Smoking in Pregnancy Mapping Project Report

A live document detailing initiatives within England that support smoking cessation in pregnancy

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Background

In 2011, the Department of Health set an ambition to reduce SATOD rates in England to 11% or less by the end of 2015. This was a bold ambition and the public health community warned that without drastic action to reduce smoking amongst pregnant women it was unlikely to be achieved.

In response, the Public Health Minister challenged tobacco control and maternity care professionals to identify ways in which progress could be made in this area and so the "Smoking in Pregnancy Challenge Group" was established. Since its formation, the Challenge Group has co-chaired a series of a meetings, produced a landmark report, followed by a number of updates, and made a series of recommendations for further action along the following themes:

1. Improved data collection
2. Implementation of NICE guidance on reducing smoking in pregnancy
3. Training
4. Communication between health professionals
5. Communication with the public
6. Research

The Mapping Project was commissioned by Public Health England as part of Recommendation Two: implementation of NICE guidance on reducing smoking in pregnancy. Case studies of services available for pregnant smokers and their families have been identified and are presented in this report alongside an overview of the evidence base which underpins this work. This report and the case studies contained within will be kept up to date on the Smokefree Action Coalition (SFAC) website so that public health professionals and commissioners can refer to the insights they contain when designing their own local programmes, and have relevant contact details for enquiry.

Thirty-seven projects across England were identified [in 2015] as potential case studies and interview requests sent to the project lead or commissioner. Of these, 23 were selected as examples of current practice supporting pregnant smokers and their partners to quit. The case studies have been produced following an in depth interview with the project lead or commissioner and written up according to an agreed template. Each case study can be found on the SFAC website and links to each one are embedded within this document for ease of use.

Examples of practice fall into one or more of these categories:

- Identification of pregnant smokers
- Referral to Stop Smoking Services
- Engagement with Stop Smoking Services
- Supporting quitting
- Relapse prevention
- Awareness raising with pregnant women
- Awareness raising in the wider community
- Awareness raising with health and social care professionals
- Behavioural insights
- Smokefree Homes
- Partners/significant others
- Whole systems approach
- E-cigarettes
- Social media
- Incentives
- Increased use of CO monitors

How to get the most from this document

The report provides an opportunity to see what services exist, where, how they have been created and in some cases, how they are doing based on evaluation. For local areas looking at developing or improving their current provision for smoking cessation in pregnancy, the document outlines details of existing services that utilise specific approaches and evidence. Cross links are integrated to help navigate the content and signpost specifically to services of relevance to the reader.

The Case studies include a variety of opportunities and barriers encountered in developing services for pregnancy and in a few instances key outcomes achieved are reported.

In addition, an update to some of the Research overview relevant to service provision is provided where topics have had significant evidence updates since the latest NICE guidance (2010).

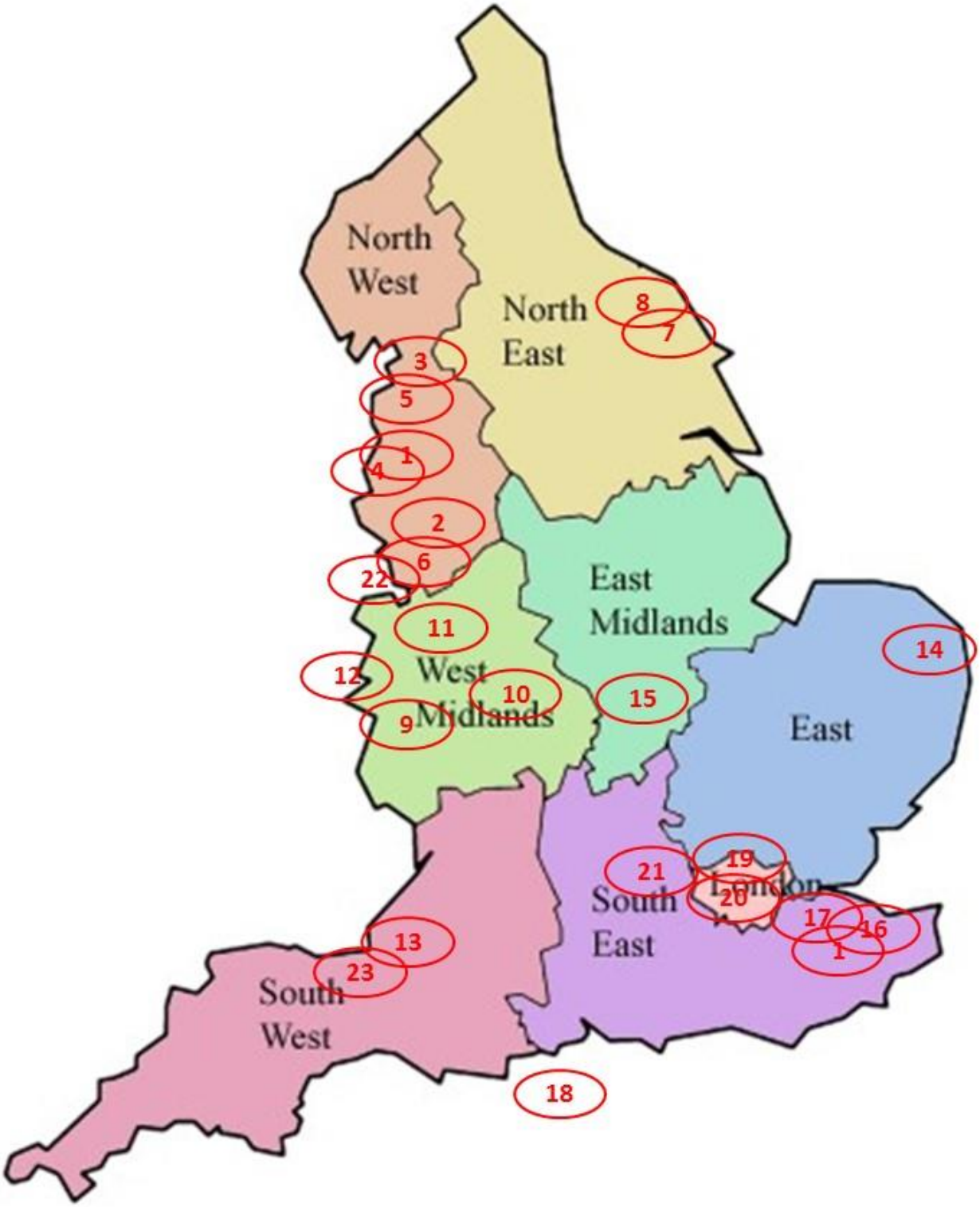
An update to the Smoking in Pregnancy Challenge Group report, published towards the end of 2015 notes that "despite the growing commitment of health professionals and local authorities to tackling (the smoking in pregnancy) agenda, the funding challenges faced by the whole system and particularly public health create uncertainties about whether this progress can be maintained." The report urges the Government to consider the implications of cuts to public health budgets in sustaining the important work of helping pregnant women to quit smoking.

The case studies identified as part of this project provide evidence that cuts are affecting service provision at a local level. Indeed, a number of the originally identified services had already been disbanded by the time we came to interview them. While the stated government ambition to reduce smoking in pregnancy prevalence to 11% by the end of 2015 will have been reached in some areas, it is very far from being achieved in others. The impact of smoking in pregnancy on both the mother to be and their babies continues to be a critical issue and one which must remain at the top of the tobacco control agenda.

Looking to 2016 and beyond, there are a number of opportunities to continue to keep smoking in pregnancy high on the agenda and to engage with service providers, commissioners and local authorities:

- The new Tobacco Control Plan for England being drawn up in 2016.
- The government's commitment to reduce the incidence of stillbirth. 2014 saw NHS England start working with key stakeholder groups to create a Care Bundle to reduce stillbirth in England as part of the *Saving Babies' Lives* programme. Reducing smoking in pregnancy is a core element within this work. The Care Bundle will provide fresh impetus when it is launched nationally in 2016.
- The Secretary of State's ambition announcement in November 2015 to reduce the rate of stillbirths, neonatal, maternal deaths and intrapartum brain injuries in babies in England by 20% by 2020 and by 50% by 2030, to help make England one of the safest places in the world to have a baby.
- The financial constraints within public health mean it is critical for services to work together and for initiatives to utilise the evidence base and robust outcome data for ensuring services are effective and value for money. This document can support local areas in sharing good practice and building on what is known to work and fail. We urge any new services created in 2016 to complete the proforma on the SFAC website so that we can keep this document up to date.

Map of case studies



Case studies

	Initiative	Location	Lead organisation	Categories included	Evaluated
1.	Baby Be Smoke Free	Blackpool, Shepway and Thanet	Tommy's the baby charity	○ Behavioural insights ○ Whole systems approach ○ Supporting quitting ○ Awareness raising with pregnant women	Not yet. Scheduled 2016-17 by University of Stirling.
2.	Supporting a smoke free pregnancy scheme	North West region	Tobacco Free Futures	○ Financial incentives ○ Stop smoking services ○ Partners and significant others ○ Smoke free home ○ Relapse prevention	Yes
3.	The north Lancashire incentive in pregnancy scheme	North Lancashire	North Lancashire stop smoking service	○ Stop smoking services ○ Financial incentives ○ Supporting quitting ○ Relapse prevention ○ Partners/significant others	Yes as part of the Tobacco Free Futures incentive scheme, but no yet at a specific local level.
4.	Multi-strand universal approach to reducing smoking in pregnancy	Blackpool	Public Health team	○ Raising awareness among pregnant women ○ Raising awareness among health professionals ○ Raising awareness across wider workforce ○ CO monitoring ○ Behavioural insights ○ Whole systems approach	No other than CO monitoring at booking, and as part of the Baby Be Smoke Free work (see above).
5.	Reducing smoking in pregnancy – a comprehensive plan for Lancashire	Lancashire (excluding Blackburn with Darwen and Blackpool)	Public Health team	○ Stop smoking services ○ Financial incentives ○ Raising awareness among health professionals ○ Raising awareness across wider workforce ○ CO monitoring ○ Behavioural insights ○ Whole systems approach	Yes, ongoing
6.	Bump the Habit	Bolton	Public Health Dept	○ Referral to Stop Smoking Services ○ Awareness raising with health professionals ○ Awareness raising with pregnant women ○ Social media	No other than SATOD monitoring

7.	babyClear	Hartlepool and Stockton, North tees	Public Health Team	○ Identification of pregnant smokers ○ Referral and engagement with stop smoking services ○ CO monitoring ○ Awareness raising with health professionals ○ NRT	
8.	babyClear	County Durham and Darlington		○ Identification of pregnant smokers ○ CO monitoring ○ Referral to stop smoking services ○ Whole systems approach	Yes, independently by Newcastle University. Awaiting results [Jan15]
9.	Bloomin'	Dudley, West Midlands	Public Health	○ Behavioural insights ○ Referral and engagement with Stop Smoking Services ○ Social media ○ CO monitoring	No
10.	Making tackling smoking in pregnancy a priority for all	Warwickshire	Public Health Team	○ Whole systems approach ○ CO monitoring ○ Referral to stop smoking services ○ Partners and significant others ○ Awareness raising with wider community	No
11.	West Midlands Smoking in Pregnancy Commissioning Pack	West Midlands CCGs	Public Health Team	○ Awareness raising among wider community ○ Supporting quitting	Yes
12.	Correct identification of pregnant smokers during maternity care	Telford and Wrekin	Health Improvement	○ Identification of pregnant smokers ○ CO monitoring ○ Referral to Stop smoking services	No
13.	Health in Pregnancy service	Bath and NE Somerset	Public Health	○ Supporting quitting ○ Smoke free homes ○ CO monitoring	Yes, available on request
14.	babyClear	Yarmouth	East Coast Community Healthcare CIC	○ CO monitoring ○ Referral and engagement with Stop Smoking Service ○ Supporting quitting	Yes, available on request
15.	E-Cigarette example	Leicester City	Stop Smoking Service	○ Referral and engagement with stop smoking services ○ NRT ○ E-Cig ○ Supporting quitting	Numbers too low at present

16.	babyClear	Kent	Public Health	○ Raise awareness among health professionals ○ CO monitoring ○ Supporting quitting ○ Referral to stop smoking services	Planned as part of the Baby Be Smoke Free project
17.	Reducing smoking in pregnancy	Medway	NHS Medway	○ Referral and engagement with stop smoking services ○ CO monitoring ○ Supporting quitting	Not yet as early days
18.	Smoking in Pregnancy	Isle of Wight	Public Health	○ Insights work ○ CO monitoring ○ Supporting quitting ○ Awareness raising with women ○ Awareness raising with wider community ○ NRT ○ Smoke free homes	No
19.	NCSCT pregnancy and postpartum specialty module	national	NCSCT	○ Training ○ Raising awareness among health professionals	No
20.	NCSCT National Referral System	England	NCSCT	○ Training ○ Raising awareness among health professionals	Yes
21.	Smoking in Pregnancy	Buckinghamshire	Public Health	○ CO monitoring ○ Awareness raising among health professionals ○ Referral to Stop Smoking Services	Yes
22.	The 'MeTime' Integrated Smoking in Pregnancy Service	The Wirral, Merseyside	Solutions for Health	○ Raising awareness among pregnant women ○ NRT ○ Supporting quitting ○ CO monitoring ○ Significant others ○ Raising awareness across wider workforce	Yes
23.	Mums2Be Smokefree	Somerset	Solutions for Health	○ Financial incentives ○ Behavioural support ○ NRT ○ Supporting quitting ○ CO monitoring ○ Referral to Stop Smoking Services ○ Supporting quitting ○ Significant others	Yes

Research overview

There is a substantial body of research evidence relating to smoking cessation in pregnancy. Services in the UK, particularly stop smoking services, deliver interventions based on this evidence. Guidance for these services and for maternity care and other services and professionals that support women during pregnancy was published by NICE guidance (NICE, 2010). Since this guidance was published the evidence-base has grown, and here we summarise some of the most salient studies, drawing in particular on systematic review evidence. Interested readers should also consult briefings prepared by the National Centre for Smoking Cessation and Training in England, particularly their Briefing for Midwifery Staff (NSCST, 2014).

Given the case studies included in this report, we focus here on key parts of the evidence-base rather than providing a comprehensive overview. The key topics of focus are: the identification of pregnant smokers, psycho-social interventions, financial incentives and pharmacological interventions. Not all categories of support are covered here e.g. self-help and digital interventions, but key references for these are included in the 'further reading' section of this report's Bibliography.

Identification of pregnant smokers

Identifying pregnant smokers should be straightforward in routine clinical practice, but is not always easy. Social and clinical pressures not to smoke during pregnancy make it difficult for some women to say that they smoke. This in turn makes it difficult to ensure they are offered appropriate support. This summary aims to describe the current evidence for optimising the identification of pregnant smokers using findings from reports that have previously informed national guidance and recent studies with direct relevance to the UK context.

This descriptive summary of the literature on identification of pregnant smokers builds on the findings from the key evidence reviews and expert reports that informed the 2010 NICE and considers research findings from five UK studies carried out since publication of the guidance: a pilot study that included a comparison of different methods of identifying pregnant smokers (Bauld 2012), a national survey of NHS SSS for pregnant women in England (Fahy 2014), and three mixed methods studies investigating various aspects of smoking cessation in pregnancy (Stenhouse 2014, Sloan 2015, Bauld 2015).

Key findings on identification and referral

Building on earlier evidence about discrepancies between self-report and validated smoking status amongst pregnant women in the UK, NICE concluded in 2010 that there was good evidence from two cross-sectional studies (Shipton 2010, Usmani 2008) that women in the UK under-report smoking during pregnancy and that CO monitoring can improve the identification of pregnant smokers. Shipton *et al* found that around one in four pregnant women in the West of Scotland did not accurately disclose their smoking status when asked during the booking visit with a midwife; Usmani *et al* described how routine CO monitoring in antenatal clinics, if implemented consistently, could improve the accurate identification of pregnant smokers and facilitate referral to smoking cessation services. At this time, NICE further recommended action be taken by midwives and others in the public, community and voluntary sectors to improve the process for identification of pregnant women who smoke through discussion and use of a CO screening test to assess exposure to tobacco smoke or other forms of CO. It was recommended that all pregnant women be asked about their smoking status at maternity booking, at regular intervals throughout their pregnancy, and postpartum. The optimum cut-off point for determining smoking status, however, remained unclear with the national guidance suggesting that a cut-off up to 7ppm be used in pregnancy. Some three years after publication of the guidance implementation of routine CO screening at maternity booking remained patchy

throughout the country despite investment in the development of resources to make it easier for maternity services to introduce and conduct CO testing. Some midwives still expressed concerns about the implications of CO screening at the booking visit despite few problems reported in areas where routine screening for all pregnant women had been introduced.

In 2012 a pragmatic pilot study involving 3712 pregnant women from two NHS areas in the West Midlands of England (Bauld 2012) concluded that implementation of routine CO monitoring via maternity services did not create too much additional work for midwives and that almost all women invited were willing to undertake a CO breath test. CO monitoring was perceived as helpful by giving midwives a tool to facilitate dialogue with women around smoking and highlighting women most at risk. The study also identified however that not all participating midwives were able (e.g. due to insufficient time, training or tools) or willing to change their practice to include routine CO monitoring, and that midwifery assistants could play a valuable role in delivering routine CO testing. The pilot concluded that routine CO monitoring introduced as part of the referral pathway should involve a cut-off of 4ppm to identify smoking in pregnancy. This revised cut off was determined by comparing self-report, CO screening results and cotinine testing and was subsequently confirmed by an unrelated study in the USA.

In 2014 results from an online survey of NHS stop smoking services for pregnant women in England (Fahy 2014) further suggested that barriers to implementation of routine CO testing still existed with less than half of these services using this method to identify pregnant smokers attending antenatal care. Stenhouse and colleagues (Stenhouse 2014) provided some insight to these barriers via a mixed methods study to evaluate a pilot CO breath test screening intervention in two areas in Plymouth. The study which included focus group interviews with 23 midwives, a postal survey to 258 women who attended an antenatal booking appointment, and an online national survey to obtain the views and experiences of pregnant women and new mothers found that in general there was a high degree of acceptability for the intervention. Both midwives and women were generally supportive of CO screening being offered to all pregnant women. Three important factors emerged however as key to the success of this process: clear communication for both women and midwives regarding the screening process and subsequent smoking cessation outcomes; training on inviting women to be screened and use of the monitor; and trust between women and their midwives. Some women felt that the CO screening was being used just to check whether or not they were smokers and some midwives also worried about the possible negative effects the CO screening may have on their relationships with women.

Findings from the qualitative elements of two recently completed mixed methods studies in the UK (Sloan 2015, Bauld 2015) again confirmed that women were generally very accepting of CO testing especially when it met their prior expectations and was perceived as a routine component of their antenatal care. In particular, women reported that visual feedback from the CO monitoring helped them to understand the potential harm of smoking (those screened often described shock and feeling “bad” or “embarrassed” at seeing the result), and when repeatedly used aided both their self-esteem and motivation to quit. Women’s partners, family and friends also recognised CO monitoring as a helpful, motivational tool although some concerns were raised about the interpretation of readings. Similarly, most healthcare professionals perceived the use of breath monitors with pregnant smokers as a useful procedure that helped to boost motivation around quitting and highlight risks from smoking in pregnancy. Some healthcare professionals however remained concerned about CO monitoring jeopardising their relationships with women and thus their willingness to continue with maternity care support (Bauld 2015).

Following CO screening the NICE guidance also recommends that an opt out referral pathway is introduced for pregnant women, putting in place an automatic referral to stop smoking services. This approach has now been tested in a very recent study in Nottinghamshire that has been presented at conferences and is in press in a journal (Campbell et al, 2016). It found that, overall, good implementation of the pathway doubled the proportion of pregnant women that were referred and also that subsequently stopped smoking. Full findings should be in the public domain shortly.

Summary

There is good evidence that implementation of CO screening within routine maternity care is acceptable to both woman and healthcare professionals, and is primarily perceived as helpful in facilitating both discussion of smoking in pregnancy and motivation to quit. Some barriers to full implementation of CO screening for pregnant women still exist within services, however, particularly in relation to communication, training, and maintenance of trust and supportive relationships with women. New findings also suggest that an opt out referral pathway, when implemented fully, can also increase the number of pregnant women who stop smoking.

Overall, studies point to acceptance of CO screening and opt out referral by both women and healthcare professionals and recognition of benefits. Some barriers still remain related primarily to service factors but these can be overcome. Guidance/training (rather than more research) is needed on communication about CO testing and opt out referral, maintaining relationships with women and interpretation of readings that draws on learning and experiences from services where CO screening has been successfully adopted. If the proportion of women smoking during pregnancy is to reduce, it is critical that guidance on identifying pregnant smokers, CO screening and opt out referral is implemented consistently in every local area.

Case studies which have a focus on the identification of pregnant women:

- babyClear, Hartlepool
- babyClear, County Durham and Darlington
- Correct identification of pregnant smokers, Telford and Wrekin

Psycho-social interventions

Behavioural interventions for smoking cessation are sometimes known as psycho-social interventions. These different types of support fall into a number of categories but exclude approaches that include medication. The best source of evidence about these types of interventions in pregnancy, bringing together all relevant studies, is the 2013 Cochrane review on this topic conducted by Catherine Chamberlain and colleagues (Chamberlain et al, 2013). This review is based on four previous Cochrane reviews of smoking cessation in pregnancy. The previous reviews also included medication but for the first time, the most recent one focused on psycho-social and medication interventions separately. Here we summarise the psycho-social review first. It looked for all relevant studies on behavioural approaches to supporting pregnant women to stop and identified six categories of interventions. These were: counselling, including approaches such as motivational interviewing, cognitive behavioural therapy and psychotherapy, among others; health education which was primarily about information giving on the risks of smoking in pregnancy and the benefits of cessation; feedback interventions, which involved giving information about fetal health status or exposures like CO testing, ultra sound monitoring or urine cotinine testing and then providing the mother with the results; incentives which were financial or in kind and which we also describe in more detail below; social support, mostly involving peer or partner support to stop smoking; and other interventions such as exercise during pregnancy. The findings of the Cochrane review are highly detailed and interested readers should consult the full version. In Box 1 below we include the main results as described in the Cochrane report.

Box 1: Findings from the Cochrane review of psycho-social interventions

In separate comparisons, counselling interventions demonstrated a significant effect compared with usual care (27 studies; average risk ratio (RR) 1.44, 95% confidence interval (CI) 1.19 to 1.75), and a borderline effect compared with less intensive interventions (16 studies; average RR 1.35, 95% CI 1.00 to 1.82). However, a significant effect was only seen in subsets where counselling was provided in conjunction with other strategies. It was unclear whether any type of counselling strategy is more effective than others (one study; RR 1.15, 95% CI 0.86 to 1.53). In studies comparing counselling and usual care (the largest comparison), it was unclear whether interventions prevented smoking relapse among women who had stopped smoking spontaneously in early pregnancy (eight studies; average RR 1.06, 95% CI 0.93 to 1.21). However, a clear effect was seen in smoking abstinence at zero to five months postpartum (10 studies; average RR 1.76, 95% CI 1.05 to 2.95), a borderline effect at six to 11 months (six studies; average RR 1.33, 95% CI 1.00 to 1.77), and a significant effect at 12 to 17 months (two studies, average RR 2.20, 95% CI 1.23 to 3.96), but not in the longer term. In other comparisons, the effect was not significantly different from the null effect for most secondary outcomes, but sample sizes were small.

Incentive-based interventions had the largest effect size compared with a less intensive intervention (one study; RR 3.64, 95% CI 1.84 to 7.23) and an alternative intervention (one study; RR 4.05, 95% CI 1.48 to 11.11).

Feedback interventions demonstrated a significant effect only when compared with usual care and provided in conjunction with other strategies, such as counselling (two studies; average RR 4.39, 95% CI 1.89 to 10.21), but the effect was unclear when compared with a less intensive intervention (two studies; average RR 1.19, 95% CI 0.45 to 3.12).

The effect of health education was unclear when compared with usual care (three studies; average RR 1.51, 95% CI 0.64 to 3.59) or less intensive interventions (two studies; average RR 1.50, 95% CI 0.97 to 2.31).

Social support interventions appeared effective when provided by peers (five studies; average RR 1.49, 95% CI 1.01 to 2.19), but the effect was unclear in a single trial of support provided by partners.

The effects were mixed where the smoking interventions were provided as part of broader interventions to improve maternal health, rather than targeted smoking cessation interventions.

Subgroup analyses on primary outcome for all studies showed the intensity of interventions and comparisons has increased over time, with higher intensity interventions more likely to have higher intensity comparisons. While there was no significant difference, trials where the comparison group received usual care had the largest pooled effect size (37 studies; average RR 1.34, 95% CI 1.25 to 1.44), with lower effect sizes when the comparison group received less intensive interventions (30 studies; average RR 1.20, 95% CI 1.08 to 1.31), or alternative interventions (two studies; average RR 1.26, 95% CI 0.98 to 1.53). More recent studies included in this update had a lower effect size (20 studies; average RR 1.26, 95% CI 1.00 to 1.59), I^2= 3%, compared to those in the previous version of the review (50 studies; average RR 1.50, 95% CI 1.30 to 1.73). There were similar effect sizes in trials with biochemically validated smoking abstinence (49 studies; average RR 1.43, 95% CI 1.22 to 1.67) and those with self-reported abstinence (20 studies; average RR 1.48, 95% CI 1.17 to 1.87). There was no significant difference between trials implemented by researchers (efficacy studies), and those implemented by routine pregnancy staff (effectiveness studies), however the effect was unclear in three dissemination trials of counselling interventions where the focus on the intervention was at an organisational level (average RR 0.96, 95% CI 0.37 to 2.50). The pooled effects were similar in interventions provided for women with predominantly low socio-economic status (44 studies; average RR 1.41, 95% CI 1.19 to 1.66), compared to other women (26 studies; average RR 1.47, 95% CI 1.21 to 1.79); though the effect was unclear in interventions among women from ethnic minority groups (five studies; average RR 1.08, 95% CI 0.83 to 1.40) and aboriginal women (two studies; average RR 0.40, 95% CI 0.06 to 2.67). Importantly, pooled results demonstrated that women who received psychosocial interventions had an 18% reduction in preterm births (14 studies; average RR 0.82, 95% CI 0.70 to 0.96), and infants born with low birthweight (14 studies; average RR 0.82, 95% CI 0.71 to 0.94). There did not appear to be any adverse effects from the psychosocial interventions, and three studies measured an improvement in women's psychological wellbeing.

Summary

The Cochrane review of psycho-social interventions for smoking cessation in pregnancy provides a comprehensive overview of what is currently known about these types of approaches. The studies identified by the review included 86 randomised trials involving over 29,000 women. It is important to point out that many studies did not reach the inclusion criteria for the review primarily because they were not trials but rather used other study designs. However, overall the authors concluded that these types of interventions can increase the proportion of women who stop smoking in pregnancy (particularly in late pregnancy as most studies measured outcomes at this point) and also yielded measureable health benefits including reducing pre-term births and the incidence of low birthweight.

Case studies which include psychosocial interventions:

- Mum2Be Smokefree

Financial Incentives

A number of trials of financial incentives were included in the Cochrane review, but more up to date evidence has been published since then. For this reason and because of UK interest in this topic we provide a fairly detailed summary of existing evidence in more detail here.

To begin, it is worth noting that financial incentives to promote smoking cessation are controversial. Although policymakers and health professionals recognise the dangers of smoking in pregnancy, critics remain unsure about using financial incentives. This summary aims to describe the current evidence on financial incentives for smoking cessation in pregnancy using findings from systematic reviews, expert reports that have previously informed national guidance, and recent studies that are directly relevant to the UK context.

The results from the included literature are summarised for *smoking cessation, acceptability, cost-effectiveness, and adverse effects/unintended consequences*. Details of other outcomes can be found in the reviews and individual studies.

Smoking cessation: Based on findings from one Cochrane systematic review that included four US-based trials of financial incentives (Lumley 2009), NICE concluded in 2010 that these trials showed incentives were an effective way to encourage pregnant women to quit smoking but that UK-specific evidence was needed. In 2013 the most recent and fifth update of the Cochrane systematic review of *Psychosocial interventions for supporting women to stop smoking in pregnancy* (Chamberlain 2013) combined results from 77 trials, including four trials of incentives and concluded that the intervention that supported the most women to stop smoking in pregnancy appeared to be providing incentives. Published *after* completion of the Chamberlain review two RCTs of financial incentives (Higgins 2014, Tappin 2015), one of which is the largest UK trial of incentives to date, similarly supported the efficacy of financial incentives for increasing smoking cessation rates. The first of these trials included 118 pregnant smokers in Vermont, USA, and showed that provision of shopping voucher incentives dependent on smoking status increased cessation in both early and late pregnancy but not in the postpartum period. The UK trial (Tappin 2015) conducted in Glasgow, UK, compared routine care (n=306) for pregnant smokers - support from a specialist pregnancy Stop Smoking Service plus NRT - with routine care plus financial incentives (n=306). Results showed that two and a half times more women in the incentives group stopped smoking than in the control group (22.5% versus 8.6%); and more than two thirds of these women self-reported as abstinent at least six months postnatally (68% versus 46%). These results support the findings of previous smaller studies and are larger than that seen in most behavioural (Chamberlain 2013) or pharmaceutical (Coleman 2012) trials of smoking cessation during pregnancy. Incorporating these two recent RCTs, the third update of the Cochrane systematic review of *Incentives for smoking cessation* (Cahill 2015), focusing on all smokers not just those that are pregnant, combined results from eight trials conducted with pregnant women and showed that women in the incentives groups were more likely to quit than those in the control groups, both at end of pregnancy, and at the longest validated follow-up (up to 24 weeks after birth).

Two recently published studies are also included here as they were conducted in the UK and are directly relevant to the UK context - a single arm intervention study (Ierfino 2015) and a mixed methods study on *Benefits of Incentives for Breastfeeding and Smoking cessation in pregnancy (BIBS)* (Morgan 2015). In the intervention study, enrolment on an incentive scheme in an English cohort of pregnant smokers was associated with prolonged cessation rates (8% were quit at delivery and 4% at 6 months postpartum). The quit rates achieved on the incentive scheme were higher than those achieved in a comparable period in the previous year without the use of incentives. Evidence from the systematic review component of the BIBS study, that included 21 studies about incentives for smoking cessation for pregnant women, indicated that shopping vouchers based on biochemically validated smoking cessation in pregnancy were effective and that these effects continued until three months postpartum (meta-analysis of four trials).

Acceptability: A UK public opinion survey conducted as part of BIBS (Morgan 2015) showed that opinions on acceptability of incentives for smoking cessation in pregnancy and after birth were mixed. Disagreement was more likely among women than men and those with lower levels of education, and support higher amongst those of child-bearing age. Quitting was reported to be more likely if services provided incentives of £40 or more, and payments were acceptable to women and health professionals if a) they worked, and b) were no more than £80 per month up to a maximum of £800 for quitting. The qualitative elements of the Tappin study (Tappin 2015) also found that incentives were acceptable to women and health professionals. No formal evaluation of acceptability was carried out in the single arm intervention study in Chesterfield (Ierfino 2015) however it was noted that initial reservations expressed by managers and clinicians about the scheme were markedly reduced when information on potential effectiveness was presented.

Cost effectiveness: Only one study (Tappin 2015) incorporated a formal cost effectiveness analyses that indicated incentives appeared cost effective with an estimated short term incremental cost of £1127 per extra quitter and a longer term cost of £482 for each quality-adjusted life year gained. This is in line with the results of a previous NICE economic analysis (Taylor 2009) of the interventions included in the 2009 Lumley Cochrane review (Lumley 2009) that concluded that financial incentive interventions produced the highest net cost benefit of all of the intervention strategies examined and estimated the benefits to be in excess of £500 million per annum in the UK.

Adverse effects/unintended consequences*:* Only the two recent UK based studies reported on unintended consequences of incentives. In both these studies there was some evidence of 'gaming' i.e. false reporting of smoking status to receive incentives. This was seen among 4% of women enrolled in one scheme (Ierfino 2015), and amongst a fifth of women in the other with a similar level (20%) of false reporting of smoking status observed amongst those receiving incentives and those that did not (Tappin 2015). No women were reported to have pretended to be smokers to enter the incentives scheme (Ierfino 2015).

Summary

There is good evidence from systematic review findings (Chamberlain 2013, Cahill 2015, Morgan 2015) on the effectiveness of financial incentives for promoting smoking cessation in pregnancy. Financial incentive schemes were found to be the most promising additional intervention when compared with counselling, feedback, health education and peer support (Chamberlain 2013), improve cessation rates, both at the of pregnancy, and postpartum (Cahill 2015), and be effective when issued based on biochemically validated smoking cessation in pregnancy and until three months postpartum. Furthermore 'if reward for cessation was effective it would be acceptable to the public and professionals' (Morgan 2015).

Recent studies have provided important new evidence to suggest that financial incentives, when combined with additional support to help women stop smoking in pregnancy, can increase quit rates whilst remaining cost-effective but the public support for these types of interventions remains limited. Whilst this evidence resonates with the 2010 NICE recommendation for a definitive trial in the UK during pregnancy (NICE 2010), gaps remain. To address this research question and provide confidence to the NHS and the public that incentives work, a well conducted and definitive UK multi-centre RCT is needed to assess if financial incentives are cost effective and should be rolled out across the UK. Future research also needs to focus on examining whether these promising findings can be extended to centres with a high proportion of black and ethnic minorities, with both affluent and deprived neighbourhoods, with generic as well as specialist Stop Smoking Services, and with geographical populations that have potentially different attitudes to financial incentives. These contextual factors, 'social, political and/or organisational setting in which an intervention was evaluated, or in which it is to be implemented' need to be examined to clarify transferability to other places (Rychetnik 2002, Burchett 2011).

Case studies which include financial incentives:

- Supporting a smoke free pregnancy scheme, North West

- North Lancashire incentives in pregnancy scheme, North Lancashire
- Reducing smoking in pregnancy, Lancashire
- Mum2Be Smokefree

Pharmacological Interventions

In addition to psycho-social (or behavioural) interventions for smoking cessation in pregnancy, women can be offered pharmacological support, commonly referred to as stop smoking medication. Although three forms of licensed medications can be prescribed to smokers in the UK (NRT, varenicline and bupropion) only one of these is available on prescription to pregnant women – NRT. This license became available in 2005 and was extended to pregnancy because smoking is so harmful to the developing fetus that it was deemed far safer to provide nicotine dependent women with another alternative in order to assist with smoking cessation. The international evidence on pharmacological interventions was very recently examined in a partner Cochrane review to the Chamberlain et al study mentioned above. This review was led by Professor Tim Coleman from the University of Nottingham.

Just six trials met the inclusion criteria for the review and these involved 1,745 pregnant women. No trials of varenicline or bupropion were found although at least one trial is underway. The main results, as set out in the main review text, are included in Box 2.

Box 2: **Findings from the Cochrane review of pharmacological interventions**

All included studies investigated the efficacy of different forms of NRT; no trials investigated other smoking cessation pharmacotherapies. All included studies investigated the efficacy of NRT provided with behavioural support and either compared this with behavioural support alone or support plus a placebo; therefore, studies measured the effect of NRT provided as an adjunct to behavioural support.

Six trials of NRT enrolling 1745 pregnant smokers were included; we found no trials of varenicline or bupropion. No statistically significant difference was seen for smoking cessation in later pregnancy after using NRT as compared to control (risk ratio (RR) 1.33, 95% confidence interval (CI) 0.93 to 1.91, six studies, 1745 women). Subgroup analysis comparing placebo-RCTs with those which did not use placebos found that efficacy estimates for cessation varied with trial design (placebo RCTs, RR 1.20, 95% CI 0.93 to 1.56, four studies, 1524 women; non-placebo RCTs, RR 7.81, 95% CI 1.51 to 40.35, two studies, 221 women; P value for random-effects subgroup interaction test = 0.03). There were no statistically significant differences in rates of miscarriage, stillbirth, premature birth, birthweight, low birthweight, admissions to neonatal intensive care or neonatal death between NRT or control groups.

No studies reported any long-term outcomes following NRT use in pregnancy.

What the Cochrane review showed is that only NRT as a stop smoking medication has been tested in pregnancy in trials. The studies in the Cochrane review did not find clear evidence of benefit of using NRT in pregnancy either in terms of efficacy or safety or in relation to birth outcomes.

It is worth noting that since the Cochrane review was published, a subsequent sizeable trial of NRT in pregnancy was concluded in France which showed similar results in that the NRT dose provided did not appear to significantly improve smoking cessation outcomes (Berlin et al, 2014). However, two other further developments are worth noting particularly for the UK context.

The first is that an observational study in the UK which did not meet the inclusion criteria for the Cochrane review did show benefits of NRT use in pregnancy for women who were prescribed it as part of a quit attempt with stop smoking services, and, interestingly, that women who received combination therapy (more than one product) were more likely to quit than those who used just one product (Brose et al, 2013). The second was that two year follow up of the Coleman trial was published, looking at outcomes for infants (Cooper et al, 2014). It found that babies born to mothers who had used NRT in the trial were more likely to have unimpaired development than those women who had smoked but received the placebo NRT. This provides additional reassuring evidence regarding the safety of NRT for use in pregnancy.

Summary

Existing evidence from trials does not suggest that Nicotine Replacement Therapy helps women stop smoking in pregnancy. However, as the Cochrane review points out there are a number of potential reasons for this and NRT is available for women who choose to use it in the UK and is approved for use. More recent evidence published since the Cochrane review provides reassurance regarding its safety for use in pregnancy, and at least one UK study using a less robust design than a trial suggests that it may be effective particularly at higher doses, which is perhaps unsurprising as nicotine is metabolized more rapidly in pregnancy. This is clearly an area for future research, particularly as more anecdotal evidence from professionals and women in the UK who use NRT during pregnancy suggests that many find it helpful for smoking cessation.

Case studies which include pharmacological interventions:

- babyClear, Hartlepool
- E-cigarette use in pregnancy, Leicester
- Smoking in pregnancy, Isle of Wight
- Me Time, Wirral Merseyside
- Mums2Be Smokefree.

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