NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

DRAFT SCOPE

1 Guideline title

Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period.

1.1 Short title

Diabetes in pregnancy.

2 The remit

This is a partial update of ‘Diabetes in pregnancy' (NICE clinical guideline 63). See section 4.3.1 for details of which sections will be updated. We will also carry out an editorial review of all recommendations to ensure that they comply with NICE’s duties under equalities legislation.

This update is being undertaken as part of the guideline review cycle.

3 Clinical need for the guideline

3.1 Epidemiology

a) Diabetes is a disorder of carbohydrate metabolism that requires immediate changes in lifestyle. In its chronic forms, diabetes is associated with major long-term complications, such as microvascular (for example, neuropathy, nephropathy and retinopathy) and macrovascular disease.

b) Diabetes that complicates pregnancy is becoming more common worldwide. Up to 5% of the approximately 700,000 women who give birth in England and Wales each year have diabetes.

c) Less than 1% of women have pre-existing diabetes. Within this 1%, around 75% have type 1 diabetes, 25% have type 2 diabetes and a small number have secondary diabetes (for example, cystic fibrosis-related or monogenic diabetes). The proportion of women with type 1 or type 2 diabetes varies depending upon the ethnic origins of the population. The duration of diabetes prior to conception also varies but is increasing because the average age of onset of type 1 diabetes is declining and more women are developing type 2 diabetes at an earlier age. This is important because duration of diabetes is one of the strongest factors associated with micro-vascular complications and therefore it is more likely that women will present with established retinopathy, nephropathy and neuropathy.

d) Gestational diabetes is defined as 'any degree of glucose intolerance with onset or first recognition during pregnancy'. This includes women whose glucose tolerance returns to normal after pregnancy and those who persist with glucose intolerance and may later be diagnosed with type 2 diabetes. The latter group, as much as 20% of the total, includes individuals who had unrecognised type 2 diabetes prior to pregnancy.

e) In the UK, at least 5% of women have gestational diabetes but this figure will vary greatly depending upon the local population. The incidence of gestational diabetes is increasing due to higher rates of obesity in the general population and more pregnancies in older women. Most of the risks of gestational diabetes occur in the second half of pregnancy because the majority of women affected are normoglycaemic at the time of conception.

f) Maternal risks of pre-existing diabetes include recurrent hypoglycaemia, progression of retinopathy, nephropathy, and increased incidence of pre-eclampsia (especially in women with micro-vascular disease) and operative delivery.

g) Fetal risks of pre-existing maternal diabetes include structural congenital abnormality, pathological fetal growth (macrosomia) and ‘unexplained’ fetal death. Neonatal complications include premature delivery, respiratory distress syndrome, transient tachypnoea, birth trauma, hypoglycaemia, hypomagnesaemia, hypocalcaemia and polycythaemia.

3.2 Current practice

a) The additional care of women with diabetes in pregnancy, as set out in NICE clinical guideline 63, can be considered according to the stage of the pregnancy.

b) Preconception care aims to enable women with established diabetes to have a positive experience of pregnancy and childbirth and to minimise the risk of structural abnormalities in the fetus. It includes information-giving and education, and emphasises the importance of planning pregnancy. Offering assessment for and management of diabetes complications, improving blood glucose control, folic acid supplementation and change of potentially teratogenic medications are also important components of this stage of care.

c) Identification of gestational diabetes is a routine element of antenatal care for all women, as set out in 'Antenatal care' (NICE clinical guideline 62). A risk factor based screening approach is recommended to identify women with gestational diabetes.

d) Antenatal care of women with diabetes follows a multidisciplinary approach characterised by an increased schedule of appointments. Care includes:

- regular blood glucose testing (fasting or preprandial, and 1-hour postprandial)
- treating diabetes with diet, insulin and/or oral hypoglycaemic drugs to maintain blood glucose profile in the normal range

- use of concentrated glucose solutions or glucagon to treat hypoglycaemic episodes
- vigilance for diabetic ketoacidosis
- regular ophthalmic review and specialist referral if necessary
- review of renal function and specialist referral if necessary
- vigilance for pre-eclampsia.

e) Antenatal care for the fetus includes offering monitoring of fetal growth and wellbeing. In special cases, monitoring may need to be individualised.

f) Care during labour includes offering elective birth after 38 completed weeks of pregnancy, maintaining blood glucose levels in the normal range and continuous electronic fetal heart rate monitoring.

g) Postnatal care for women with diabetes includes:

- resuming pre-pregnancy diabetes treatment in those with pre-existing diabetes
- stopping all diabetic treatment initiated during pregnancy in those with gestational diabetes and monitoring their blood glucose levels to confirm euglycaemia
- referring those with gestational diabetes who have persistently high blood glucose levels after delivery for management of their type 2 diabetes
- offering contraceptive advice.

h) Additional postnatal and neonatal care for women and their babies includes encouraging breastfeeding and vigilance to prevent neonatal hypoglycaemia.

i) Since publication of NICE clinical guideline 63, new evidence has been published on levels of hyperglycaemia in pregnancy. The blood glucose level at which intervention becomes cost effective

and the importance that should be given to different outcomes remain issues for debate.

j) Consideration is also being given to early screening in pregnancy to identify and treat women with gestational diabetes who may have undiagnosed pre-existing diabetes and be unaware of the risk of diabetes in pregnancy.

k) New evidence has also been identified that may alter recommendations on:

- target ranges for preconception care
- continuous glucose monitoring
- the appropriate test to undertake at the postnatal check-up to diagnose type 2 diabetes in women who had gestational diabetes in pregnancy but who are euglycaemic on discharge to community care.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

For the topic of screening for gestational diabetes:

a) All pregnant women who do not have previously diagnosed diabetes (new 2012).

For all other topics:

b) Women of reproductive age who have pre-existing diabetes or who develop diabetes during pregnancy, and their newborn babies.

c) Where the evidence supports it, the following subgroups will be given special consideration:

- women of reproductive age with type 1 or type 2 diabetes.
- women with gestational diabetes or a history of gestational diabetes.
- young women of reproductive age with diabetes whose care has not yet transferred from paediatric to adult services.

4.1.2 Groups that will not be covered

For the topic of screening for gestational diabetes:

a) Women of reproductive age who are not pregnant (new 2012)

b) Women who have previously diagnosed type 1 or type 2 diabetes (new 2012) .

For all other topics:

c) Women of reproductive age who do not have diabetes.

4.2 Healthcare setting

All healthcare settings.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

Areas from the original guideline that will be updated

a) Target ranges for HbA1c and blood glucose for women with type 1 and type 2 diabetes in the preconception period and for women with type 1, type 2 and gestational diabetes during pregnancy

b) Effectiveness of the following screening procedures, to detect women with gestational diabetes between 24–28 weeks:

- risk factor based screening
- urine test for glycosuria
- random blood glucose test
- 50 g oral glucose challenge test
- fasting blood glucose test
- HbA1c test.

c) Diagnostic criteria that should be used to diagnose diabetes in pregnant women using 75 g oral glucose tolerance test (OGTT). There are two options:

- World Health Organization (WHO)
- International Association of Diabetes and Pregnancy Study (IADPS).

d) The most effective (including adverse events and costeffectiveness) intervention(s) (alone or in combination) for women with gestational diabetes, including:

- lifestyle interventions (diet and/or exercise)
- drugs[1] (metformin, glibenclamide or insulin).

e) The effectiveness of continuous glucose monitoring in pregnant women with diabetes when compared with intermittent capillary blood glucose monitoring.

f) The effectiveness of specialist teams for pregnant women with type 1 or type 2 diabetes.

g) The gestational age specific risk of intrauterine death in type 1, type 2 and gestational diabetes and the optimal timing of delivery.

[1] Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

h) The comparative effectiveness of the following tests in the detection of type 2 diabetes after pregnancy in women who have had gestational diabetes (but are not hyperglycaemic before they are transferred to community care):

- fasting plasma glucose test
- HbA_{1c} test
- random blood glucose test
- glucose challenge test
- 75 g OGTT
- urinalysis.

i) The optimal timing of the postnatal test, following transfer to community care, to identify type 2 diabetes in women who have had gestational diabetes.

Areas not in the original guideline that will be included in the update

j) Effectiveness of the following screening procedures, to detect women with undetected impaired glucose intolerance in the first trimester:

- risk factor based screening
- urine test for glycosuria
- random blood glucose test
- 50 g oral glucose challenge test
- fasting blood glucose test
- HbA1c test.

4.3.2 Clinical issues that will not be covered

Areas from the original guideline that will not be updated

The following areas addressed in NICE clinical guideline 63 will not be updated (the existing recommendations will remain as current guidance):

a) All aspects of pre-conception care, gestational diabetes, antenatal care, intrapartum care, postnatal care that are not listed in section 4.3.1.

b) Neonatal care.

Areas not covered by the original guideline or the update

k) Aspects of routine antenatal, intrapartum and postnatal care that apply equally to women with or without diabetes.

c) Aspects of routine care for women with diabetes that do not change during the preconception, antenatal, intrapartum and postnatal periods.

d) Advice about contraception methods for women with diabetes.

e) Investigation, management and treatment of comorbidities, for example fertility problems or pre-eclampsia.

f) Management of morbidity in newborn babies of women with diabetes beyond initial assessment and diagnosis.

4.4 Main outcomes

Outcomes will vary by the type of clinical question and systematic review undertaken. No more than seven outcomes will be prioritised for each topic.

a) Diagnostic accuracy:

- sensitivity and specificity.

b) Effectiveness:

- diabetes-specific health-related quality of life.

c) Neonatal outcomes:

- admission to neonatal intensive care unit/special care baby unit/transitional care unit

- miscarriage, stillbirth (fetal death), neonatal or infant death
- macrosomia, large for gestational age, small for gestational age and intrauterine growth restriction
- neonatal hypoglycaemia requiring active management
- respiratory distress
- shoulder dystocia and birth trauma (bone fracture, nerve palsy)
- other neonatal complications (jaundice, polycythaemia, sepsis, hypocalcaemia, hypoxic ischaemic encephalopathy)
- congenital abnormality.

d) Maternal outcomes:

- maternal death
- perineal trauma
- preterm birth
- mode of birth (spontaneous vaginal, instrumental, caesarean section)
- mode of infant feeding
- diabetic complications (hypoglycaemia, diabetic ketoacidosis, retinopathy, nephropathy, macrovascular disease)
- antenatal and intrapartum complications in the unborn baby
- development of type 2 diabetes
- obstetric complications (haemorrhage, infection, thrombosis, admission to critical care, incontinence)
- diabetes control (HbA1c, fructosamine, mean glucose)
- postnatal mental health
- maternal health-related quality of life (validated questionnaire)
- maternal satisfaction.

4.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness

is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

4.6 Status

4.6.1 Scope

This is the consultation draft of the scope. The consultation dates are 4 July to 29 August 2012.

4.6.2 Timing

The development of the guideline recommendations is expected to begin in September/October 2012.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be updated

This guideline will update and replace parts of the following NICE guidance (in relation to gestational diabetes only):

- Antenatal care. NICE clinical guideline 62 (2008).

5.1.2 Related NICE guidance

- Caesarean section. NICE clinical guideline 132 (2011).
- Multiple pregnancy. NICE clinical guideline 129 (2011).
- Diabetic foot problems. NICE clinical guideline 119 (2011).
- Preventing type 2 diabetes. NICE public health guidance 35 (2011).
- Hypertension in pregnancy. NICE clinical guideline 107 (2010).
- Dietary interventions and physical activity interventions for weight management before, during and after pregnancy. NICE public health guidance 27 (2010).
- Type 2 diabetes: newer agents. NICE clinical guideline 87 (2009)

- Induction of labour. NICE clinical guideline 70 (2008).
- Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. NICE technology appraisal guidance 151 (2008).
- Intrapartum care. NICE clinical guideline 55 (2007).
- Antenatal and postnatal mental health. NICE clinical guideline 45 (2007).
- Routine postnatal care of women and their babies. NICE clinical guideline 37 (2006).
- Type 1 diabetes. NICE clinical guideline 15 (2004).
- Type 2 diabetes: prevention and management of foot problems. NICE clinical guideline 10 (2004).

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website):

- Preventing type 2 diabetes – risk identification and interventions for individuals at high risk. NICE public health guidance. Publication expected June 2012.
- Type 1 diabetes (update). NICE clinical guideline. Publication expected 2014.
- Type 2 diabetes (update). NICE clinical guideline. Publication expected 2014.
- Diabetes in children (update). NICE clinical guideline. Publication expected 2014.

6 Further information

Information on the guideline development process is provided in the following documents, available from the NICE website:

- 'How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS'
- 'The guidelines manual'.

Information on the progress of the guideline will also be available from the NICE website.