. Optimum # of contacts between 4-6	Paper presents results of a nation-wide survey of smoking cessation services for pregnant women. Provides useful recommendations re: models of best practice.