



Inequalities in Infant Mortality Project Evidence Map Report 3

The effectiveness of interventions targeting major potentially modifiable risk factors for infant mortality: a user's guide to the systematic review evidence

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October 2009

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Overview of the evidence map

This report provides a systematic description of published systematic reviews assessing the effectiveness of interventions to reduce the following potentially modifiable risk factors for infant mortality.

- Smoking during pregnancy
- Infant risk factors for sudden infant death syndrome/sudden unexpected deaths in infancy (SIDS/SUDI):
 - exposure to environmental tobacco smoke
 - non-supine sleeping position
 - adverse sleeping environment, e.g. bed-sharing (particularly if parents smoke, have been drinking alcohol or have taken drugs), 'rooming alone'
- Obesity and overweight, but restricted to interventions targeting preconception weight loss, avoidance of excessive weight gain during pregnancy and weight reduction after childbirth

This report also includes a description of recent evidence-based reports, reviews and guidelines on these topics published in the grey literature.

This report can be used to rapidly identify and access systematic review evidence on interventions. All sections include clickable hyperlinks to full text articles, published reports and Pubmed abstracts.

Methods used to construct the evidence map, and to identify other evidence-based material, are outlined briefly below; fuller details are available in a separate 'Technical Guide' (Allen et al., 2009).

The Inequalities in Infant Mortality Project Evidence Map is made up of four reports and a searchable database that can be accessed online via <http://www.npeu.ox.ac.uk/infant-mortality>.

What is an Evidence Map?

- A comprehensive and systematic description of the existing literature on a particular topic.
- It provides an overview of research on a given topic; also highlights gaps in the available literature.
- It does not involve quality appraisal and synthesis of results as undertaken in a systematic review.

What does this Evidence Map include?

- Systematic reviews assessing the effectiveness of interventions to reduce the potentially modifiable risk factors described above.
- It includes all relevant systematic reviews published in the scientific literature in English, from 1990 to early 2009.
- This User's Guide also describes other evidence-based reports, reviews and guidelines from the 'grey literature', published from 2000 to mid-2009

How did we find the information?

- Extensive systematic literature searches of relevant databases (Medline, Embase, Cinahl and The Cochrane Library) and searches of other online resources.

- Full details of the methodology can be found in the 'Technical guide to the infant mortality evidence map: systematic reviews of interventions targeting major potentially modifiable risk factors for infant mortality' (Allen et al., 2009) available online at <http://www.npeu.ox.ac.uk/infant-mortality>.

What did we find?

- 23 systematic reviews
 - The majority of information was found on interventions for smoking cessation during pregnancy and the postpartum period (14 systematic reviews).
 - The systematic review-level evidence relating to interventions to reduce SIDS / SUDI was limited to interventions which targeted maternal smoking (see above) and infant exposure to second-hand smoke (4 systematic reviews); no systematic reviews that evaluated interventions to modify infant sleeping position or adverse sleeping environments were identified.
 - The systematic reviews evaluating interventions to reduce obesity and overweight predominantly related to the postnatal period (3 systematic reviews); one systematic review looked at the prevention of excessive weight gain during pregnancy and another evaluated the effect of dietary interventions in pregnancy on weight gain.
- 12 other evidence-based reports, reviews and guidelines
 - 6 related to smoking cessation during pregnancy and the postpartum period.
 - 3 related to interventions targeting infant risk factors for SIDS.
 - 3 related to weight management before, during and after pregnancy.

1 Interventions targeting smoking during pregnancy and the postpartum period

1.1 Evidence overview

- Evidence found: 14 systematic reviews.
- The most comprehensive and up-to-date evidence on smoking cessation in pregnancy and during the postpartum period was provided by the Cochrane review by Lumley et al.
- There was some overlap of studies in the systematic reviews.
- The most frequently evaluated smoking cessation intervention was self-help materials with or without added counselling.
- Two reviews looked specifically at pharmacologic agents for smoking cessation during pregnancy.
- Although a number of interventions significantly increased cessation rates, the absolute change in the proportion of women who continued to smoke during pregnancy was often modest.
- Reviews evaluating effects on smoking in the postpartum period are included in this section; reviews evaluating effects on infant exposure to environmental tobacco smoke are covered in section 2.

1.2 Summary of systematic review evidence

1.2.1 Reviews covering a range of interventions

The most comprehensive evidence on the effectiveness of smoking interventions during pregnancy was provided by the Cochrane review '*Interventions for promoting smoking cessation during pregnancy*' (Lumley et al., 2004). The recent update of this review (Lumley et al., 2009) looked at the evidence from 72 randomised trials conducted between 1975 and 2008, and found 65 trials which reported on the principal outcome measure of continued smoking in late pregnancy (number of women included in the trials=21,258).

Interventions included:

- Educational interventions: cognitive behavioural therapy, motivational interviewing therapies
- Interventions based on assessment of the women's 'stage of change'
- Feedback on fetal health status or measurement of by-products of tobacco smoking to the mother
- Provision of rewards and incentives for smoking cessation
- Provision of pharmacotherapies
- Other strategies, including hypnosis

There was a wide range of interventions studied; the two most common strategies considered were cognitive behavioural therapy (n=31) and interventions based on the woman's 'stage of change' (n=11).

Pooled data from 65 trials revealed a significant reduction in continued smoking in late pregnancy in the intervention groups (pooled risk ratio (RR) 0.94, 95% confidence interval (CI) 0.93 to 0.96). This equates to an absolute difference in the proportion continuing to smoke of 6%. Smoking cessation intervention strategies involving incentives had a significantly larger effect than other strategies. No differences in effectiveness were found between nicotine replacement therapy (NRT) and cognitive behavioural therapy (CBT). Twenty-one trials with information on perinatal outcomes showed that smoking cessation interventions significantly reduced low birthweight (RR 0.83, 95% CI 0.73 to 0.95) and preterm birth (RR 0.86, 95% CI 0.74 to 0.98). The authors concluded that smoking cessation programmes in pregnancy are effective both in reducing the proportion of women who continue to smoke in late pregnancy and in reducing low birth weight and preterm birth.

Kelley et al. ('*Effective approaches to persuading pregnant women to quit smoking: A meta-analysis of intervention evaluation studies*') reviewed the evidence from controlled evaluations of service-based interventions designed to encourage smoking cessation among pregnant women, and considered whether specific intervention components are related to effectiveness (Kelley et al., 2001). Their meta analysis of 36 studies covered a wide range of interventions, the majority of which (n=31) provided information leaflets and manuals alongside additional components. Of these 31 interventions, the authors classified ten as targeting threat perception (emphasis on the risks of smoking), and twenty-one as focussing on cognitive preparation (addressing cognitive resources that may facilitate cessation). The five remaining interventions delivered one component only (advice, ultrasound feedback, midwife training, or telephone support). The authors concluded that the effectiveness of service-based interventions was demonstrated across a wide range of studies, with evidence suggesting that interventions incorporating follow-up contact tended to be more effective; and that interventions designed to enhance cognitive preparation for quitting seemed to be more effective than those focussing on threat perception.

The systematic review '*Smoking in pregnancy and lactation: a review of risks and cessation strategies*' (Einarson and Riordan, 2009), reviewed risks associated with smoking during pregnancy and breastfeeding and provided an overview of the effectiveness of a range of smoking cessation interventions (behavioural programmes, nicotine replacement and antidepressants). The authors concluded that pharmacological treatments appeared to have a higher success rate than behavioural interventions, but that effects were mixed and generally modest.

'*A meta-evaluation of smoking cessation intervention research among pregnant women: improving the science and art*' (Windsor et al., 1998) summarised the smoking cessation intervention research in the time period 1986 to 1998. The focus of the review was on the methods used to evaluate the different interventions.

1.2.2 Reviews looking at counselling interventions

Melvin et al. reviewed the evidence on smoking cessation counselling for pregnant women ('*Recommended cessation counselling for pregnant women who smoke: a review of the evidence*') (Melvin et al., 2000). Based on the evidence, the authors recommended a brief counselling intervention delivered by a trained provider with the provision of pregnancy specific self-help materials. They noted that this intervention type appeared to be less effective in 'more addicted' pregnant smokers. The conclusions of this review were based on the findings of a meta-analysis of 16 trials ('*Maternal smoking during pregnancy and evidence-based intervention to promote cessation*') (Mullen, 1999), the results of which demonstrated that brief counselling interventions achieved a modest, but clinically important, increase in smoking cessation amongst pregnant smokers, with an average risk ratio of 1.7 (95% CI of 1.3 to 2.2). This meta-analysis was an updated version of an earlier report by the same author ('*A meta-analysis of randomized trials of prenatal smoking cessation interventions*') (Dolan-Mullen et al., 1994).

1.2.3 Reviews looking at self-help interventions

The systematic review, '*Self-help smoking cessation interventions in pregnancy: a systematic review and meta-analysis*' (Naughton et al., 2008) analysed studies of self-help interventions for pregnant smokers, and assessed whether the type and intensity of self-help materials (written, audio, video, computer-based, etc) was important. The primary meta-analysis from this systematic review indicated that self-help interventions increased cessation rates over usual care (odds ratio (OR) 1.83, 95% CI 1.23 to 2.73); however, the overall effectiveness was low (median quit rate 4.9% for usual care vs. 13.2% for self-help). The authors reported that there was insufficient evidence to indicate whether more sophisticated or intensive approaches were more effective.

1.2.4 Reviews looking at telephone interventions

'*A Systematic Review of Telephone Support for Women During Pregnancy and the Early Postpartum Period*' (Dennis and Kingston, 2008) assessed the effects of telephone-based support for women during pregnancy and the early post-partum period. The review evaluated effects on a range of outcomes and was not restricted to interventions specifically targeting smoking. Fourteen trials evaluating telephone support for smoking cessation and smoking relapse were included. The authors concluded that proactive telephone support may assist in preventing smoking relapse; and that telephone interventions were not effective in improving smoking cessation.

1.2.5 Reviews looking at pharmacologic agents

'*Smoking cessation in pregnancy*' (Rore et al., 2008) summarised the known safety and efficacy of pharmacologic agents used for smoking cessation during pregnancy. The review identified limited evidence in this area. Two trials of nicotine replacement therapy (NRT) use in pregnancy showed no significant effect of NRT on smoking cessation, however

patient numbers were small. The safety of bupropion during pregnancy was discussed in this review, but no trials of the efficacy of bupropion on smoking cessation during pregnancy were found by the authors.

'*Smoking Cessation Therapy in Pregnancy*' (Smith et al., 2006) also looked at pharmacologic interventions for smoking cessation during pregnancy. Much of the evidence covered by Rore et al (Rore, Brace et al. 2008) was summarised in this review. One additional small trial (n=21) on NRT efficacy and safety outcomes in pregnant women who smoked at least 15 cigarettes per day was included but the study lacked a control group and had a high drop-out rate.

1.2.6 Reviews looking at smoking cessation and relapse prevention interventions in the postpartum period

The review '*Systematic Review of the Literature on Postpartum Care: Effectiveness of Interventions for Smoking Relapse Prevention, Cessation, and Reduction in Postpartum Women*' (Levitt et al., 2007), considered the effect of interventions initiated in the postpartum period (birth to one year) on smoking relapse, cessation and reduction. Three trials of interventions involving advice materials and counselling, delivered in three settings (hospital, paediatricians' offices and child health centres) were included. The review found no evidence of a significant effect of these interventions on cessation rates, relapse prevention or smoking reduction.

'*Smoking Cessation in Pregnancy: A Review of Postpartum Relapse Prevention Strategies*' (Fang et al., 2004) also addressed relapse prevention in the postpartum period. This review found 13 studies that focused on pre- or postpartum smoking relapse prevention. The main focus of this systematic review was on the profiles of women who relapsed postpartum and the variables associated with postpartum smoking relapse, rather than on the effectiveness of the interventions. Breastfeeding and stable mental health were found to have protective effects whereas having a partner who smoked and the woman having smoked a greater amount before pregnancy had adverse effects on postpartum smoking relapse. They also found an association between early weaning and postpartum cessation relapse. The authors concluded that successful postpartum relapse prevention strategies should involve the woman's social network, including her partner.

A systematic review by the Effective Public Health Practice Project (EPHPP), '*The Effectiveness of Postpartum Smoking Relapse Prevention Strategies: A Systematic Review of the Evidence 1992-1999*' (Edwards et al., 2000), considered the effectiveness of strategies initiated during pregnancy and the postpartum period to reduce smoking relapse during the postpartum period. The review also examined the evidence relating to the optimal timing of the intervention (pre- or post-natal) and whether interventions that targeted the partner or family yielded improved benefits compared with those that target the woman alone. The review found 19 relevant studies of which four were rated as having 'good' or 'moderate' quality. The authors concluded that there was some evidence that a theoretically based, multi-component intervention of sufficient intensity, provided during the postpartum period, could have a modest effect on patterns of smoking relapse at six months. The report identified a number of ineffective strategies and noted that the presence of a smoking partner was a strong determinant of postpartum relapse but that evidence relating to interventions targeting the woman and her partner was lacking.

1.3 Other evidence-based reports, reviews and guidelines

The NICE public health guidance, '*Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities*' (NICE, 2008) forms a comprehensive resource for NHS or

other professionals who have a responsibility for smoking cessation services. Additionally, a NICE public health guidance, '*How to stop smoking in pregnancy and following childbirth*' is being developed and due to be published in May 2010.

NHS Yorkshire and The Humber produced a review titled '*Reducing smoking pre-conception, during pregnancy and postpartum Integrating high impact actions into routine healthcare practice*' (NHS Yorkshire and The Humber, 2007). This review was developed with the input of policy makers and practitioners and gives examples of good practice from the region.

The BMA published a report '*Smoking and reproductive life*' (BMA, 2004) which looked at the impact of smoking on sexual, reproductive and child health. The report outlined the risks associated with smoking in pregnancy and provided an overview of smoking cessation interventions.

A review of pregnancy smoking cessation services by NHS Health Scotland titled '*Smoking cessation support in Scotland*' (NHS Health Scotland, 2008) identified strengths and weaknesses within the service and provided examples of promising practice in Scotland.

The evidence briefing produced by the Health Development Agency, '*Prevention of low birth weight: assessing the effectiveness of smoking cessation and nutritional interventions*' (Bull et al., 2003) included a chapter on smoking cessation interventions; however the majority of this information came from an earlier version of the systematic review by Lumley et al (Lumley et al., 2000) and a review by Mullen (Mullen, 1999).

2 Interventions targeting risk factors for SIDS/SUDI

2.1 Evidence overview

- Evidence found: 4 systematic reviews.
- Four systematic reviews considered interventions specifically targeting exposure to environmental tobacco smoke.
- The studies included in these four reviews overlapped considerably.
- No relevant systematic reviews were found that evaluated the effectiveness of interventions targeting other risk factors for SIDS/SUDI (non-supine sleeping position, adverse sleeping environment).
- Reviews relating to smoking cessation and relapse prevention in pregnancy and the postpartum period are covered in section 1 above.

2.2 Summary of systematic review evidence

A recent Cochrane review '*Family and carer smoking control programmes for reducing children's exposure to environmental tobacco smoke*' (Priest et al., 2008) identified thirty-six controlled trials on interventions to reduce children's exposure to environmental tobacco smoke. Four studies related to interventions targeted at a population/community level; the remaining 32 studies were conducted in healthcare settings covering 'well child' and 'ill child' study populations or a mixture of the two groups. The authors concluded that there was insufficient evidence to recommend one strategy over another to reduce the prevalence of children's environmental tobacco smoke exposure or to indicate that any of the settings was more effective. The authors commented that the evidence provided greater support for interventions concentrating primarily on changing parental attitude and behaviours, rather than on changes in knowledge.

The review '*How to prevent exposure to tobacco smoke among small children: a literature review*' (Arborelius et al., 2000) looked at interventions in the antenatal care and child healthcare settings. The review included a narrative overview of studies covered by two of the Cochrane reviews discussed above (Priest et al., 2008; Lumley et al., 2009).

A third systematic review, '*A review of interventions for residential environmental tobacco smoke exposures among children*' (Adair and Patten, 2001), considered only individual-level interventions. It included evaluations of nine interventions, all involving personal counselling and education. The authors concluded that most interventions included in the review had no effect on reducing environmental tobacco smoke exposure among infants and children.

The systematic review '*Protecting children from environmental tobacco smoke (ETS) exposure: A critical review*' (Gehrman and Hovell, 2003) covered interventions aimed at reducing exposure to environmental tobacco smoke from birth through to adolescence. The review included 19 studies, many of which were included in one of the three reviews discussed above (Arborelius et al., 2000; Adair and Patten, 2001; Priest et al., 2008).

2.3 Other evidence-based reports, reviews and guidelines

- A *BMJ clinical evidence SIDS review* (Hauck and O'Tanabe, 2009) provided a systematic summary of the evidence relating to the benefits and harms of advice to avoid potential risk factors for SIDS/SUDI:
 - Advice to avoid prone sleeping
 - Advice to avoid tobacco-smoke exposure
 - Advice to avoid bed sharing
 - Advice to avoid overheating or overwrapping
 - Advice to avoid soft sleeping surfaces
 - Advice to breastfeed
 - Advice to promote soother/ pacifier use
 - Advice to promote room sharing

The report included a GRADE evaluation of the quality of the evidence for each of these interventions. The authors concluded that there was clear evidence that advice to avoid prone sleeping was beneficial and that there was weaker evidence that advice to avoid tobacco-smoke exposure was likely to be beneficial. They found insufficient evidence to draw conclusions about the effectiveness of advice in the other six areas.

- '*Factfile 2. Research background to the Reduce the Risk of Cot Death advice by the Foundation for the Study of Infant Deaths*' (Foundation for the Study of Infant Deaths, 2003) provided an overview of SIDS research.
- A 2006 briefing paper by ASH in Scotland, '*Second-hand Smoke Exposure in the Home*' (Action on Smoking and Health (ASH), 2006), provided an overview of the evidence-base regarding second-hand smoke exposure in the home.

3 Interventions targeting obesity and overweight: preconception weight loss, avoidance of excessive weight gain during pregnancy and weight reduction after childbirth

3.1 Evidence overview

- Evidence found: 5 systematic reviews.
- Two systematic reviews reported on weight loss interventions in postpartum women and one looked at weight loss interventions in both pregnancy and the postpartum period.
- There was considerable overlap of studies in the reviews which considered postpartum weight loss.
- One systematic review looked at interventions to prevent excessive weight gain during pregnancy.
- One systematic review evaluated dietary interventions in pregnancy with a primary focus on effects on fetal and maternal health, including possible adverse effects of protein/energy restriction in pregnancy.

3.2 Summary of systematic review evidence

A Cochrane review, '*Diet or exercise, or both, for weight reduction in women after childbirth*' (Amorim Adegboye et al., 2007), included six trials involving 245 women in total: one involved diet alone, four involved diet plus exercise and one involved exercise alone. The review considered both the potential benefits and harms of these interventions. The authors concluded that this preliminary evidence suggested that diet and exercise together and diet alone helped women to lose weight after childbirth and that both appeared safe for breastfeeding mothers. They found only one small trial (n=33) evaluating the effect of exercise alone as a weight loss intervention in the postpartum period: this found no difference in weight loss between the exercise and usual care groups.

A second systematic review looking at postpartum weight loss, '*Interventions for Weight Management in Postpartum Women*' (Keller et al., 2008), covered much of the same material as the previously cited review (Amorim Adegboye et al., 2007). The only additional study included reported only qualitative results. The authors concluded that diet and exercise interventions showed a beneficial effect on a range of measures of body composition.

A systematic review by the Effective Public Health Practice Project, '*Effectiveness of interventions to prevent excessive weight gain during pregnancy*' (Liu et al., 2005), considered the evidence relating to the effectiveness of a broad range of approaches (public health, health promotion and primary care) to prevent excessive weight gain during pregnancy. The review found only three relevant studies, two involving interventions delivered in obstetric (antenatal) clinics, and one evaluating the effect of exercise during pregnancy. The authors considered that the evidence was weak but concluded that "interventions involving educational and behavioural strategies to promote healthy, low-fat eating, modest exercise and appropriate weight gain during pregnancy could be effective in reducing the frequency of excessive weight gain."

A fourth systematic review, '*Weight-Management Interventions for Pregnant or Postpartum Women*' (Kuhlmann et al., 2008), looked at interventions to help women either achieve appropriate weight gain during pregnancy or manage their weight during the postpartum period. The review included three weight management studies, all of which were also included in the reviews described above.

A Cochrane review '*Energy and protein intake in pregnancy*' (Kramer and Kakuma, 2003) evaluated the effects of dietary advice, supplementation, or restriction on a range of outcomes including gestational weight gain. A number of the interventions considered involved increased or balanced energy/protein intake and were aimed at improving fetal growth and maternal health rather than reducing excessive weight gain. The authors concluded that protein/energy restriction in pregnant women who were overweight, or exhibit high weight gain, was unlikely to be beneficial and may be harmful to the fetus.

3.3 Additional systematic reviews of interest

We identified three systematic reviews which examined the effects of exercise and nutrition on pregnancy outcomes. These included some relevant data on maternal weight but predominantly focused on the safety of exercise on the fetus.

- *Aerobic exercise for women during pregnancy* (Kramer and McDonald, 2006)
- *Physical activity during pregnancy and maternal-child health outcome: a systematic literature review* (Schlüssel et al., 2008)
- *Effect of physical exercise on pregnancy outcomes: a meta-analytic review* (Lokey et al., 1991)

A further review by Smith et al, which primarily focused on the effects of obesity on pregnancy outcome, '*Effects of obesity on Pregnancy*' (Smith et al., 2008), included a brief section providing a selective review of community and individual approaches to pregnancy weight management.

3.4 Other evidence-based reports, reviews and guidelines

- Two NICE public health guides were in development at the time this User Guide was written; one looking at weight management during pregnancy and the other focusing on weight management after pregnancy (both due to be published in July 2010):
 - *Weight management in pregnancy*
 - *Weight management following childbirth*
- A NICE public health guidance included a section on obesity in pregnancy *Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households* (NICE, 2008).

Acknowledgement

This is an independent report from a study which is funded by the Policy Research Programme in the Department of Health. The views expressed are not necessarily those of the Department.

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Please cite this document as:

Felicity Allen, Ron Gray, Laura Oakley, Jennifer J Kurinczuk, Peter Brocklehurst, Jennifer Hollowell. Inequalities in Infant Mortality Project Evidence Map Report 3. The effectiveness of interventions targeting major potentially modifiable risk factors for infant mortality: a user's guide to the systematic review evidence. Oxford: National Perinatal Epidemiology Unit, 2009

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