

Antenatal care

Evidence Update May 2013

A summary of selected new evidence relevant to NICE clinical guideline 62 'Antenatal care' (2008)

Evidence Update 41



Evidence Updates provide a summary of selected new evidence published since the literature search was last conducted for the accredited guidance they relate to. They reduce the need for individuals, managers and commissioners to search for new evidence. Evidence Updates highlight key points from the new evidence and provide a commentary describing its strengths and weaknesses. They also indicate whether the new evidence may have a potential impact on current guidance. For contextual information, this Evidence Update should be read in conjunction with the relevant clinical guideline, available from the NICE Evidence Services topic page for [antenatal care](#).

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Introduction

This Evidence Update identifies new evidence that is relevant to, and may have a potential impact on, the following reference guidance:

¹  [Antenatal care](#). NICE clinical guideline 62 (2008).

A search was conducted for new evidence from 19 November 2010 to 21 December 2012. A total of 7602 pieces of evidence were initially identified. Following removal of duplicates and a series of automated and manual sifts, 12 items were selected for the Evidence Update (see Appendix A for details of the evidence search and selection process). An [Evidence Update Advisory Group](#), comprising topic experts, reviewed the prioritised evidence and provided a commentary.

Although the process of updating NICE guidance is distinct from the process of an Evidence Update, the relevant NICE guidance development centres have been made aware of the new evidence, which will be considered when guidance is reviewed.

Other relevant NICE guidance

The focus of the Evidence Update is on the guidance stated above. However, overlap with other accredited guidance has been outlined as part of the Evidence Update process. Where relevant, this Evidence Update therefore makes reference to the following guidance:

¹  [Weight management before, during and after pregnancy](#). NICE public health guidance 27 (2010).

- ² [Maternal and child nutrition](#). NICE public health guidance 11 (2008).

Quality standards

- [Antenatal care](#). NICE quality standard 22 (2012).

Feedback

If you have any comments you would like to make on this Evidence Update, please email contactus@evidence.nhs.uk

¹ NICE-accredited guidance is denoted by the Accreditation Mark 

² Guidance published prior to NICE accreditation

Key points

The following table summarises what the Evidence Update Advisory Group (EUAG) decided were the key points for this Evidence Update. It also indicates the EUAG's opinion on whether the new evidence may have a potential impact on the current guidance listed in the introduction. For further details of the evidence behind these key points, please see the full commentaries.

The section headings used in the table below are taken from the guidance.

Evidence Updates do not replace current accredited guidance and do not provide formal practice recommendations.

Key point	Potential impact on guidance	
	Yes	No
Lifestyle considerations <ul style="list-style-type: none"> Vitamin D supplementation in pregnant women appears to increase serum levels of vitamin D in both mothers and newborn babies. However, evidence of the effects of vitamin D supplementation on maternal or fetal outcomes, such as risk of pre-eclampsia or birthweight, is insufficient. 		✓
Clinical examination of pregnant women <ul style="list-style-type: none"> Lower weight gain in pregnancy may be associated with less postpartum weight retention in the medium term. Diet and exercise interventions may reduce the amount of weight gained in pregnancy. Interventions to reduce domestic violence in pregnant women do not seem to show consistent effects on reducing incidents of domestic violence or improving birth outcomes. 		✓ ✓
Fetal growth and well-being <ul style="list-style-type: none"> Fetal-movement counting does not seem to affect fetal outcomes such as perinatal death. 		✓
Areas not currently covered by NICE guidance <ul style="list-style-type: none"> Treatment for periodontal disease may reduce rates of preterm birth; however, further research is needed. 		✓

1 Commentary on new evidence

These commentaries analyse the key references identified specifically for the Evidence Update. The commentaries focus on the 'key references' (those identified through the search process and prioritised by the EUAG for inclusion in the Evidence Update), which are identified in bold text. Supporting references provide context or additional information to the commentary. Section headings are taken from the guidance.

1.1 [Woman-centred care and informed decision-making](#)

No new key evidence was found for this section.

1.2 [Provision and organisation of care](#)

No new key evidence was found for this section.

1.3 [Lifestyle considerations](#)

Vitamin D supplementation

[NICE clinical guideline \(CG\) 62](#) recommends that all women should be informed at the booking appointment about the importance for their own and their baby's health of maintaining adequate vitamin D stores during pregnancy and whilst breastfeeding. In order to achieve this, women may choose to take 10 micrograms of vitamin D per day, as found in the [Healthy Start](#) multivitamin supplement. Particular care should be taken to enquire as to whether women at greatest risk are following advice to take this daily supplement. These include:

- women of South Asian, African, Caribbean or Middle Eastern family origin
- women who have limited exposure to sunlight, such as women who are predominantly housebound, or usually remain covered when outdoors
- women who eat a diet particularly low in vitamin D, such as women who consume no oily fish, eggs, meat, vitamin D-fortified margarine or breakfast cereal
- women with a pre-pregnancy body mass index above 30 kg/m².

[Christesen et al. \(2012a\)](#) did a systematic review of the effects of vitamin D supplementation in pregnancy. 7 randomised controlled trials (RCTs) and 32 cohort and case-control were identified. No pooling or meta-analysis of results was performed.

In 6 of the 7 included RCTs, serum 25-hydroxyvitamin D levels at delivery were increased after supplementation compared with lower-dose or no supplementation; the remaining trial did not report on this outcome. Only 2 of the RCTs were judged to be of high methodological quality. Among the cohort and case-control studies, several studies showed some evidence that vitamin D supplementation reduced the risk of pre-eclampsia, but others showed no effect. Similarly mixed results were seen for gestational diabetes, bacterial vaginosis, length of gestation and preterm birth.

In another systematic review, [Christesen et al \(2012b\)](#) evaluated the possible association between maternal vitamin D levels in pregnancy and extraskeletal effects in their babies. 6 RCTs and 24 cohort and case-control studies were identified. No meta-analysis of results was performed. Of the 6 included RCTs, only 1 showed an extraskeletal effect (an increase in birthweight after giving mothers 2 doses of vitamin D 600,000 IU). The cohort and case-control studies generally showed no effect of maternal vitamin D on birthweight. Possible beneficial effects on infections, wheezing and asthma were seen.

The authors did not discuss limitations of either review, but concluded that the evidence of an effect of vitamin D supplementation on maternal and infant outcomes remains insufficient.

One of the RCTs included in the 2 systematic reviews above was by [Hollis et al. \(2011\)](#). This single-centre double-blind trial (n=350) was conducted in South Carolina, USA. It assessed the effects of supplementation of vitamin D on levels of serum 25-hydroxyvitamin D in mothers and infants (the primary outcome). Women were assigned to 1 of 3 active treatment groups and received 400 IU (10 micrograms), 2000 IU (50 micrograms), or 4000 IU (100 micrograms) of vitamin D daily. Baseline vitamin D levels were measured, and vitamin D supplementation began at 12–16 weeks of gestation. Women aged 16 years or over with singleton pregnancies of less than 16 weeks' gestation were included. Those with active or untreated thyroid disease, calcium or parathyroid conditions, hypertension, or taking diuretics or cardiac drug treatment were excluded.

Treatment allocation was not fully randomised, with the mother's baseline vitamin D level determining eligibility for allocation to: any of the 3 doses; either the 400 or 2000 IU dose; or the 400 IU dose only. Stratified block randomisation was used to ensure that ethnicity (defined as black, Hispanic, and white) was balanced in each treatment group. Of women completing the study, adherence to protocol was around 69% across treatment groups.

Serum vitamin D levels at birth increased in both mothers and infants with increasing dose of vitamin D.

Mean maternal serum 25-hydroxyvitamin D was:

- 78.9 standard deviation (SD) 36.5 nmol/litre for the 400 IU (10 micrograms) group
- 98.3 SD 34.2 nmol/litre for the 2000 IU (50 micrograms) group and
- 111.0 SD 40.4 nmol/litre for the 4000 IU (100 micrograms) group (p<0.0001).

Mean infant serum 25-hydroxyvitamin D was:

- 45.5 SD 25.3 nmol/litre for the 400 IU (10 micrograms) group
- 57.0 SD 24.5 nmol/litre for the 2000 IU (50 micrograms) group and
- 66.3 SD 25.8 nmol/litre for the 4000 IU (100 micrograms) group (p<0.0001).

No significant differences were seen in any safety measure (serum calcium, creatinine and phosphorus, and urinary calcium and creatinine ratios). The authors stated that no adverse events were attributable to vitamin D supplementation, but that one woman ceased supplementation after a single blood measurement of 233.3 nmol/litre.

The authors noted that observations from their study setting may not be representative of vitamin D needs at latitudes further north. Additionally, supplementation began after 12 weeks of gestation, so the safety of earlier supplementation could not be assessed.

Although the evidence of the effects of vitamin D supplementation during pregnancy on maternal or fetal outcomes seems to be insufficient, supplementation does appear to increase serum levels of vitamin D in both mothers and newborn babies; therefore no impact on [NICE CG62](#) is expected.

Key references

[Christesen HT, Falkenberg T, Lamont RF et al. \(2012a\) The impact of vitamin D on pregnancy: a systematic review. Acta Obstetrica et Gynecologica Scandinavica 91: 1357–67](#)

[Christesen HT, Elvander C, Lamont RF et al. \(2012b\) The impact of vitamin D in pregnancy on extraskeletal health in children: a systematic review. Acta Obstetrica et Gynecologica Scandinavica 91: 1368–80](#)

[Hollis BW, Johnson D, Hulsey TC et al. \(2011\) Vitamin D supplementation during pregnancy: double-blind, randomized clinical trial of safety and effectiveness. Journal of Bone and Mineral Research 26: 2341–57](#)

1.4 [Management of common symptoms of pregnancy](#)

No new key evidence was found for this section.

1.5 [Clinical examination of pregnant women](#)

Gestational weight gain

[NICE CG62](#) recommends that maternal weight and height should be measured at the booking appointment, and the woman's body mass index should be calculated (weight[kg]/height[m]²). Repeated weighing during pregnancy should be confined to circumstances in which clinical management is likely to be influenced.

'Weight management before, during and after pregnancy' ([NICE public health guidance 27](#)) and 'Maternal and child nutrition' ([NICE public health guidance 11](#)) also cover diet and exercise during pregnancy. Recommendations include:

- dispelling any myths about what and how much to eat during pregnancy. For example, advising that there is no need to 'eat for two' or to drink full-fat milk. Health professionals should explain that energy needs do not change in the first 6 months of pregnancy and increase only slightly in the last 3 months (and then only by around 200 calories per day).
- advising that moderate-intensity physical activity will not harm her or her unborn child. At least 30 minutes per day of moderate intensity activity is recommended.
- informing women with a body mass index of over 30 about the increased risks this poses to themselves and their babies, and offer referral to a dietitian for advice on healthy eating and exercise. Women should be advised not to attempt to lose weight during pregnancy.

[Nehring et al. \(2011\)](#) did a meta-analysis of 9 observational studies about the short-term and long-term effects of gestational weight gain. Weight gain was reported in accordance with guidelines on postpartum weight retention from the US Institute of Medicine.

These recommendations were

- 12.5–18.0 kg for underweight women
- 11.5–16 kg for women at normal weight and
- 7–11.5 kg for overweight women.

The number of participants in included studies was not reported.

The postpartum time points at which weight retention was measured were categorised as: up to 6 months; 6 months to 1 year; 3 years; and more than 15 years. These time points were based on the available data. Data were analysed with a random-effects model.

Absolute postpartum weight retention increased from 3 years after birth to 15 years after birth irrespective of whether gestational weight gain had been below, within, or above the recommended amount.

- At up to 6 months postpartum, women who gained less weight than recommended retained 2.99 kg (95% confidence interval [CI] -3.72 to -2.27 kg) less than women whose weight gain was within recommendations; however this association reduced over time and was not significant after 15 years.
- Women who gained more gestational weight than recommended retained 4.29 kg (95% CI 3.15 to 5.43 kg) more at up to 6 months postpartum than women who gained weight within recommendations.
- At 6 months to 1 year, weight retention was 2.45 kg (95% CI 1.95 to 2.95 kg) higher in the women who gained more than recommended gestational weight.
- By 15 years this had increased to 4.72 kg more (95% CI 2.94 to 6.50 kg).

Limitations reported by the authors included that several studies related to this topic were excluded because they did not report weight before pregnancy. The methodological quality of the included studies was reported as acceptable by the authors. However, in 2 studies, weight was self-reported (although in most studies the woman's weight was measured by investigators at delivery and at the postpartum time point). Additionally only 3 included studies reported data stratified by high or normal weight before pregnancy. Therefore, no analysis was possible to address whether gestational weight gain and postpartum weight retention was more of an issue for women who were obese compared with normal weight.

[Thangaratinam et al. \(2012\)](#) did a meta-analysis of 44 RCTs of dietary and lifestyle interventions (n=7278) with potential to affect maternal and fetal weight-related outcomes. Studies in pregnant women who were underweight were excluded. Diet was the main intervention in 13 trials, physical activity was the main intervention in 18 trials, and 13 trials used a mixed approach that was sometimes underpinned by behavioural counselling.

Most included trials were in pregnant women with any body-mass index (BMI), but some were in obese or overweight women. Typical dietary interventions were a balanced diet with a food diary. Typical physical activity interventions were light intensity resistance training, weight-bearing exercises, or walking for 30 minutes. The mixed approaches included counselling and education on potential benefits of diet and exercise, and behaviour modification to help with emotional eating and binge eating.

Overall, interventions were associated with a reduction in maternal weight gain of 1.42 kg compared with control (95% CI 0.95 to 1.89 kg, $p < 0.001$). Dietary intervention gave the largest reduction in weight gain, of 3.84 kg (95% CI 2.45 to 5.22 kg). The groups did not differ significantly in adherence to US Institute of Medicine recommendations on gestational weight gain. No significant effects on fetal weight were noted.

For other obstetric outcomes, overall interventions were associated with a reduction in pre-eclampsia (relative risk [RR]=0.74, 95% CI 0.60 to 0.92). However, no significant differences were seen for gestational diabetes, gestational hypertension, preterm delivery, gestational age at delivery, caesarean sections, induction of labour, or postpartum haemorrhage. Dietary interventions were associated with a larger reduction in pre-eclampsia than all interventions (RR=0.67, 95% CI 0.53 to 0.85), and were also associated with reduced risk of gestational diabetes (RR=0.39, 95% CI 0.23 to 0.69). None of the interventions were associated with adverse maternal or fetal outcomes.

The authors noted that the quality of outcomes as assessed by GRADE was generally moderate for gestational weight gain, but was low for the other obstetric outcomes. The low GRADE rating was because of heterogeneity in effect sizes, issues with the quality of individual studies, and risk of publication and other biases.

[Streuling et al. \(2011\)](#) reported a meta-analysis of 12 RCTs looking at the effects of regular exercise in pregnancy on gestational weight gain. To be included, studies had to be RCTs measuring gestational weight gain in healthy women using an intervention consisting solely of physical activity (n=1073) compared with a control group (n=906). In the control groups, women were not offered an exercise intervention, although they were offered a stretching programme in 1 control group. Women had not exercised regularly before pregnancy in 7 of the included studies.

Interventions varied by intensity, duration (10–32 weeks) and type of activity, but generally women exercised about 3 times a week for 20 minutes to 1 hour. Exercise was supervised in 9 trials and the remaining 3 used home-based exercise programmes controlled by heart rate monitor, activity diary, or pedometer.

The definition of gestational weight gain differed across trials:

- 3 used the difference between bodyweight before pregnancy and at delivery
- 3 used the difference between early and late gestational weight
- 1 measured the weight change during the intervention and
- the remainder did not report a clear definition.

Overall, exercise was associated with a significant reduction in gestational weight gain (mean difference = -0.61 kg, 95% CI -1.17 to -0.06 kg, $p=0.03$). Sensitivity analysis excluding 3 trials judged to be at high risk of bias resulted in a mean difference of -0.93 kg (95% CI -1.35 to -0.50 kg). For each intervention, the metabolic equivalent was calculated. No association was seen between the amount of energy used in the exercise intervention and the amount of gestational weight gained.

Methodological quality of the included trials varied, with only 2 clearly reporting an intention-to-treat analysis. Blind allocation was reported in 6 studies, but the remainder did not report details of allocation. 5 studies had losses to follow-up of more than 15%, and no study had the primary outcome of effect on gestational weight gain.

In a systematic review, [Tanentspaf et al. \(2011\)](#) assessed 13 RCTs and quasi-RCTs ($n=1802$) of dietary interventions for preventing excessive gestational weight gain or related complications. The primary outcomes analysed were the proportion of women who gained more weight than recommended by the US Institute of Medicine, or who gained excess gestational weight.

Trials were included if their participants were healthy pregnant women aged 18 years or older with singleton pregnancies and who were normal weight, overweight or obese. Studies of women taking drug treatment that may interfere with their body weight, or of women at increased risk of insufficient weight gain or having very low birthweight babies were excluded. All studies included a dietary intervention. Seven were of general lifestyle interventions with a dietary component. All but two studies included at least one session of dietary counselling. Two studies focused solely on calorie reduction.

In 10 studies, the pooled estimate showed a reduction in gestational weight gain of -1.92 kg with dietary intervention compared with control (95% CI -3.65 to -0.19 kg). A random effects model was used because of significant heterogeneity between studies ($p<0.0001$). When the 2 studies with the largest effect sizes were removed, the difference in weight gain between the intervention and control was -1.0 kg (95% CI -1.58 to -0.45), and there was no significant heterogeneity ($p=0.08$). Dietary interventions did not significantly reduce the risk of gaining more weight than recommended by the US Institute of Medicine (RR=0.90, 95% CI 0.77 to 1.05, $p=0.18$).

For secondary outcomes, weight retention did not differ significantly between groups at 6 weeks postpartum, but at 6 months postpartum, weight retention was lower in the dietary intervention group (-1.90 kg, 95% -2.69 to -1.12 kg). No significant differences were seen for pre-eclampsia or gestational diabetes, low birthweight, or preterm birth.

The results of these studies suggest that lower weight gain in pregnancy may be associated with less weight retention in the medium term. Additionally, diet and exercise interventions may reduce the amount of weight gained in pregnancy. However, the limitations of the studies mean that no impact on [NICE CG62](#) is expected.

Key references

[Nehring I, Scholl S, Beyerlein A et al. \(2011\) Gestational weight gain and long-term postpartum weight retention: a meta-analysis. American Journal of Clinical Nutrition 94: 1225–31](#)

[Streuling I, Beyerlein A, Rosenfeld E et al. \(2011\) Physical activity and gestational weight gain: a meta-analysis of intervention trials. BJOG 118: 278–84](#)

Tanentsapf I, Heitmann BL, Adegboye ARA (2011) [Systematic review of clinical trials on dietary interventions to prevent excessive weight gain during pregnancy among normal weight, overweight and obese women](#). BMC Pregnancy and Childbirth 11: 81

Thangaratinam S, Rogozińska E, Jolly K et al. (2012) [Effects of interventions in pregnancy on maternal weight and obstetric outcomes: meta-analysis of randomised evidence](#). BMJ 344: doi: 10.1136/bmj.e2088

Domestic violence

[NICE CG62](#) recommends that healthcare professionals need to be alert to the symptoms or signs of domestic violence and women should be given the opportunity to disclose domestic violence in an environment in which they feel secure.

[Nelson et al. \(2012\)](#) did a systematic review to investigate the effectiveness, diagnostic accuracy, and adverse effects of screening and interventions in women for reducing domestic violence. RCTs and diagnostic accuracy studies were included. Studies included women presenting to health services for reasons not directly related to abuse. Self-administered or face-to-face screening techniques were included. Outcomes were reduced exposure to, and harm or mortality from, intimate partner violence. Other study types were included in assessing adverse effects of screening. Overall, 6 RCTs, 15 diagnostic studies, and 14 studies reporting adverse events were included. No pooling or meta-analysis of results was performed.

Of 6 RCTs to identify women with current, past or increased risk of domestic violence, 3 were targeted at pregnant women or those who had recently given birth. These studies suggested that interventions could affect outcomes such as episodes of domestic violence, and rates of preterm birth and very low birthweight, but the evidence does not seem to be consistent.

Among 14 studies reporting the adverse effects of screening, interventions seemed to have generally low levels of adverse effects. Adverse effects included reporting discomfort with screening, loss of privacy, worries about provoking abuse by disclosing domestic violence, and feelings of being judged. However, most of these studies were not targeted at pregnant women.

Limitations reported by the authors included the use of only English language publications that were applicable to US clinical practice, and that they excluded non-randomised intervention studies. The authors additionally noted that this area of research might not be compatible with RCTs because of methodological and ethical issues.

Although interventions to reduce domestic violence in pregnant women do not seem to show consistent effects on reducing incidents of domestic violence or improving birth outcomes, the evidence provides some support for the need for an environment in which women feel secure to disclose domestic violence, as recommended in [NICE CG62](#).

Key reference

Nelson HD, Bougatsos C, Blazina I (2012) [Screening women for intimate partner violence: a systematic review to update the U.S. Preventive Services Task Force recommendation](#). Annals of Internal Medicine 156: 796–808

1.6 Screening for haematological conditions

No new key evidence was found for this section.

1.7 Screening for fetal anomalies

No new key evidence was found for this section.

1.8 [Screening for infections](#)

No new key evidence was found for this section.

1.9 [Screening for clinical conditions](#)

No new key evidence was found for this section.

1.10 [Fetal growth and well-being](#)

Fetal movement counting

[NICE CG62](#) recommends that routine formal fetal-movement counting should not be offered.

[Saastad et al. \(2011\)](#) reported on an RCT (n=1076) comparing fetal-movement counting with standard antenatal care to investigate the outcomes of antenatal identification of fetal pathology.

The primary outcome was defined as a combined measure of:

- fetal growth restriction of more than the 2.5th centile
- emergency caesarean section for fetal indications
- deficiency of amniotic fluid as defined by the clinician
- abnormal blood flow in the umbilical arteries
- maternal perception of absent fetal movements for more than 24 hours before admission to hospital or
- perinatal death.

Women with singleton pregnancies were eligible to join the study. Those with pregnancies with severe anomalies or other reasons for the mother considering termination were excluded. Written informed consent was obtained from 1155 women, and 1076 women were included in the analyses.

Reasons for exclusion from analyses were:

- not completing the baseline questionnaire
- delivery before week 28
- withdrawal from the study
- multiple pregnancy and
- loss to follow-up because of delivery at a different hospital.

In the intervention group, women received written instructions on using a fetal-movement chart and were asked to count fetal movements daily from gestational week 28. Within 2 weeks of the start of fetal movement counting, participating women were called by a midwife or obstetrician who supported them in interpreting the counting method. The fetal-movement chart was returned by 427 women, and 331 women completed the chart on at least 50% of the days during the study and at least 2 days per week.

No significant difference was seen for the primary outcome between groups: 63 of 433 (11.6%) in the intervention group versus 53 of 532 (10.7%) in the control group (RR=1.1, 95% CI 0.7 to 1.5, p=0.652).

The authors noted that in retrospect, their stated primary outcome may not have been amenable to meaningful interpretation for 3 reasons. First, fetal growth restriction has no treatment so screening does not affect incidence. Second, the clinical decisions leading to emergency caesarean could be viewed as the result of successful screening or as an adverse outcome. Third, the maternal outcome of perception of reduced fetal movement implies fetal movement counting or monitoring and thus associated with the intervention so cannot be

considered an independent pregnancy outcome. Additionally the study was underpowered to detect a difference in perinatal death: the power calculation specified a sample of 538 in each arm.

In a further report from the above RCT, [Saastad et al. \(2012\)](#) investigated maternal concern as measured by a questionnaire (the Cambridge Worry Scale) distributed in week 35 of pregnancy. Women in the intervention group had a significantly lower worry score than those in the control group (mean=0.77, SD=0.55 for intervention and mean=0.90, SD=0.62 for control; difference=0.14, 95% CI 0.06 to 0.21, $p<0.001$). No significant difference in reporting concern about decreased fetal activity was seen between groups: 222 women (45%) in the intervention group and 211 women (42%) in the control group (RR=1.1, 95% CI 0.9 to 1.2, $p=0.37$).

Evidence suggests that fetal-movement counting does not affect fetal outcomes, which is consistent with current recommendations in [NICE CG62](#) not to offer this intervention routinely. Further research into the effect of fetal movement counting is needed, focusing on clinical outcomes such as stillbirth rates.

Key references

[Saastad E, Winje BA, Pedersen BS et al. \(2011\) Fetal movement counting improved identification of fetal growth restriction and perinatal outcomes – a multi-centre, randomized, controlled trial. PLoS One 6: e28482](#)

[Saastad E, Winje BA, Israel P et al. \(2012\) Fetal movement counting – maternal concern and experiences: a multicenter, randomized, controlled trial. Birth 39: 10–20](#)

1.11 [Management of specific clinical conditions](#)

No new key evidence was found for this section.

Areas not currently covered by NICE guidance

Periodontal treatment

[NICE CG62](#) does not contain recommendations about dental treatment in pregnancy.

[George et al. \(2011\)](#) did a meta-analysis of 10 RCTs ($n=5645$) to evaluate whether periodontal treatment during pregnancy affected the rates of preterm birth or low birthweight babies. Trials were included if they compared periodontal treatment with control in pregnant women aged 18 years or older who had documented periodontal disease. Periodontal treatment included scaling or root planing or oral hygiene education. The primary outcome was preterm birth, low birthweight, and stillbirth.

Periodontal treatment was associated with a reduction in preterm birth (OR=0.65, 95% CI 0.45 to 0.93, $p=0.02$) and a reduction in low birthweight (OR=0.53, 95% CI 0.31 to 0.92, $p=0.02$). These outcomes had moderate heterogeneity. The rate of spontaneous abortion and stillbirth was not significantly different between treatment and control (OR=0.71, 95% CI 0.43 to 1.16, $p=0.17$), with low heterogeneity.

The authors noted several limitations of their study including possible publication and search biases, and differences in the definition of periodontal disease and exclusion criteria between studies. Additionally, the size of included studies varied, but the authors stated that they used a random-effects model to minimise the effect of sample size variation.

In an RCT, [Jeffcoat et al. \(2011\)](#) investigated whether successful periodontal treatment was associated with a reduction in spontaneous preterm birth. All participants were attending a single US hospital for obstetric and gynaecological care.

The trial consisted of 3 phases:

- determining the minimum severity of periodontal disease for inclusion
- treatment and
- analysis based on successful treatment.

Women participating in the first phase (n=75) to determine the criteria for severity of periodontal disease did not take part in the treatment or analysis phases. The number of sites at which gum attachment loss exceeded the threshold of 4 mm was counted at baseline. A receiver operating characteristic curve was created for preterm births against the number of sites of attachment loss exceeding 4 mm. These results showed the strongest association with preterm birth was 3 sites exceeding 4 mm. This value was then used as the minimum level of periodontal disease for inclusion in the treatment and analysis phases.

The treatment phase assessed periodontal treatment (dental scaling and root planing) plus oral hygiene instruction (n=160) versus control consisting of oral hygiene instruction only (n=162). Most participants were black (88%) and 90% had never seen a dentist for tooth cleaning. Overall, the preterm birth rate was 45.6% in the treatment group compared with 52.4% in the control group (p=0.13).

Success of treatment was determined after 20 weeks by an examiner blind to the woman's allocation and gestational age at delivery. Successful treatment was defined as resolution of gingivitis and no progression of attachment loss or increase in depth of periodontal probing. Unsuccessful treatment was defined as increased inflammation, increased periodontal probing depth, or attachment loss in at least 5 sites. Women whose treatment was successful had a significantly higher likelihood of full-term birth (adjusted OR=6.01, 95% CI 2.57 to 14.03, p<0.00001).

The authors did not discuss potential limitations of their study, although they noted that the results may not be extrapolated to populations other than that studied (predominantly black people with little previous dental care). However, the lack of reporting of drop-outs, missing data, and description of the oral hygiene instruction, and use of blinding only at the follow-up exam may affect the robustness of the results.

The evidence suggests that periodontal treatment may have an effect on reducing preterm birth, however further studies relevant to the UK healthcare setting are needed to support this conclusion; therefore no effect on [NICE CG62](#) is anticipated.

Key references

George A, Shamim S, Johnson M et al. (2011) [Periodontal treatment during pregnancy and birth outcomes: a meta-analysis of randomised trials](#). *International Journal of Evidence-Based Healthcare* 9: 122-47

Jeffcoat M, Parry S, Sammel M et al. (2011) [Periodontal infection and preterm birth: successful periodontal therapy reduces the risk of preterm birth](#). *BJOG* 118: 250-6

2 New evidence uncertainties

During the development of the Evidence Update, the following evidence uncertainties were identified for the UK Database of Uncertainties about the Effects of Treatments (UK DUETs).

Clinical examination of pregnant women

- [The effect of high and low gestational weight gain stratified by prepregnancy BMI, on post-pregnancy weight retention](#)
- [The effect of interventions to reduce gestational weight gain on long term post-partum weight retention](#)
- [Dietary and physical activity interventions on maternal weight in pregnant women for long term maternal and fetal outcomes](#)

Areas not currently covered by NICE guidance

- [Periodontal treatment \(scaling, root planing, oral hygiene education\) versus no treatment in pregnant women with periodontitis for reducing stillbirth, preterm birth and low birth weight](#)

Further evidence uncertainties for antenatal care can be found in the [UK DUETs database](#) and in the [NICE research recommendations database](#).

UK DUETs was established to publish uncertainties about the effects of treatments that cannot currently be answered by referring to reliable up-to-date systematic reviews of existing research evidence.

Appendix A: Methodology

Scope

The scope of this Evidence Update is taken from the scope of the reference guidance:

- [Antenatal care](#). NICE clinical guideline 62 (2008).

The high number of topics covered by the reference guidance and the volume of the available evidence resulted in amendments to the scope: systematic reviews and randomised controlled trials only were included; the themes of breech presentation and prolonged pregnancy were omitted on advice from the Chair; themes covered by subsequent NICE guidance or Evidence Updates were omitted; and geographical coverage was defined as developed countries only.

Searches

The literature was searched to identify studies and reviews relevant to the scope. Searches were conducted of the following databases, covering the dates 19 November 2010 (the end of the search period of the most recent decision on whether to [review NICE clinical guideline 62](#)) to 21 December 2012:

- CDSR (Cochrane Database of Systematic Reviews)
- CENTRAL (Cochrane Central Register of Controlled Trials)
- CINAHL (Cumulative Index to Nursing and Allied Health Literature)
- DARE (Database of Abstracts of Reviews of Effects)
- EMBASE (Excerpta Medica database)
- MEDLINE (Medical Literature Analysis and Retrieval System Online)
- NHS EED (Economic Evaluation Database)
- PreMEDLINE

Table 1 provides details of the MEDLINE search strategy used, which was adapted to search the other databases listed above. The search strategy was based on the searches used for the original guideline, with amendments to provide a focused set of results, which was thoroughly tested to ensure that comprehensiveness was not compromised. The search strategy was used in conjunction with validated Scottish Intercollegiate Guidelines Network [search filters for RCTs and systematic reviews](#).

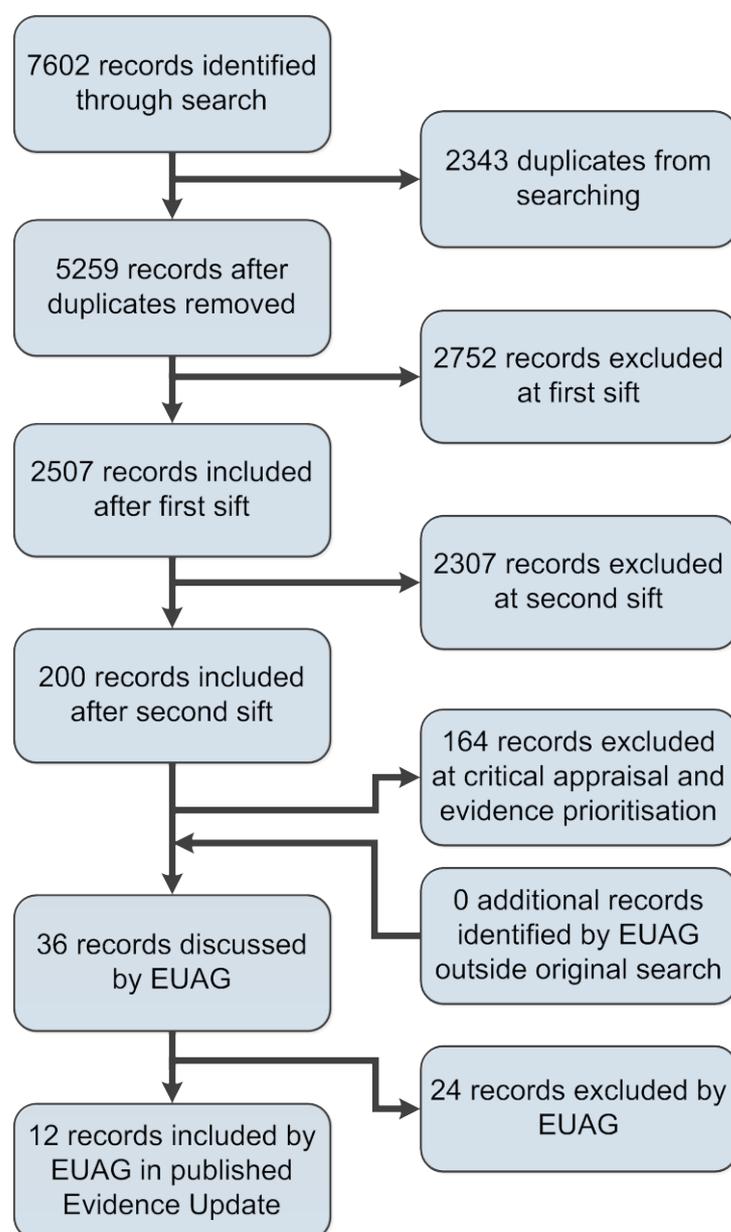
Figure 1 provides details of the evidence selection process. The long list of evidence excluded after review by the Chair of the EUAG, and the full search strategies, are available on request from contactus@evidence.nhs.uk

There is more information about [how NICE Evidence Updates are developed](#) on the NICE Evidence Services website.

Table 1 MEDLINE search strategy (adapted for individual databases)

1	exp Pregnancy/		pregnan\$ or trimester\$).ti,ab.
2	Pregnant women/	6	1 or 2 or 3 or 4 or 5
3	exp Prenatal care/	7	limit 6 to (english language and yr="2010 -Current")
4	exp Prenatal diagnosis/	8	limit 7 to ed=20101119-20121217
5	(antenatal\$ or ante natal\$ or ante-natal\$ or prenatal\$ or pre natal\$ or pre-natal\$ or maternity or obstetric\$ or		

Figure 1 Flow chart of the evidence selection process



EUAG – Evidence Update Advisory Group

Appendix B: The Evidence Update Advisory Group and Evidence Update project team

Evidence Update Advisory Group

The Evidence Update Advisory Group is a group of topic experts who review the prioritised evidence obtained from the literature search and provide the commentary for the Evidence Update.

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