

Issue date: March 2008 (reissued July 2008)

Diabetes in pregnancy

**Management of diabetes and its
complications from pre-conception to
the postnatal period**

NICE clinical guideline 63

Diabetes in pregnancy: management of diabetes and its complications from pre-conception to the postnatal period

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National Institute for Health and Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

www.nice.org.uk

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Introduction

Diabetes is a disorder of carbohydrate metabolism that requires immediate changes in lifestyle. In its chronic forms, diabetes is associated with long-term vascular complications, including retinopathy, nephropathy, neuropathy and vascular disease. Approximately 650,000 women give birth in England and Wales each year, and 2–5% of pregnancies involve women with diabetes. Approximately 87.5% of pregnancies complicated by diabetes are estimated to be due to gestational diabetes (which may or may not resolve after pregnancy), with 7.5% being due to type 1 diabetes and the remaining 5% being due to type 2 diabetes. The prevalence of type 1 and type 2 diabetes is increasing. In particular, type 2 diabetes is increasing in certain minority ethnic groups (including people of African, black Caribbean, South Asian, Middle Eastern and Chinese family origin).

Diabetes in pregnancy is associated with risks to the woman and to the developing fetus. Miscarriage, pre-eclampsia and preterm labour are more common in women with pre-existing diabetes. In addition, diabetic retinopathy can worsen rapidly during pregnancy. Stillbirth, congenital malformations, macrosomia, birth injury, perinatal mortality and postnatal adaptation problems (such as hypoglycaemia) are more common in babies born to women with pre-existing diabetes.

This clinical guideline contains recommendations for the management of diabetes and its complications in women who wish to conceive and those who are already pregnant. The guideline builds on existing clinical guidelines for routine care during the antenatal, intrapartum and postnatal periods. It focuses on areas where additional or different care should be offered to women with diabetes and their newborn babies.

Where the evidence supports it, the guideline makes separate recommendations for women with pre-existing diabetes (type 1 diabetes, type 2 diabetes and other forms of diabetes, such as maturity onset diabetes of the young) and gestational diabetes. The term 'women' is used in the guideline to

refer to all females of childbearing age, including young women who have not yet transferred from paediatric to adult services.

The guideline will assume that prescribers will use a drug's summary of product characteristics (SPC) to inform their decisions for individual women.

Woman- and baby-centred care

This guideline offers best practice advice on the care of women with diabetes who are planning to become pregnant, or who are already pregnant, and their newborn babies.

Treatment and care should take into account women's needs and preferences. Women with diabetes should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If women do not have the capacity to make decisions, healthcare professionals should follow the Department of Health guidelines – 'Reference guide to consent for examination or treatment' (2001) (available from www.dh.gov.uk). Healthcare professionals should also follow a code of practice accompanying the Mental Capacity Act (summary available from www.publicguardian.gov.uk).

Good communication between healthcare professionals and women is essential. It should be supported by evidence-based written information tailored to the woman's needs. Treatment and care, and the information women are given about it, should be culturally appropriate. It should also be accessible to women with additional needs such as physical, sensory or learning disabilities, and to women who do not speak or read English.

Care of young women in transition between paediatric and adult services should be planned and managed according to the best practice guidance described in 'Transition: getting it right for young people' (available from www.dh.gov.uk). Adult and paediatric healthcare teams should work jointly to provide care for young women with diabetes.

Key priorities for implementation

Pre-conception care

- Women with diabetes who are planning to become pregnant should be informed that establishing good glycaemic control before conception and continuing this throughout pregnancy will reduce the risk of miscarriage, congenital malformation, stillbirth and neonatal death. It is important to explain that risks can be reduced but not eliminated.
- The importance of avoiding unplanned pregnancy should be an essential component of diabetes education from adolescence for women with diabetes.
- Women with diabetes who are planning to become pregnant should be offered pre-conception care and advice before discontinuing contraception.

Antenatal care

- If it is safely achievable, women with diabetes should aim to keep fasting blood glucose between 3.5 and 5.9 mmol/litre and 1-hour postprandial blood glucose below 7.8 mmol/litre during pregnancy.
- Women with insulin-treated diabetes should be advised of the risks of hypoglycaemia and hypoglycaemia unawareness in pregnancy, particularly in the first trimester.
- During pregnancy, women who are suspected of having diabetic ketoacidosis should be admitted immediately for level 2 critical care¹, where they can receive both medical and obstetric care.
- Women with diabetes should be offered antenatal examination of the four-chamber view of the fetal heart and outflow tracts at 18–20 weeks.

¹ Level 2 critical care is defined as care for patients requiring detailed observation or intervention, including support for a single failing organ system or postoperative care and those 'stepping down' from higher levels of care.

Neonatal care

- Babies of women with diabetes should be kept with their mothers unless there is a clinical complication or there are abnormal clinical signs that warrant admission for intensive or special care.

Postnatal care

- Women who were diagnosed with gestational diabetes should be offered lifestyle advice (including weight control, diet and exercise) and offered a fasting plasma glucose measurement (but not an oral glucose tolerance test) at the 6-week postnatal check and annually thereafter.

1 Guidance

The following guidance is based on the best available evidence. The full guideline (www.nice.org.uk/CG063fullguideline) gives details of the methods and the evidence used to develop the guidance.

In this reissued guidance, the information on the therapeutic indications, contraindications and use in pregnancy and lactation of drugs used in diabetes management and retinal assessment (specifically insulins, the oral hypoglycaemic agents metformin and glibenclamide, and tropicamide) has been corrected to follow the relevant SPCs (July 2008). Changes have been made to the introduction, to recommendation 1.1.6.2 and to the footnotes of recommendations 1.1.6.1, 1.2.2.12 and 1.6.1.4. Footnotes have been deleted from recommendations 1.1.6.2, 1.1.6.3, 1.1.10.2, 1.3.3.1 and 1.3.4.1.

1.1 *Pre-conception care*

1.1.1 **Outcomes and risks for the woman and baby**

- 1.1.1.1 Healthcare professionals should seek to empower women with diabetes to make the experience of pregnancy and childbirth a positive one by providing information, advice and support that will help to reduce the risks of adverse pregnancy outcomes for mother and baby.
- 1.1.1.2 Women with diabetes who are planning to become pregnant should be informed that establishing good glycaemic control before conception and continuing this throughout pregnancy will reduce the risk of miscarriage, congenital malformation, stillbirth and neonatal death. It is important to explain that risks can be reduced but not eliminated.
- 1.1.1.3 Women with diabetes who are planning to become pregnant and their families should be offered information about how diabetes affects pregnancy and how pregnancy affects diabetes. The information should cover:

- the role of diet, body weight and exercise
- the risks of hypoglycaemia and hypoglycaemia unawareness during pregnancy
- how nausea and vomiting in pregnancy can affect glycaemic control
- the increased risk of having a baby who is large for gestational age, which increases the likelihood of birth trauma, induction of labour and caesarean section
- the need for assessment of diabetic retinopathy before and during pregnancy
- the need for assessment of diabetic nephropathy before pregnancy
- the importance of maternal glycaemic control during labour and birth and early feeding of the baby in order to reduce the risk of neonatal hypoglycaemia
- the possibility of transient morbidity in the baby during the neonatal period, which may require admission to the neonatal unit
- the risk of the baby developing obesity and/or diabetes in later life.

1.1.2 The importance of planning pregnancy and the role of contraception

1.1.2.1 The importance of avoiding unplanned pregnancy should be an essential component of diabetes education from adolescence for women with diabetes.

1.1.2.2 Women with diabetes who are planning to become pregnant should be advised:

- that the risks associated with pregnancies complicated by diabetes increase with the duration of diabetes

- to use contraception until good glycaemic control (assessed by HbA_{1c}²) has been established
- that glycaemic targets, glucose monitoring, medications for diabetes (including insulin regimens for insulin-treated diabetes) and medications for complications of diabetes will need to be reviewed before and during pregnancy
- that additional time and effort is required to manage diabetes during pregnancy and that there will be frequent contact with healthcare professionals. Women should be given information about the local arrangements for support, including emergency contact numbers.

1.1.3 Diet, dietary supplements, body weight and exercise

1.1.3.1 Women with diabetes who are planning to become pregnant should be offered individualised dietary advice.

1.1.3.2 Women with diabetes who are planning to become pregnant and who have a body mass index above 27 kg/m² should be offered advice on how to lose weight in line with 'Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children' (NICE clinical guideline 43), available from www.nice.org.uk/CG043.

1.1.3.3 Women with diabetes who are planning to become pregnant should be advised to take folic acid (5 mg/day) until 12 weeks of gestation to reduce the risk of having a baby with a neural tube defect.

1.1.4 Target ranges for blood glucose in the pre-conception period

1.1.4.1 Individualised targets for self-monitoring of blood glucose should be agreed with women who have diabetes and are planning to become pregnant, taking into account the risk of hypoglycaemia.

² Diabetes Control and Complications Trial (DCCT)-aligned haemoglobin A1c (HbA_{1c}) test.

1.1.4.2 If it is safely achievable, women with diabetes who are planning to become pregnant should aim to maintain their HbA_{1c} below 6.1%. Women should be reassured that any reduction in HbA_{1c} towards the target of 6.1% is likely to reduce the risk of congenital malformations.

1.1.4.3 Women with diabetes whose HbA_{1c} is above 10% should be strongly advised to avoid pregnancy.

1.1.5 Monitoring blood glucose and ketones in the pre-conception period

1.1.5.1 Women with diabetes who are planning to become pregnant should be offered monthly measurement of HbA_{1c}.

1.1.5.2 Women with diabetes who are planning to become pregnant should be offered a meter for self-monitoring of blood glucose.

1.1.5.3 Women with diabetes who are planning to become pregnant and who require intensification of hypoglycaemic therapy should be advised to increase the frequency of self-monitoring of blood glucose to include fasting and a mixture of pre- and postprandial levels.

1.1.5.4 Women with type 1 diabetes who are planning to become pregnant should be offered ketone testing strips and advised to test for ketonuria or ketonaemia if they become hyperglycaemic or unwell.

1.1.6 The safety of medications for diabetes before and during pregnancy

1.1.6.1 Women with diabetes may be advised to use metformin³ as an adjunct or alternative to insulin in the pre-conception period and

³ Metformin is used in UK clinical practice in the management of diabetes in pregnancy and lactation. There is strong evidence for its effectiveness and safety, which is presented in the full version of the guideline (www.nice.org.uk/CG063fullguideline). This evidence is not currently reflected in the SPC (July 2008). The SPC advises that when a patient plans to become pregnant and during pregnancy, diabetes should not be treated with metformin but insulin should be used to maintain blood glucose levels. Informed consent on the use of metformin in these situations should be obtained and documented.

during pregnancy, when the likely benefits from improved glycaemic control outweigh the potential for harm. All other oral hypoglycaemic agents should be discontinued before pregnancy and insulin substituted.

1.1.6.2 Healthcare professionals should be aware that data from clinical trials and other sources do not suggest that the rapid-acting insulin analogues (aspart and lispro) adversely affect the pregnancy or the health of the fetus or newborn baby.

1.1.6.3 Women with insulin-treated diabetes who are planning to become pregnant should be informed that there is insufficient evidence about the use of long-acting insulin analogues during pregnancy. Therefore isophane insulin (also known as NPH insulin) remains the first choice for long-acting insulin during pregnancy.

1.1.7 The safety of medications for diabetic complications before and during pregnancy

1.1.7.1 Angiotensin-converting enzyme inhibitors and angiotensin-II receptor antagonists should be discontinued before conception or as soon as pregnancy is confirmed. Alternative antihypertensive agents suitable for use during pregnancy should be substituted.

1.1.7.2 Statins should be discontinued before pregnancy or as soon as pregnancy is confirmed.

1.1.8 Removing barriers to the uptake of pre-conception care and when to offer information

1.1.8.1 Women with diabetes should be informed about the benefits of pre-conception glycaemic control at each contact with healthcare professionals, including their diabetes care team, from adolescence.

1.1.8.2 The intentions of women with diabetes regarding pregnancy and contraceptive use should be documented at each contact with their diabetes care team from adolescence.

1.1.8.3 Pre-conception care for women with diabetes should be given in a supportive environment and the woman's partner or other family member should be encouraged to attend.

1.1.9 Self-management programmes

1.1.9.1 Women with diabetes who are planning to become pregnant should be offered a structured education programme as soon as possible if they have not already attended one (see 'Guidance on the use of patient-education models for diabetes' [NICE technology appraisal guidance 60], available from www.nice.org.uk/TA060⁴).

1.1.9.2 Women with diabetes who are planning to become pregnant should be offered pre-conception care and advice before discontinuing contraception.

1.1.10 Retinal assessment in the pre-conception period

1.1.10.1 Women with diabetes seeking pre-conception care should be offered retinal assessment as detailed in recommendation 1.1.10.2 at their first appointment (unless an annual retinal assessment has occurred within the previous 6 months) and annually thereafter if no diabetic retinopathy is found.

1.1.10.2 Retinal assessment should be carried out by digital imaging with mydriasis using tropicamide, in line with the UK National Screening Committee's recommendations for annual mydriatic two-field digital photographic screening as part of a systematic screening programme.

⁴ 'Type 2 diabetes: the management of type 2 diabetes' (NICE clinical guideline 66), available from www.nice.org.uk/CG066, updates the information on type 2 diabetes in this technology appraisal.

1.1.10.3 Women with diabetes who are planning to become pregnant should be advised to defer rapid optimisation of glycaemic control until after retinal assessment and treatment have been completed.

1.1.11 Renal assessment in the pre-conception period

1.1.11.1 Women with diabetes should be offered a renal assessment, including a measure of microalbuminuria, before discontinuing contraception. If serum creatinine is abnormal (120 micromol/litre or more) or the estimated glomerular filtration rate (eGFR) is less than 45 ml/minute/1.73 m², referral to a nephrologist should be considered before discontinuing contraception.

1.2 Gestational diabetes

1.2.1 Risk factors for gestational diabetes

1.2.1.1 Healthcare professionals should be aware that the following have been shown to be independent risk factors for gestational diabetes:

- body mass index above 30 kg/m²
- previous macrosomic baby weighing 4.5 kg or above
- previous gestational diabetes
- family history of diabetes (first-degree relative with diabetes)
- family origin with a high prevalence of diabetes:
 - South Asian (specifically women whose country of family origin is India, Pakistan or Bangladesh)
 - black Caribbean
 - Middle Eastern (specifically women whose country of family origin is Saudi Arabia, United Arab Emirates, Iraq, Jordan, Syria, Oman, Qatar, Kuwait, Lebanon or Egypt).

1.2.2 Screening, diagnosis and treatment for gestational diabetes

The following recommendations, numbered 1.2.2.1, 1.2.2.2 and 1.2.2.3, are taken from 'Antenatal care: routine care for the healthy pregnant woman' (NICE clinical guideline 62), available from www.nice.org.uk/CG062.

1.2.2.1 Screening for gestational diabetes using risk factors is recommended in a healthy population. At the booking appointment, the following risk factors for gestational diabetes should be determined:

- body mass index above 30 kg/m²
- previous macrosomic baby weighing 4.5 kg or above
- previous gestational diabetes
- family history of diabetes (first-degree relative with diabetes)
- family origin with a high prevalence of diabetes:
 - South Asian (specifically women whose country of family origin is India, Pakistan or Bangladesh)
 - black Caribbean
 - Middle Eastern (specifically women whose country of family origin is Saudi Arabia, United Arab Emirates, Iraq, Jordan, Syria, Oman, Qatar, Kuwait, Lebanon or Egypt).

Women with any one of these risk factors should be offered testing for gestational diabetes (see recommendation 1.2.2.4).

1.2.2.2 In order to make an informed decision about screening and testing for gestational diabetes, women should be informed that:

- in most women, gestational diabetes will respond to changes in diet and exercise
- some women (between 10% and 20%) will need oral hypoglycaemic agents or insulin therapy if diet and exercise are not effective in controlling gestational diabetes

- if gestational diabetes is not detected and controlled there is a small risk of birth complications such as shoulder dystocia
- a diagnosis of gestational diabetes may lead to increased monitoring and interventions during both pregnancy and labour.

- 1.2.2.3 Screening for gestational diabetes using fasting plasma glucose, random blood glucose, glucose challenge test and urinalysis for glucose should not be undertaken.
- 1.2.2.4 The 2-hour 75 g oral glucose tolerance test (OGTT) should be used to test for gestational diabetes and diagnosis made using the criteria defined by the World Health Organization⁵. Women who have had gestational diabetes in a previous pregnancy should be offered early self-monitoring of blood glucose or an OGTT at 16–18 weeks, and a further OGTT at 28 weeks if the results are normal. Women with any of the other risk factors for gestational diabetes (see recommendation 1.2.2.1) should be offered an OGTT at 24–28 weeks.
- 1.2.2.5 Women with gestational diabetes should be instructed in self-monitoring of blood glucose. Targets for blood glucose control should be determined in the same way as for women with pre-existing diabetes.
- 1.2.2.6 Women with gestational diabetes should be informed that good glycaemic control throughout pregnancy will reduce the risk of fetal macrosomia, trauma during birth (to themselves and the baby), induction of labour or caesarean section, neonatal hypoglycaemia and perinatal death.

⁵ Fasting plasma venous glucose concentration greater than or equal to 7.0 mmol/litre or 2-hour plasma venous glucose concentration greater than or equal to 7.8 mmol/litre. World Health Organization Department of Noncommunicable Disease Surveillance (1999) Definition, diagnosis and classification of diabetes mellitus and its complications. Report of a WHO consultation. Part 1: diagnosis and classification of diabetes mellitus. Geneva: World Health Organization.

- 1.2.2.7 Women with gestational diabetes should be offered information covering:
- the role of diet, body weight and exercise
 - the increased risk of having a baby who is large for gestational age, which increases the likelihood of birth trauma, induction of labour and caesarean section
 - the importance of maternal glycaemic control during labour and birth and early feeding of the baby in order to reduce the risk of neonatal hypoglycaemia
 - the possibility of transient morbidity in the baby during the neonatal period, which may require admission to the neonatal unit
 - the risk of the baby developing obesity and/or diabetes in later life.
- 1.2.2.8 Women with gestational diabetes should be advised to choose, where possible, carbohydrates from low glycaemic index sources, lean proteins including oily fish and a balance of polyunsaturated fats and monounsaturated fats.
- 1.2.2.9 Women with gestational diabetes whose pre-pregnancy body mass index was above 27 kg/m² should be advised to restrict calorie intake (to 25 kcal/kg/day or less) and to take moderate exercise (of at least 30 minutes daily).
- 1.2.2.10 Hypoglycaemic therapy should be considered for women with gestational diabetes if diet and exercise fail to maintain blood glucose targets during a period of 1–2 weeks.
- 1.2.2.11 Hypoglycaemic therapy should be considered for women with gestational diabetes if ultrasound investigation suggests incipient fetal macrosomia (abdominal circumference above the 70th percentile) at diagnosis.

- 1.2.2.12 Hypoglycaemic therapy for women with gestational diabetes (which may include regular insulin, rapid-acting insulin analogues [aspart and lispro] and/or oral hypoglycaemic agents [metformin⁶ and glibenclamide⁷]) should be tailored to the glycaemic profile of, and acceptability to, the individual woman.

1.3 Antenatal care

This section should be read in conjunction with 'Antenatal care: routine care for the healthy pregnant woman' (NICE clinical guideline 62), available from www.nice.org.uk/CG062.

1.3.1 Target ranges for blood glucose during pregnancy

- 1.3.1.1 Individualised targets for self-monitoring of blood glucose should be agreed with women with diabetes in pregnancy, taking into account the risk of hypoglycaemia.
- 1.3.1.2 If it is safely achievable, women with diabetes should aim to keep fasting blood glucose between 3.5 and 5.9 mmol/litre and 1-hour postprandial blood glucose below 7.8 mmol/litre during pregnancy.
- 1.3.1.3 HbA_{1c} should not be used routinely for assessing glycaemic control in the second and third trimesters of pregnancy.

⁶ Metformin is used in UK clinical practice in the management of diabetes in pregnancy and lactation. There is strong evidence for its effectiveness and safety, which is presented in the full version of the guideline (www.nice.org.uk/CG063fullguideline). This evidence is not currently reflected in the SPC (July 2008). The SPC advises that when a patient plans to become pregnant and during pregnancy, diabetes should not be treated with metformin but insulin should be used to maintain blood glucose levels. Informed consent on the use of metformin in these situations should be obtained and documented.

⁷ Glibenclamide is used in UK clinical practice in the management of diabetes in pregnancy and lactation. There is strong evidence for its effectiveness and safety, which is presented in the full version of the guideline (www.nice.org.uk/CG063fullguideline). This evidence is not currently reflected in the SPC (July 2008). The SPC advises that glibenclamide is contraindicated in pregnancy. Informed consent on the use of glibenclamide in pregnancy should be obtained and documented.

1.3.2 Monitoring blood glucose and ketones during pregnancy

- 1.3.2.1 Women with diabetes should be advised to test fasting blood glucose levels and blood glucose levels 1 hour after every meal during pregnancy.
- 1.3.2.2 Women with insulin-treated diabetes should be advised to test blood glucose levels before going to bed at night during pregnancy.
- 1.3.2.3 Women with type 1 diabetes who are pregnant should be offered ketone testing strips and advised to test for ketonuria or ketonaemia if they become hyperglycaemic or unwell.

1.3.3 Management of diabetes during pregnancy

- 1.3.3.1 Healthcare professionals should be aware that the rapid-acting insulin analogues (aspart and lispro) have advantages over soluble human insulin during pregnancy and should consider their use.
- 1.3.3.2 Women with insulin-treated diabetes should be advised of the risks of hypoglycaemia and hypoglycaemia unawareness in pregnancy, particularly in the first trimester.
- 1.3.3.3 During pregnancy, women with insulin-treated diabetes should be provided with a concentrated glucose solution and women with type 1 diabetes should also be given glucagon; women and their partners or other family members should be instructed in their use.
- 1.3.3.4 During pregnancy, women with insulin-treated diabetes should be offered continuous subcutaneous insulin infusion (CSII or insulin pump therapy) if adequate glycaemic control is not obtained by multiple daily injections of insulin without significant disabling hypoglycaemia⁸.

⁸ For the purpose of this guidance, 'disabling hypoglycaemia' means the repeated and unpredicted occurrence of hypoglycaemia requiring third-party assistance that results in continuing anxiety about recurrence and is associated with significant adverse effect on quality of life.

1.3.3.5 During pregnancy, women with type 1 diabetes who become unwell should have diabetic ketoacidosis excluded as a matter of urgency.

1.3.3.6 During pregnancy, women who are suspected of having diabetic ketoacidosis should be admitted immediately for level 2 critical care⁹, where they can receive both medical and obstetric care.

1.3.4 Retinal assessment during pregnancy

1.3.4.1 Pregnant women with pre-existing diabetes should be offered retinal assessment by digital imaging with mydriasis using tropicamide following their first antenatal clinic appointment and again at 28 weeks if the first assessment is normal. If any diabetic retinopathy is present, an additional retinal assessment should be performed at 16–20 weeks.

1.3.4.2 If retinal assessment has not been performed in the preceding 12 months, it should be offered as soon as possible after the first contact in pregnancy in women with pre-existing diabetes.

1.3.4.3 Diabetic retinopathy should not be considered a contraindication to rapid optimisation of glycaemic control in women who present with a high HbA_{1c} in early pregnancy.

1.3.4.4 Women who have preproliferative diabetic retinopathy diagnosed during pregnancy should have ophthalmological follow-up for at least 6 months following the birth of the baby.

1.3.4.5 Diabetic retinopathy should not be considered a contraindication to vaginal birth.

⁹ Level 2 critical care is defined as care for patients requiring detailed observation or intervention, including support for a single failing organ system or postoperative care and those 'stepping down' from higher levels of care.

1.3.5 Renal assessment during pregnancy

1.3.5.1 If renal assessment has not been undertaken in the preceding 12 months in women with pre-existing diabetes, it should be arranged at the first contact in pregnancy. If serum creatinine is abnormal (120 micromol/litre or more) or if total protein excretion exceeds 2 g/day, referral to a nephrologist should be considered (eGFR should not be used during pregnancy). Thromboprophylaxis should be considered for women with proteinuria above 5 g/day (macroalbuminuria).

1.3.6 Screening for congenital malformations

1.3.6.1 Women with diabetes should be offered antenatal examination of the four-chamber view of the fetal heart and outflow tracts at 18–20 weeks.

1.3.7 Monitoring fetal growth and well-being

1.3.7.1 Pregnant women with diabetes should be offered ultrasound monitoring of fetal growth and amniotic fluid volume every 4 weeks from 28 to 36 weeks.

1.3.7.2 Routine monitoring of fetal well-being before 38 weeks is not recommended in pregnant women with diabetes, unless there is a risk of intrauterine growth restriction.

1.3.7.3 Women with diabetes and a risk of intrauterine growth restriction (macrovascular disease and/or nephropathy) will require an individualised approach to monitoring fetal growth and well-being.

1.3.8 Timetable of antenatal appointments

1.3.8.1 Women with diabetes who are pregnant should be offered immediate contact with a joint diabetes and antenatal clinic.

1.3.8.2 Women with diabetes should have contact with the diabetes care team for assessment of glycaemic control every 1–2 weeks throughout pregnancy.

1.3.8.3 Antenatal appointments for women with diabetes should provide care specifically for women with diabetes, in addition to the care provided routinely for healthy pregnant women (see ‘Antenatal care: routine care for the healthy pregnant woman’ [NICE clinical guideline 62], available from www.nice.org.uk/CG062). Table 1 describes where care for women with diabetes differs from routine antenatal care. At each appointment women should be offered ongoing opportunities for information and education.

Table 1 Specific antenatal care for women with diabetes

Appointment	Care for women with diabetes during pregnancy^a
First appointment (joint diabetes and antenatal clinic)	Offer information, advice and support in relation to optimising glycaemic control. Take a clinical history to establish the extent of diabetes-related complications. Review medications for diabetes and its complications. Offer retinal and/or renal assessment if these have not been undertaken in the previous 12 months.
7–9 weeks	Confirm viability of pregnancy and gestational age.
Booking appointment (ideally by 10 weeks)	Discuss information, education and advice about how diabetes will affect the pregnancy, birth and early parenting (such as breastfeeding and initial care of the baby).
16 weeks	Offer retinal assessment at 16–20 weeks to women with pre-existing diabetes who showed signs of diabetic retinopathy at the first antenatal appointment.
20 weeks	Offer four-chamber view of the fetal heart and outflow tracts plus scans that would be offered at 18–20 weeks as part of routine antenatal care.
28 weeks	Offer ultrasound monitoring of fetal growth and amniotic fluid volume. Offer retinal assessment to women with pre-existing diabetes who showed no diabetic retinopathy at their first antenatal clinic visit.
32 weeks	Offer ultrasound monitoring of fetal growth and amniotic fluid volume. Offer to nulliparous women all investigations that would be offered at 31 weeks as part of routine antenatal care.
36 weeks	Offer ultrasound monitoring of fetal growth and amniotic fluid volume. Offer information and advice about: <ul style="list-style-type: none"> • timing, mode and management of birth • analgesia and anaesthesia • changes to hypoglycaemic therapy during and after birth • management of the baby after birth • initiation of breastfeeding and the effect of breastfeeding on glycaemic control • contraception and follow-up.
38 weeks	Offer induction of labour, or caesarean section if indicated, and start regular tests of fetal well-being for women with diabetes who are awaiting spontaneous labour.
39 weeks	Offer tests of fetal well-being.
40 weeks	Offer tests of fetal well-being.
41 weeks	Offer tests of fetal well-being.
^a Women with diabetes should also receive routine care according to the schedule of appointments in ‘Antenatal care: routine care for the healthy pregnant woman’ (NICE clinical guideline 62), including appointments at 25 weeks (for nulliparous women) and 34 weeks, but with the exception of the appointment for nulliparous women at 31 weeks	

1.3.9 Preterm labour in women with diabetes

- 1.3.9.1 Diabetes should not be considered a contraindication to antenatal steroids for fetal lung maturation or to tocolysis.
- 1.3.9.2 Women with insulin-treated diabetes who are receiving steroids for fetal lung maturation should have additional insulin according to an agreed protocol and should be closely monitored.
- 1.3.9.3 Betamimetic drugs should not be used for tocolysis in women with diabetes.

1.4 Intrapartum care

This section should be read in conjunction with 'Intrapartum care: care of healthy women and their babies during childbirth' (NICE clinical guideline 55), available from www.nice.org.uk/CG055. This guideline includes information on timing and mode of birth for uncomplicated births at term.

1.4.1 Timing and mode of birth

- 1.4.1.1 Pregnant women with diabetes who have a normally grown fetus should be offered elective birth through induction of labour, or by elective caesarean section if indicated, after 38 completed weeks.
- 1.4.1.2 Diabetes should not in itself be considered a contraindication to attempting vaginal birth after a previous caesarean section.
- 1.4.1.3 Pregnant women with diabetes who have an ultrasound-diagnosed macrosomic fetus should be informed of the risks and benefits of vaginal birth, induction of labour and caesarean section.

1.4.2 Analgesia and anaesthesia

- 1.4.2.1 Women with diabetes and comorbidities such as obesity or autonomic neuropathy should be offered an anaesthetic assessment in the third trimester of pregnancy.

1.4.2.2 If general anaesthesia is used for the birth in women with diabetes, blood glucose should be monitored regularly (every 30 minutes) from induction of general anaesthesia until after the baby is born and the woman is fully conscious.

1.4.3 Glycaemic control during labour and birth

1.4.3.1 During labour and birth, capillary blood glucose should be monitored on an hourly basis in women with diabetes and maintained at between 4 and 7 mmol/litre.

1.4.3.2 Women with type 1 diabetes should be considered for intravenous dextrose and insulin infusion from the onset of established labour.

1.4.3.3 Intravenous dextrose and insulin infusion is recommended during labour and birth for women with diabetes whose blood glucose is not maintained at between 4 and 7 mmol/litre.

1.5 Neonatal care

1.5.1 Initial assessment and criteria for admission to intensive or special care

1.5.1.1 Women with diabetes should be advised to give birth in hospitals where advanced neonatal resuscitation skills are available 24 hours a day.

1.5.1.2 Babies of women with diabetes should be kept with their mothers unless there is a clinical complication or there are abnormal clinical signs that warrant admission for intensive or special care.

1.5.1.3 Blood glucose testing should be carried out routinely in babies of women with diabetes at 2–4 hours after birth. Blood tests for polycythaemia, hyperbilirubinaemia, hypocalcaemia and hypomagnesaemia should be carried out for babies with clinical signs.

1.5.1.4 Babies of women with diabetes should have an echocardiogram performed if they show clinical signs associated with congenital heart disease or cardiomyopathy, including heart murmur. The timing of the examination will depend on the clinical circumstances.

1.5.1.5 Babies of women with diabetes should be admitted to the neonatal unit if they have:

- hypoglycaemia associated with abnormal clinical signs
- respiratory distress
- signs of cardiac decompensation due to congenital heart disease or cardiomyopathy
- signs of neonatal encephalopathy
- signs of polycythaemia and are likely to need partial exchange transfusion
- need for intravenous fluids
- need for tube feeding (unless adequate support is available on the postnatal ward)
- jaundice requiring intense phototherapy and frequent monitoring of bilirubinaemia
- been born before 34 weeks (or between 34 and 36 weeks if dictated clinically by the initial assessment of the baby and feeding on the labour ward).

1.5.1.6 Babies of women with diabetes should not be transferred to community care until they are at least 24 hours old, and not before healthcare professionals are satisfied that the babies are maintaining blood glucose levels and are feeding well.

1.5.2 Prevention and assessment of neonatal hypoglycaemia

1.5.2.1 All maternity units should have a written policy for the prevention, detection and management of hypoglycaemia in babies of women with diabetes.

- 1.5.2.2 Babies of women with diabetes should have their blood glucose tested using a quality-assured method validated for neonatal use (ward-based glucose electrode or laboratory analysis).
- 1.5.2.3 Babies of women with diabetes should feed as soon as possible after birth (within 30 minutes) and then at frequent intervals (every 2–3 hours) until feeding maintains pre-feed blood glucose levels at a minimum of 2.0 mmol/litre.
- 1.5.2.4 If blood glucose values are below 2.0 mmol/litre on two consecutive readings despite maximal support for feeding, if there are abnormal clinical signs or if the baby will not feed orally effectively, additional measures such as tube feeding or intravenous dextrose should be given. Additional measures should only be implemented if one or more of these criteria are met.
- 1.5.2.5 Babies of women with diabetes who present with clinical signs of hypoglycaemia should have their blood glucose tested and be treated with intravenous dextrose as soon as possible.

1.6 Postnatal care

This section should be read in conjunction with ‘Postnatal care: routine postnatal care of women and their babies’ (NICE clinical guideline 37, available from www.nice.org.uk/CG037). This guideline includes information on the care that all women and babies should receive in the first 6–8 weeks after birth (including information about breastfeeding).

1.6.1 Breastfeeding and effects on glycaemic control

- 1.6.1.1 Women with insulin-treated pre-existing diabetes should reduce their insulin immediately after birth and monitor their blood glucose levels carefully to establish the appropriate dose.
- 1.6.1.2 Women with insulin-treated pre-existing diabetes should be informed that they are at increased risk of hypoglycaemia in the postnatal period, especially when breastfeeding, and they

should be advised to have a meal or snack available before or during feeds.

- 1.6.1.3 Women who have been diagnosed with gestational diabetes should discontinue hypoglycaemic treatment immediately after birth.
- 1.6.1.4 Women with pre-existing type 2 diabetes who are breastfeeding can resume or continue to take metformin¹⁰ and glibenclamide¹¹ immediately following birth but other oral hypoglycaemic agents should be avoided while breastfeeding.
- 1.6.1.5 Women with diabetes who are breastfeeding should continue to avoid any drugs for the treatment of diabetes complications that were discontinued for safety reasons in the pre-conception period.

1.6.2 Information and follow-up after birth

- 1.6.2.1 Women with pre-existing diabetes should be referred back to their routine diabetes care arrangements.
- 1.6.2.2 Women who were diagnosed with gestational diabetes should have their blood glucose tested to exclude persisting hyperglycaemia before they are transferred to community care.
- 1.6.2.3 Women who were diagnosed with gestational diabetes should be reminded of the symptoms of hyperglycaemia.
- 1.6.2.4 Women who were diagnosed with gestational diabetes should be offered lifestyle advice (including weight control, diet and exercise)

¹⁰ Metformin is used in UK clinical practice in the management of diabetes in pregnancy and lactation. There is strong evidence for its effectiveness and safety, which is presented in the full version of the guideline (www.nice.org.uk/CG063fullguideline). This evidence is not currently reflected in the SPC (July 2008). The SPC advises that metformin is contraindicated in lactation. Informed consent on the use of metformin during lactation should be obtained and documented.

¹¹ Glibenclamide is used in UK clinical practice in the management of diabetes in pregnancy and lactation. There is strong evidence for its effectiveness and safety, which is presented in the full version of the guideline (www.nice.org.uk/CG063fullguideline). This evidence is not currently reflected in the SPC (July 2008). The SPC advises that there is insufficient/limited information on the excretion of glibenclamide in human or animal breast milk. Informed consent on the use of glibenclamide during lactation should be obtained and documented.

and offered a fasting plasma glucose measurement (but not an OGTT) at the 6-week postnatal check and annually thereafter.

- 1.6.2.5 Women who were diagnosed with gestational diabetes (including those with ongoing impaired glucose regulation) should be informed about the risks of gestational diabetes in future pregnancies and they should be offered screening (OGTT or fasting plasma glucose) for diabetes when planning future pregnancies.
- 1.6.2.6 Women who were diagnosed with gestational diabetes (including those with ongoing impaired glucose regulation) should be offered early self-monitoring of blood glucose or an OGTT in future pregnancies. A subsequent OGTT should be offered if the test results in early pregnancy are normal (see recommendation 1.2.2.4).
- 1.6.2.7 Women with diabetes should be reminded of the importance of contraception and the need for pre-conception care when planning future pregnancies.

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available from <http://www.nice.org.uk/page.aspx?o=284822>

How this guideline was developed

NICE commissioned the National Collaborating Centre for Women's and Children's Health to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations. An independent Guideline Review Panel oversaw the development of the guideline (see appendix B).

There is more information in the booklet: 'The guideline development process: an overview for stakeholders, the public and the NHS' (third edition, published

April 2007), which is available from www.nice.org.uk/guidelinesprocess or by telephoning NICE publications on 0845 003 7783 or emailing publications@nice.org.uk (quote reference N1233).

3 Implementation

The Healthcare Commission assesses the performance of NHS organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health'. Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/CG063).

- Slides highlighting key messages for local discussion.
- Costing tools:
 - costing report to estimate the national savings and costs associated with implementation
 - costing template to estimate the local costs and savings involved.
- Audit support for monitoring local practice.

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and the care of women with diabetes and their newborn babies in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline (see section 5).

4.1 *Screening, diagnosis and treatment for gestational diabetes*

What is the clinical and cost effectiveness of the three main available screening techniques for gestational diabetes: risk factors, two-stage

screening by the glucose challenge test and OGTT, and universal OGTT (with or without fasting)?

Why this is important

Following the Australian carbohydrate intolerance study in pregnant women (ACHOIS) it seems that systematic screening for gestational diabetes may be beneficial to the UK population. A multicentre randomised controlled trial is required to test the existing screening techniques, which have not been systematically evaluated for clinical and cost effectiveness (including acceptability) within the UK.

4.2 *Monitoring blood glucose and ketones during pregnancy*

How effective is ambulatory continuous blood glucose monitoring in pregnancies complicated by diabetes?

Why this is important

The technology for performing ambulatory continuous blood glucose monitoring is only just becoming available, so there is currently no evidence to assess its effectiveness outside the laboratory situation. Research is needed to determine whether the technology is likely to have a place in the clinical management of diabetes in pregnancy. The new technology may identify women in whom short-term postprandial peaks of glycaemia are not detected by intermittent blood glucose testing. The aim of monitoring is to adjust insulin regimens to reduce the incidence of adverse outcomes of pregnancy (for example, fetal macrosomia, caesarean section and neonatal hypoglycaemia), so these outcomes should be assessed as part of the research.

4.3 *Management of diabetes during pregnancy*

Do new-generation CSII pumps offer an advantage over traditional intermittent insulin injections in terms of pregnancy outcomes in women with type 1 diabetes?

Why this is important

Randomised controlled trials have shown no advantage or disadvantage of using CSII pumps over intermittent insulin injections in pregnancy. A new generation of CSII pumps may offer technological advantages that would make a randomised controlled trial appropriate, particularly with the availability of insulin analogues (which may have improved the effectiveness of intermittent insulin injections).

4.4 *Monitoring fetal growth and well-being*

How can the fetus at risk of intrauterine death be identified in women with diabetes?

Why this is important

Unheralded intrauterine death remains a significant contributor to perinatal mortality in pregnancies complicated by diabetes. Conventional tests of fetal well-being (umbilical artery Doppler ultrasound, cardiotocography and other biophysical tests) have been shown to have poor sensitivity for predicting such events. Alternative approaches that include measurements of liquor erythropoietin and magnetic resonance imaging spectroscopy may be effective, but there is currently insufficient clinical evidence to evaluate them. Well-designed randomised controlled trials that are sufficiently powered are needed to determine whether these approaches are clinically and cost effective.

4.5 *Glycaemic control during labour and birth*

What is the optimal method for controlling glycaemia during labour and birth?

Why this is important

Epidemiological studies have shown that poor glycaemic control during labour and birth is associated with adverse neonatal outcomes (in particular, neonatal hypoglycaemia and respiratory distress). However, no randomised controlled trials have compared the effectiveness of intermittent subcutaneous insulin injections and/or CSII with that of intravenous dextrose plus insulin during labour and birth. The potential benefits of intermittent insulin injections and/or CSII over intravenous dextrose plus insulin during the intrapartum

period include patient preference due to the psychological effect of the woman feeling in control of her diabetes and having increased mobility. Randomised controlled trials are therefore needed to evaluate the safety of intermittent insulin injections and/or CSII during labour and birth compared with that of intravenous dextrose plus insulin.

5 Other versions of this guideline

5.1 Full guideline

The full guideline, 'Diabetes in pregnancy: management of diabetes and its complications from pre-conception to the postnatal period', contains details of the methods and evidence used to develop the guideline. It is published by the National Collaborating Centre for Women's and Children's Health, and is available from www.ncc-wch.org.uk, our website (www.nice.org.uk/CG063fullguideline) and the National Library for Health (www.nlh.nhs.uk).

5.2 Quick reference guide

A quick reference guide for healthcare professionals is available from www.nice.org.uk/CG063quickrefguide

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N1484).

5.3 Understanding NICE guidance

Information for women with diabetes ('Understanding NICE guidance') is available from www.nice.org.uk/CG063publicinfo

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N1485).

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about diabetes in pregnancy.

6 Related NICE guidance

Published

Induction of labour. NICE clinical guideline 70 (2008). Available from www.nice.org.uk/CG070

Type 2 diabetes: the management of type 2 diabetes. NICE clinical guideline 66 (2008). Available from www.nice.org.uk/CG066

Antenatal care: routine care for the healthy pregnant woman. NICE clinical guideline 62 (2008). Available from www.nice.org.uk/CG062

Intrapartum care: care of healthy women and their babies during childbirth. NICE clinical guideline 55 (2007). Available from www.nice.org.uk/CG055

Postnatal care: routine postnatal care of women and their babies. NICE clinical guideline 37 (2006). Available from www.nice.org.uk/CG037

Type 1 diabetes: diagnosis and management of type 1 diabetes in children, young people and adults. NICE clinical guideline 15 (2004). Available from www.nice.org.uk/CG015

Caesarean section. NICE clinical guideline 13 (2004). Available from www.nice.org.uk/CG013

Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. NICE technology appraisal guidance 151 (2008). Available from www.nice.org.uk/TA151

Guidance on the use of patient-education models for diabetes. NICE technology appraisal guidance 60 (2003). Available from www.nice.org.uk/TA060

Guidance on the use of glitazones for the treatment of type 2 diabetes. NICE technology appraisal guidance 63 (2003). Available from www.nice.org.uk/TA063

Guidance on the use of long-acting insulin analogues for the treatment of diabetes – insulin glargine. NICE technology appraisal guidance 53 (2002). Available from www.nice.org.uk/TA053

Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households. NICE public health guidance 11 (2008). Available from www.nice.org.uk/PH011

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

- Diabetes (type 2): newer agents for blood glucose control. NICE short clinical guideline (publication expected February 2009).

7 Updating the guideline

NICE clinical guidelines are updated as needed so that recommendations take into account important new information. We check for new evidence 2 and 4 years after publication, to decide whether all or part of the guideline should be updated. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations.

Appendix A: The Guideline Development Group

Dominique Acolet (until October 2007)

Clinical Director (Perinatal Epidemiology), Confidential Enquiry into Maternal and Child Health (CEMACH), London

Lynne Carney

Development Officer, Fair Share Trust, Community Foundation for Shropshire and Telford (Lay Representative)

Anne Dornhorst

Consultant Physician and Honorary Senior Lecturer in Metabolic Medicine, Hammersmith Hospital, London

Robert Fraser

Reader in Obstetrics and Gynaecology, University of Sheffield

Roger Gadsby

General Practitioner, Nuneaton, and Senior Lecturer in Primary Care, University of Warwick

Jane Hawdon (from October 2007)

Consultant Neonatologist, University College Hospitals London NHS Foundation Trust

Richard Holt

Reader of Endocrinology and Metabolism, University of Southampton

Ann Parker

Diabetes Advisory Midwife, Royal Shrewsbury Hospital

Nickey Tomkins

Advanced Nurse Practitioner in Diabetes/Diabetes Specialist Midwife, Medway Primary Care Trust, Kent

Stephen Walkinshaw

Consultant in Maternal and Fetal Medicine, Liverpool Women's Hospital

Jackie Webb

Diabetes Specialist Nurse Manager, Heart of England NHS Foundation Trust,
Birmingham

Saiyyidah Zaidi

Programme Manager, Building Schools for the Future, London (Lay
Representative)

NCC staff

Paula Broughton-Palmer

Senior Work Programme Coordinator

Michael Corkett

Senior Information Specialist

Anthony Danso-Appiah

Research Fellow

Paul Jacklin

Senior Health Economist

Lorelei Jones

Research Fellow, London School of Hygiene and Tropical Medicine (formerly
Research Fellow, National Collaborating Centre for Women's and Children's
Health)

Moira Mugglestone

Deputy Director

Jeffrey Round

Health Economist

Anuradha Sekhri

Research Fellow

Appendix B: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

Professor Mike Drummond – Chair

Director, Centre for Health Economics, University of York

Dr Graham Archard

General Practitioner, Dorset

Ms Karen Cowley

Practice Development Nurse, York

Mr Barry Stables

Lay member

Dr David Gillen

Medical Director, Wyeth Pharmaceuticals

Ms Catherine Arkley

Lay member