NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

Review consultation document

Review of Clinical Guideline (CG62) -Antenatal care: routine care of the healthy pregnant woman

1. Background information

Guideline issue date: 2003
5 year review: 2008
8 year review: 2011
National Collaborating Centre: Women's and Children's Health

2. Consideration of the evidence

Literature search

From initial intelligence gathering and a high-level randomised control trial (RCT) search clinical areas were identified to inform the development of clinical questions for focused searches. Through this stage of the process 147 studies were identified relevant to the guideline scope. The identified studies were related to the following clinical areas within the guideline:

- Women-centred care (provision of information and antenatal classes)
- Lifestyle considerations (diet and exercise, prescribed medications, alternative therapies, nutritional supplements and smoking)
- Management of common symptoms of pregnancy (nausea and vomiting in early pregnancy and backache/pain)

- Clinical examination of pregnant women (pelvic examination and psychiatric screening)
- Screening for clinical problems (pre-eclampsia and gestational diabetes)
- Screening for haematological problems (sickle cell and thalassaemia, blood grouping and red cell autoantibodies)
- Screening for fetal anomalies (structural anomalies and Down's syndrome)
- Screening for infections (Toxoplasma, Chlamydia, HIV, Hepatitis B, streptococcus group B, bacterial vaginosis, syphilis and asymptomatic bacteriuria)
- Fetal growth and wellbeing (amniotic fluid volume, cardiotocography and ultrasound)

In particular, 24 Cochrane systematic reviews were identified through the initial intelligence gathering and RCT process. Twelve reviews presented conclusions that supported the current guideline recommendations particularly in relation to use of ultrasound, antenatal cardiotocography, support during pregnancy, management of back pain and vitamin A and iron supplementation. In addition, 12 reviews were unable to present definitive conclusions due to a paucity of RCTs on the topic. These reviews were related to screening for Down's syndrome, screening for gestational diabetes, antenatal education, fetal surveillance (in particular ultrasound, fetal movement counting and cardiotocography for fetal assessment) and management of nausea during pregnancy.

Two clinical questions were developed based on the clinical areas above, qualitative feedback from other NICE departments and the views expressed by the Guideline Development Group, for more focused literature searches. The results of the focused searches are summarised in the table below. In addition, the results of a focused search on screening for gestational diabetes

mellitus (GDM) conducted for the CG63: Diabetes in Pregnancy review has been included in the table below as the Antenatal Care guideline addresses screening for GDM. All references identified through the initial intelligence gathering, high-level RCT search and the focused searches can be viewed in Appendix 1.

Clinical area 1: Lifestyle considerations (vitamin D supplementation)		
Clinical question	**Summary of evidence**	**Relevance to guideline recommendations**
Q1: What is the effectiveness of routine vitamin D supplementation for pregnant and breastfeeding women? (research recommendation)	Through the focused search 11 studies relevant to the clinical question were identified. <u>Systematic reviews (three studies)</u> • A systematic review was identified which evaluated the evidence for the relationship between vitamin D, calcium and a combination of both nutrients on a wide range of health outcomes. Identified evidence was related to calcium and preeclampsia, hypertension in pregnancy, preterm birth or small infant for gestational age. • An additional review article evaluated the available data concerning vitamin D status and health effects of vitamin D in pregnancy through to and including adolescence. • A protocol for a Cochrane systematic review was identified. The aim	No new evidence was identified which would invalidate current guideline recommendations.

	of this review is to assess the effects and safety of vitamin D supplementation in pregnancy. <u>Vitamin D supplementation during pregnancy (three studies)</u> • One study investigated whether maternal vitamin D intake in pregnancy is associated with decreased risks of wheezing symptoms in young children. Lower vitamin D intakes during pregnancy were associated with decreased bronchodilator response although no associations were observed between maternal vitamin D intakes and spirometry or exhaled nitric oxide concentrations. • The effect of cholecalciferol supplementation during pregnancy on maternal 25-OH D at delivery was assessed in a study conducted in India. The results indicated that cholcalciferol in doses of 120 000 IU each in the fifth and seventh month of pregnancy was effective in raising 25-OH D at delivery. • A prospective RCT evaluated the effects of daily and of single-dose vitamin D supplementation during pregnancy. The results	

	demonstrated that the final maternal levels were higher in the group receiving supplementation. <u>Vitamin D supplementation during breastfeeding (five studies)</u> • A questionnaire study investigated the vitamin D status and the effect of vitamin D supplementation in Korean breast-fed infants. Three groups of newborns were identified: formula-fed, breast-fed only and breast-fed with vitamin D supplementation with serum concentrations of vitamin D and bone mineral density measured at 6 and 12 months of age. The results of the study indicated that breast-fed infants showed lower vitamin D status and bone mineralisation than formula-fed infants whilst vitamin D supplementation in breast-fed infants increased serum 25-OH vitamin D3 but not bone mineral density. • A cross-sectional study conducted in Turkey concluded that vitamin D intake of 400 IU/day was favourable during the first year for breastfed children although vitamin D deficiency was still evident after prophylaxis.	

	• A prospective trial conducted in the USA compared vitamin D supplementation with placebo in breast-fed infants. The results indicated that vitamin D supplementation did not reduce the risk of rickets in the study population. • The effect of combined maternal and infant vitamin D supplementation on the vitamin D status of the breast-fed infant was assessed in one RCT conducted in the Middle East. The results demonstrated that serum 25-OH D concentrations increased from baseline. Hypervitaminosis D was not observed. • One study was identified which assessed the effect of daily and monthly supplementation with vitamin D2 in nulliparous and lactating women within the United Arab Emirates. The results demonstrated that monthly dosing appeared to be a safe and effective alternative to daily dosing. In summary, identified evidence indicates that vitamin D supplementation during pregnancy and breastfeeding confers some benefit.	

Clinical area 2: Screening for Down's syndrome		
Clinical question	**Summary of evidence**	**Relevance to guideline recommendations**
Q2: What is the diagnostic value and effectiveness of screening methods in identifying babies with Down's syndrome?	Sixteen studies were identified through the focused search relating to this clinical question. <u>Systematic reviews (one study)</u> A protocol for a Cochrane systematic review was identified. The aim of this review is to compare the accuracy of screening tests (both individual markers and combinations of markers) for the detection of Down's syndrome during the antenatal period. <u>First trimester screening (nine studies)</u> *Combined test: nuchal translucency (NT), beta-human chorionic gonadotrophin (β-HCG) and pregnancy associated plasma protein-A (PAPP-A)* Five studies assessed the use of the combined test:	No new evidence was identified which would change the direction of current guideline recommendations.

	• A study conducted in Taiwan assessed detection rates of the combined test for trisomy 21, trisomy 18, Turner syndrome and other chromosome abnormalities in women <35 years of age during the first trimester. The detection rates for trisomy 21, trisomy 18, Turner syndrome and other chromosome abnormalities were 87.5%, 50%, 80% and 63% respectively with a false positive rate of 5.5%. • The performance of the combined test for screening for trisomy 21, trisomy 18 and trisomy 13 at 11 + 0 – 13 + 6 weeks gestation was assessed in one study. The detection risk and false positive rate were 90% and 3% respectively for trisomy 21, 91% and 0.2% for trisomy 18 and 87% and 0.2% for trisomy 13. • A new algorithm for screening for trisomy 21 was assessed in one study. The algorithm included a combination of maternal age, NT + β-HCG + PAPP-A at 11 + 0 – 13 + 6 weeks gestation. The detection rate of combined screening for maternal age, NT and biochemical markers was 90%.	

	• A study conducted in China concluded that first-trimester combined screening for trisomy 21 is effective. • The addition of ductus venous flow in the combined test for trisomies 21, 18 and 13 and Turner syndrome was assessed in one study. Assessment of ductus venous flow was conducted in all patients. First-stage screening using the combined test followed by ductus venous flow assessment was then carried out only in those patients with an intermediate risk after the first stage. Incorporation of ductus venous flow did not change the detection rate of trisomies 21, 18 and 13 and Turner syndrome however, the false positive rate decreased. *Fetal nasal bone (NB) evaluation* Two studies assessed the use of NB assessment for Down's syndrome screening during the first trimester following the combined test: • In one study incorporation of NB did not change the detection rate of trisomy 21 however, the false positive rate decreased.	

	• In the second study first-stage screening using the combined test was followed by NB assessment only in those patients with an intermediate risk after the first stage. Inclusion of the NB increased the detection rate. One study evaluated the role of NB assessment at 11-14 weeks gestation in screening for Down's syndrome. The results indicated that sensitivity and specificity of this screening method were 53.3% and 99.8% respectively. *Ultrasound* One study was identified which evaluated the value of choroid plexus cyst, intracardiac echogenic focus, hydronephrosis and hyperechogenic bowel as markers of trisomy 21 at 11 + 0 - 13 + 6 weeks. The results indicated that the prevalence of intracardiac echogenic focus, hydronephrosis and hyperechogenic bowel was higher in trisomy 21 compared with chromosomally normal fetuses.	

	<u>Second trimester screening (five studies)</u> *Double test:β-HCG + alpha-fetoprotein (AFP)* Second trimester screening for Down's syndrome at 14-19 weeks gestation combining ultrasound nuchal fold (NF) measurement with maternal serum biochemistry (AFP + β-HCG) was assessed in one study. The results indicated that the addition of NF to biochemical markers in the second trimester improved screening performance. *Triple test:(β-HCG + AFP + unconjugated estriol (uE3))* One study assessed the performance of triple screening in women at risk of Down's syndrome following the double test. The results indicated that compared with routine double screening, the detection rate of contingent triple screening increased by 10% without a significant increase in the false positive rate. *Quadruple test (β-HCG + AFP + uE3 + inhibin A)* A study conducted in Taiwan assessed the performance of the quadruple	

	test for Down's syndrome screening at 15-20 weeks gestation. The detection rate was 81.8% with a false positive rate of 4.4%. *Ultrasound* Two studies assessed the use of ultrasound for Down's syndrome screening during the second trimester: • One study evaluated the performance of ultrasound during second trimester screening (21 + 0 – 25 + 6 weeks gestation) for Down's syndrome. The detection rate for a combined test of ultrasound markers and maternal age was 72.2% with a false positive rate of 1%. • A modeling study assessed the effectiveness of screening for Down's syndrome through the sequential provision of second trimester serum tests and ultrasound. <u>First and second trimester screening (one study)</u> *Serum tests* A modeling study was identified which compared the detection rate of	

	different screening policies. Contingent screening included the combined test (*NT + β-HCG + PAPP-A)* at 11-13 weeks gestation with borderline risks recalculated using AFP + β-HCG + uE3 + inhibin A at 15-18 weeks gestation. Integrated screening included NT + PAPP-A and second trimester markers. The detection rates for contingent (false positive rate 4.5%) and integrated screening (false positive rate 4.9%) were 91% and 88% respectively. In summary, no new evidence was indentified which would change the direction of current guideline recommendations.	
Clinical area 3: Screening for gestational diabetes		
Clinical question	**Summary of evidence**	**Relevance to guideline recommendations**
Q3: What is the clinical and cost effectiveness of the three main available screening	The results of a focused search on screening for GDM conducted for the CG63: Diabetes in Pregnancy review has been included in this table as the Antenatal Care guideline addresses screening for GDM.	Potential new evidence (relating to the results of the HAPO study and the criteria for diagnosis of

techniques for gestational diabetes: risk factors, two-stage screening by the glucose challenge test and oral glucose tolerance test (OGTT), and universal OGTT (with or without fasting)? (This question was a research recommendation presented in the Diabetes in Pregnancy guideline).	Through the focused search 14 studies relevant to the clinical question were identified. <u>Systematic reviews (four studies)</u> Two systematic reviews were identified which reviewed the available evidence about the benefits and harms of screening for gestational diabetes mellitus (GDM). The review concluded that the literature is limited by lack of a consistent standard for screening or diagnosis of GDM. In addition, evidence on screening before 24 weeks gestation is sparse. A Cochrane systematic review assessed the effects of different methods of screening for GDM and maternal and infant outcomes. The review concluded that there was insufficient evidence to determine what types of screening for GDM can improve maternal and infant health outcomes. A Health Technology Assessment reviewed literature on screening for GDM and assessed the case for screening against the criteria set by the National Screening Committee. The results of the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study, Australian Carbohydrate	GDM). The Antenatal Care guideline should cross-refer to the Diabetes in Pregnancy guideline in terms of screening tests for GDM.

	Intolerance Study in Pregnant Women (ACHOIS) study and the Maternal Fetal Medicine Units Network (MFMUN) trial were reviewed. <u>Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study (three studies)</u> An article was identified which described the results of the HAPO study. Recommendations were made namely that diagnosis of GDM be made when any of the following 3.75-g, 2-hour oral glucose tolerance test thresholds are met or exceeded: fasting 92 mg/dl, 1-hour 180 mg/dl, or 2 hours 153 mg/dl. Similarly, two reviews of the HAPO study were identified. The reviews discussed the results of the HAPO study which demonstrated that fasting glucose levels and post 75 g OGTT are correlated to maternal, perinatal and neonatal outcomes. <u>Risk factors (one study)</u> One study assessed risk factors for GDM among pregnant Chinese women. Advanced maternal age, obesity and a family history of diabetes were found to be risk factors.	

	<u>Two-stage screening by the glucose challenge test (GCT) and oral glucose tolerance test (OGTT) (three studies)</u> Three studies were identified: • One study was identified which determined obstetric outcomes for pregnant women with a positive GCT but negative OGTT versus women with a negative GCT at 24-28 weeks gestation. Prevalence of preterm labour, hypertension, and caesarean delivery were similar in both groups. • A 5-year cohort study investigated GDM using new diagnostic criteria and predictive factors for maternal and fetal outcomes. Women underwent a 50-g GCT at 24-28 weeks gestation with diagnosis of GDM based on a one-hour plasma glucose level 140 mg/dl on the 50 g GCT, followed by at least two abnormal values on a 100-g OGTT. A value exceeding 90 mg/dl was 80% sensitive and 50% specific for macrosomia. • One study described the obstetric and postpartum metabolic significance of an abnormal GCT in women with a normal OGTT.	

	The results of the study indicated that an abnormal GCT even if followed by a normal OGTT is associated with postpartum glycemia and beta-cell dysfunction. <u>Universal OGTT (with or without fasting) (two studies)</u> Two studies were identified: • One study explored the impact of individual blood glucose values (fasting and 1, 2 and 3 hours following oral glucose administration) obtained during OGTT in predicting pregnancy outcomes and maternal insulin need. The number of abnormal OGTT values significantly contributed to insulin need during pregnancy. • A cohort study was identified which compared the different diagnostic criteria for GDM proposed by the American Diabetes Association (ADA), World Health Organization (WHO) and Australian Diabetes in Pregnancy Society (ADiPS) in a 75-g, 2-hour OGTT. The test was conducted at 24-28 weeks gestation and followed up to delivery. The frequency of occurrence of GDM was 6.1%, 12.1% and 18.8% in a 75-g OGTT based on ADA, WHO and	

	ADiPS criteria respectively. <u>Two-stage screening versus OGTT only (one study)</u> One study was identified which conducted a cost minimisation analysis of three methods of screening for GDM (group 1: 1-hour 50-g GCT and 100-g OGTT, group 2: 1-hour 50-g GCT and 75-g OGTT and group 3: 2-hour, 75-g OGTT). The study concluded that the two-step method provided better diagnostic accuracy and had lower costs compared with the one-step method. In summary, there is potential new evidence (relating to the results of the HAPO study and the criteria for diagnosis of GDM). The Antenatal Care guideline should cross-refer to the Diabetes in Pregnancy guideline in terms of screening tests for GDM.	

Several ongoing clinical trials (publication dates unknown) were identified focusing on prenatal nutritional supplementation (including vitamin D3 supplementation) and weight management for improved pregnancy outcomes.

Guideline Development Group and National Collaborating Centre perspective

A questionnaire was distributed to GDG members and the National Collaborating Centre to consult them on the need for an update of the guideline. Six responses were received with respondents highlighting that since publication of the guideline more literature has become available on screening for Down's syndrome and vitamin D supplementation as part of antenatal care. In addition, update of the National Screening Committee Fetal Anomaly Screening Programme (particularly relating to Down's syndrome screening) was highlighted by GDG members.

Ongoing research relevant to the guideline was highlighted by GDG members addressing obesity in pregnancy and appropriate interventions and screening for Down's syndrome (nasal bones, ductus venosus and tricuspid regurgitation in improving screening performance). This feedback contributed towards the development of the clinical questions for the focused searches.

Feedback from the NCC indicated that any review of the guideline should include:

- Risk assessment of women (enabling midwives and women to identify when women require additional care)

Four respondents agreed that there is insufficient variation in current practice supported by adequate evidence at this time to warrant an update of the current guideline.

Implementation and post publication feedback

In total 190 enquiries were received from post-publication feedback, most of which were routine. Key themes emerging from post-publication feedback were:

- Discrepancy over recommendations for caffeine intake in the NICE guideline and The Pregnancy Book (Department of Health publication)
- Queries regarding the recommendations relating to consumption of alcohol during pregnancy
- HypnoBirthing®, antenatal education to prepare for labour, birth and parenting

An analysis by the NICE implementation team highlighted several implementation studies relating to antenatal care from the published literature:

- A Confidential Enquiry into Maternal and Child Health (CEMACH) report on perinatal mortality
- Healthcare Commission review of maternity services in England
- A national Centre for Maternal and Child Enquiries (CMACE) report on maternal obesity in the UK

Qualitative input from the field team indicated that the guideline has been helpful although the size of the guideline has made it a challenge to implement. Additional practical issues were highlighted including screening for Down's syndrome and the challenge of working with partners, particularly when a pathway crosses numerous agencies.

Relationship to other NICE guidance

The following NICE guidance is related to CG62:

Guidance	Review date
CG110: A model for service provision for pregnant women with complex social factors, 2010.	Expected to be reviewed for update September 2013.
CG107: The management of hypertensive disorders during pregnancy, 2010.	Expected to be reviewed for update August 2013.
PH27: Dietary interventions and physical activity interventions for weight management before, during and after pregnancy, 2010.	Expected review date: TBC.
PH26: How to stop smoking in pregnancy and following childbirth, 2010.	Expected review date: TBC.
PH11: Guidance for midwives, health visitors, pharmacists and other primary care services to improve the nutrition of pregnant and breastfeeding mothers and children in low income households, 2008.	Expected review date: TBC.
PH10: Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities, 2008.	Expected review date: TBC.
TA156: Pregnancy - routine anti-D prophylaxis for rhesus negative women (review of TA41), 2008.	Expected to be reviewed for update May 2011.
CG70: Induction of labour, 2008.	Expected to be reviewed for

	update July 2011.
CG63: Diabetes in pregnancy, 2008.	Expected to be reviewed for update March 2011.
CG55: Intrapartum care, 2007.	Review decision published February 2011.
CG45: Antenatal and postnatal mental health: clinical management and service guidance, 2007.	Expected to be reviewed for update February 2012.
CG37: Postnatal care: routine postnatal care of women and their babies, 2006.	Expected to be reviewed for update July 2012.
Related NICE guidance in progress	
Clinical Guideline: Multiple pregnancy: the management of twin and triplet pregnancies in the antenatal period.	Currently in progress. Provisional publication date: September 2011.
Clinical Guideline: Pain and bleeding in early pregnancy.	Currently in progress.

Anti-discrimination and equalities considerations

No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation. The original guideline offers information on best practice for baseline clinical care of all pregnancies and comprehensive information on the antenatal care of the healthy woman with an uncomplicated singleton pregnancy.

Conclusion

Through the process no additional areas were identified which were not covered in the original guideline scope or would indicate a significant change in clinical practice. A review of the Diabetes in Pregnancy guideline (CG63) indicated that there is potential new evidence (relating to the results of the HAPO study and the criteria for diagnosis of GDM). As such, any future update of the recommendations relating to screening of GDM in the Diabetes in Pregnancy guideline would subsequently update the relevant section in the Antenatal Care guideline. No additional factors were identified which would invalidate or change the direction of current guideline recommendations. The Antenatal Care guideline should not be updated at this time.

3. Review recommendation

The guideline should not be updated at this time.

The guideline will be reviewed again according to current processes.

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07.03.11

Appendix I

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