Diabetes in pregnancy: management from preconception to the postnatal period

NICE guideline
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Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.
This guideline replaces CG63.

This guideline is the basis of QS109 and QS22.

Overview

This guideline covers managing diabetes and its complications in women who are planning pregnancy or are already pregnant. It aims to improve the diagnosis of gestational diabetes and help women with diabetes to self-manage their blood glucose levels before and during pregnancy.

In December 2020, we reviewed the evidence and changed the recommendations on intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as ‘flash’) and real-time CGM (rtCGM) during pregnancy for women with type 1 diabetes.

Who is it for?

- Healthcare professionals
- Commissioners and providers
- Women with diabetes who are planning a pregnancy or are pregnant and women at risk of, or diagnosed with, gestational diabetes
Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE’s information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

Blood glucose and plasma glucose

'Blood glucose' is the more commonly used term. However, a lot of the evidence this guideline is based on uses 'plasma' rather than 'blood' glucose, and patient-held glucose meters and monitoring systems are calibrated to plasma glucose equivalents. Because of this, in this guideline we use the term 'blood glucose', except when referring to specific concentration values.

1.1 Preconception planning and care

Information about outcomes and risks for mother and baby

1.1.1 Provide information, advice and support, to empower women to have a positive experience of pregnancy and to reduce the risks of adverse pregnancy outcomes for mother and baby. [2008]

1.1.2 Explain to women with diabetes who are planning a pregnancy that:

- if they have good blood glucose control before conception and throughout their pregnancy, this will reduce the risk of miscarriage, congenital malformation, stillbirth and neonatal death but

- the risks can be reduced but not eliminated. [2008]
1.1.3 When women with diabetes are planning a pregnancy, provide them and their families with 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 impaired awareness of hypoglycaemia during pregnancy
- how nausea and vomiting in pregnancy can affect blood glucose 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 instrumental and caesarean section deliveries
- the need for diabetic retinopathy assessment before and during pregnancy
- the need for diabetic nephropathy assessment before pregnancy
- the importance of maternal blood glucose control during labour and birth, and the need for early feeding of the baby, in order to reduce the risk of neonatal hypoglycaemia
- the possibility of that the baby may have health problems in the first 28 days, and may need admitting to a neonatal unit
- the risk of the baby developing obesity, diabetes and/or other health problems in later life. [2008]

The importance of planning pregnancy and the role of contraception

1.1.4 Emphasise the importance of planning for pregnancy, as part of diabetes education from adolescence for women with diabetes. [2008, amended 2015]

1.1.5 Explain to women with diabetes that their choice of contraception should be based on their own preferences and any risk factors (covered in the Faculty of Sexual and Reproductive Healthcare UK medical eligibility criteria for contraceptive use). [2015]
1.1.6 Advise women with diabetes that they can use oral contraceptives. [2015]

1.1.7 Advise women with diabetes who are planning to become pregnant:

- that the risks associated with diabetes in pregnancy will increase the longer they have had diabetes
- to use contraception until they have good blood glucose control (assessed by HbA1c levels – see recommendation 1.1.18)
- that blood glucose targets, glucose monitoring, medicines for treating diabetes (including insulin regimens) and medicines for complications of diabetes will need to be reviewed before and during pregnancy
- that extra time and effort is needed to manage diabetes during pregnancy, and that more frequent contact is needed with healthcare professionals. [2015]

1.1.8 For women with diabetes who are planning a pregnancy, provide information about the local arrangements for support, including emergency contact numbers. [2015]

### Diet, dietary supplements and body weight

1.1.9 Offer individualised dietary advice to women with diabetes who are planning a pregnancy. [2008]

1.1.10 For women with diabetes who are planning a pregnancy and who have a body mass index (BMI) above 27 kg/m², offer advice on how to lose weight, in line with the NICE guideline on identifying, assessing and managing obesity. See the NICE guideline on BMI for guidance on using variations on the BMI cut-off, based on the risk for different ethnic groups. [2008]

1.1.11 Advise women with diabetes who are planning a pregnancy 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. [2008]
Monitoring blood glucose and ketones before pregnancy

1.1.12 Offer up to monthly measurement of HbA1c levels for women with diabetes who are planning a pregnancy. [2008, amended 2020]

1.1.13 Offer blood glucose meters for self-monitoring to women with diabetes who are planning a pregnancy. [2008]

1.1.14 If a woman with diabetes who is planning a pregnancy needs to intensify blood glucose-lowering therapy, advise her to monitor her blood glucose more often, to include fasting levels and a mixture of pre-meal and post-meal levels. [2008]

1.1.15 Offer blood ketone testing strips and a meter to women with type 1 diabetes who are planning a pregnancy, and advise them to test for ketonaemia if they become hyperglycaemic or unwell. [2015]

Target blood glucose and HbA1c levels before pregnancy

1.1.16 Agree individualised targets for self-monitoring of blood glucose with women who have diabetes and are planning a pregnancy, taking into account the risk of hypoglycaemia. [2008]

1.1.17 Advise women with type 1 diabetes who are planning a pregnancy to aim for the normal capillary plasma glucose target ranges:

- a fasting plasma glucose level of 5 mmol/litre to 7 mmol/litre on waking and
- a plasma glucose level of 4 mmol/litre to 7 mmol/litre before meals at other times of the day.

For more information, see the section on blood glucose targets in the NICE guideline on type 1 diabetes in adults. [2015]

1.1.18 Advise women with diabetes who are planning a pregnancy to aim to keep their HbA1c level below 48 mmol/mol (6.5%), if this is achievable without causing problematic hypoglycaemia. [2015]

1.1.19 Reassure women that any reduction in HbA1c level towards the target is
likely to reduce the risk of congenital malformations in the baby. [2015]

1.1.20 Strongly advise women with diabetes whose HbA1c level is above 86 mmol/mol (10%) not to get pregnant until their HbA1c level is lower, because of the associated risks (see recommendation 1.1.2). [2015]

Safety of medicines for diabetes before and during pregnancy

1.1.21 Women with diabetes may be advised to use metformin as an adjunct or alternative to insulin in the preconception period and during pregnancy, when the likely benefits from improved blood glucose control outweigh the potential for harm. Stop all other oral blood glucose-lowering agents before pregnancy, and use insulin instead. [2008]

1.1.22 Be aware that the available evidence on rapid-acting insulin analogues (aspart and lispro) does not show an adverse effect on the pregnancy or the health of baby. [2008]

1.1.23 Use isophane insulin (also known as NPH insulin) as the first choice for long-acting insulin during pregnancy. Consider continuing treatment with long-acting insulin analogues (insulin detemir or insulin glargine) for women with diabetes who have established good blood glucose control before pregnancy.

Note that this is an off-label use of long-acting insulin analogues. See NICE’s information on prescribing medicines. [2008, amended 2015]

Safety of medicines for complications of diabetes before and during pregnancy

1.1.24 Stop angiotensin-converting enzyme inhibitors and angiotensin-II receptor antagonists before conception, or as soon as pregnancy is confirmed. Use alternative antihypertensive agents that are suitable for pregnant women. [2008]

1.1.25 Stop statins before pregnancy, or as soon as pregnancy is confirmed. [2008]
Making it easier for women to access preconception care

1.1.26 From adolescence onwards, at every contact with women with diabetes:

- healthcare professionals (including the diabetes care team) should explain the benefits of preconception blood glucose control
- the diabetes care team should record the plans women have for pregnancy and conception. [2008]

1.1.27 Provide preconception care for women with diabetes in a supportive environment, and encourage partners or other family members to attend. [2008, amended 2015]

Education and advice

1.1.28 As early as possible, offer a structured education programme to women with diabetes who are planning a pregnancy (if they have not already attended one). For more guidance, see the education and information section in the NICE guideline on type 1 diabetes in adults, and the patient education section in the NICE guideline on type 2 diabetes in adults. [2008]

1.1.29 Offer preconception care and advice before stopping contraception for women with diabetes who are planning a pregnancy. [2008]

Retinal assessment before pregnancy

1.1.30 For women with diabetes who are seeking preconception care, offer a retinal assessment at their first appointment (unless they have had a retinal assessment in the last 6 months). [2008, amended 2020]

1.1.31 Advise women with diabetes who are planning a pregnancy to defer rapid optimisation of blood glucose control until after they have had retinal assessment and treatment. [2008]

Renal assessment before pregnancy

1.1.32 Offer women with diabetes a renal assessment (including a measure of
albuminuria) before stopping contraception. [2008, amended 2015]

1.1.33 Consider referring women with diabetes to a nephrologist before stopping contraception if:

- serum creatinine is 120 micromol/litre or more or
- the urinary albumin:creatinine ratio is greater than 30 mg/mmol or
- the estimated glomerular filtration rate (eGFR) is less than 45 ml/minute/1.73 m$^2$. [2008, amended 2015]

1.2 Gestational diabetes

Risk assessment, testing and diagnosis

Risk assessment

1.2.1 To help women make an informed decision about risk assessment and testing for gestational diabetes, explain that:

- some women find that gestational diabetes can be controlled with changes in diet and exercise
- most women with gestational diabetes will need oral blood glucose-lowering agents or insulin
- if gestational diabetes is not detected and controlled, there is a small increase in the risk of serious adverse birth complications such as shoulder dystocia
- women with gestational diabetes will need more monitoring, and may need more interventions during pregnancy and labour. [2015]

1.2.2 Assess the risk of gestational diabetes using risk factors in a healthy population. At the booking appointment, check for the following risk factors:

- BMI above 30 kg/m$^2$
• previous macrosomic baby weighing 4.5 kg or more

• previous gestational diabetes

• family history of diabetes (first-degree relative with diabetes)

• an ethnicity with a high prevalence of diabetes.

Offer women with any of these risk factors testing for gestational diabetes (see recommendations 1.2.5 to 1.2.7). [2008, amended 2015]

1.2.3 Do not use fasting plasma glucose, random blood glucose, HbA1c, glucose challenge test or urinalysis for glucose to assess the risk of developing gestational diabetes. [2015]

**Glycosuria detected by routine antenatal testing**

1.2.4 Consider further testing to exclude gestational diabetes in women who have the following reagent strip test results during routine antenatal care:

- glycosuria of 2+ or above on 1 occasion

- glycosuria of 1+ or above on 2 or more occasions. [2015]

**Testing**

1.2.5 Use the 75-g 2-hour oral glucose tolerance test (OGTT) to test for gestational diabetes in women with risk factors (see recommendation 1.2.2). [2015]

1.2.6 For women who have had gestational diabetes in a previous pregnancy, offer:

- early self-monitoring of blood glucose or

- a 75-g 2-hour OGTT as soon as possible after booking (whether in the first or second trimester), and a further 75-g 2-hour OGTT at 24 to 28 weeks if the results of the first OGTT are normal. [2015]

1.2.7 Offer women with any of the other risk factors for gestational diabetes (see recommendation 1.2.2) a 75-g 2-hour OGTT at 24 to 28 weeks.
Diagnosis

1.2.8 Diagnose gestational diabetes if the woman has either:

- a fasting plasma glucose level of 5.6 mmol/litre or above or

- a 2-hour plasma glucose level of 7.8 mmol/litre or above. [2015]

1.2.9 When women are diagnosed with gestational diabetes:

- offer a review with the joint diabetes and antenatal clinic within 1 week.

- tell their primary healthcare team (see also the section on continuity of care in the NICE guideline on patient experience in adult NHS services). [2015]

Interventions

1.2.10 Explain to women with gestational diabetes:

- the implications (both short and long term) of the diagnosis for her and her baby (including UK government advice on driving with diabetes)

- that good blood glucose control throughout pregnancy will reduce the risk of fetal macrosomia, trauma during birth (for her and her baby), induction of labour and/or caesarean section, neonatal hypoglycaemia, and perinatal death

- that treatment includes changes in diet and exercise, and could involve medicines. [2015]

1.2.11 Teach women with gestational diabetes how to self-monitor their blood glucose. [2015]

1.2.12 Use the same capillary plasma glucose target levels for women with gestational diabetes as for women with pre-existing diabetes (see recommendations 1.3.5 and 1.3.6). [2015]

1.2.13 Tailor blood glucose-lowering therapy to the blood glucose profile and personal preferences of the woman with gestational diabetes. [2015]
When women are diagnosed with gestational diabetes, offer advice about changes in diet and exercise. [2015]

Advise women with gestational diabetes to eat a healthy diet during pregnancy, and to switch from high to low glycaemic index food. [2015]

Refer all women with gestational diabetes to a dietitian. [2015]

Advise women with gestational diabetes to exercise regularly (for example, walking for 30 minutes after a meal). [2015]

For women with gestational diabetes who have a fasting plasma glucose level below 7 mmol/litre at diagnosis, offer a trial of diet and exercise changes. [2015]

If blood glucose targets are not met with diet and exercise changes within 1 to 2 weeks, offer metformin. [2015]

If metformin is contraindicated or unacceptable to the woman, offer insulin. [2015]

If blood glucose targets are not met with diet and exercise changes plus metformin, offer insulin as well. [2015]

For women with gestational diabetes who have a fasting plasma glucose level of 7.0 mmol/litre or above at diagnosis, offer:

- immediate treatment with insulin, with or without metformin and
- diet and exercise changes. [2015]

For women with gestational diabetes who have a fasting plasma glucose level of between 6.0 and 6.9 mmol/litre and complications such as macrosomia or hydramnios, consider:

- immediate treatment with insulin, with or without metformin and
- diet and exercise changes. [2015]
1.3  Antenatal care for women with diabetes

See also the NICE guideline on antenatal care for uncomplicated pregnancies.

Monitoring blood glucose

1.3.1  Advise pregnant women with type 1 diabetes to test their fasting, pre-meal, 1-hour post-meal and bedtime blood glucose levels daily. [2015]

1.3.2  Advise pregnant women with type 2 diabetes or gestational diabetes who are on a multiple daily insulin injection regimen to test their fasting, pre-meal, 1-hour post-meal and bedtime blood glucose levels daily. [2015]

1.3.3  Advise pregnant women with type 2 diabetes or gestational diabetes to test their fasting and 1-hour post-meal blood glucose levels daily if they are:

- managing their diabetes with diet and exercise changes alone or
- taking oral therapy (with or without diet and exercise changes) or single-dose intermediate-acting or long-acting insulin. [2015]

Target blood glucose levels

1.3.4  Agree individualised targets for self-monitoring of blood glucose with pregnant women with diabetes, taking into account the risk of hypoglycaemia. [2008]

1.3.5  Advise pregnant women with any form of diabetes to maintain their capillary plasma glucose below the following target levels, if these are achievable without causing problematic hypoglycaemia:

- fasting: 5.3 mmol/litre

and
• 1 hour after meals: 7.8 mmol/litre or
• 2 hours after meals: 6.4 mmol/litre. [2015]

1.3.6 Advise pregnant women with diabetes who are taking insulin to maintain their capillary plasma glucose level above 4 mmol/litre. [2015, amended 2020]

Monitoring HbA1c

1.3.7 Measure HbA1c levels at the booking appointment for all pregnant women with pre-existing diabetes, to determine the level of risk for the pregnancy. [2015]

1.3.8 Consider measuring HbA1c levels in the second and third trimesters of pregnancy for women with pre-existing diabetes, to assess the level of risk for the pregnancy. [2015]

1.3.9 Be aware that the level of risk for the pregnancy for women with pre-existing diabetes increases with an HbA1c level above 48 mmol/mol (6.5%). [2015]

1.3.10 Measure HbA1c levels when women are diagnosed with gestational diabetes, to identify women who may have pre-existing type 2 diabetes. [2015]

1.3.11 Do not routinely use HbA1c levels to assess a woman's blood glucose control in the second and third trimesters of pregnancy. [2008]

Managing diabetes during pregnancy

Insulin treatment and risks of hypoglycaemia

A 2020 Medicines and Healthcare products Regulatory Agency drug safety update highlights the need to rotate insulin injection sites within the same body area to avoid cutaneous amyloidosis.

1.3.12 Consider rapid-acting insulin analogues (aspart and lispro) for pregnant
women with diabetes. Be aware that these insulin analogues have advantages over soluble human insulin during pregnancy. [2008]

1.3.13 Advise women with insulin-treated diabetes of the risks of hypoglycaemia and impaired awareness of hypoglycaemia in pregnancy, particularly in the first trimester. [2008]

1.3.14 Advise pregnant women with insulin-treated diabetes to always have a fast-acting form of glucose available (for example, dextrose tablets or glucose-containing drinks). [2008, amended 2015]

1.3.15 Provide glucagon to pregnant women with type 1 diabetes, for use if needed. Explain to the woman and her partner or other family members how to use it. [2008, amended 2015]

1.3.16 Offer continuous subcutaneous insulin infusion (CSII; also known as insulin pump therapy) to pregnant women with insulin-treated diabetes who:

- are using multiple daily injections of insulin and

- do not achieve blood glucose control without significant disabling hypoglycaemia. [2008]

Continuous glucose monitoring

1.3.17 Offer real-time continuous glucose monitoring (rtCGM) to all pregnant women with type 1 diabetes to help them meet their pregnancy blood glucose targets and improve neonatal outcomes. [2020]

1.3.18 Offer intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as ‘flash’) to pregnant women with type 1 diabetes who are unable to use rtCGM or express a clear preference for isCGM. [2020]

1.3.19 Consider rtCGM for pregnant women who are on insulin therapy but do not have type 1 diabetes, if:
• they have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) or

• they have unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control. [2015, amended 2020]

1.3.20 For pregnant women who are using continuous glucose monitoring (CGM), a member of the joint diabetes and antenatal care team with expertise in these systems should provide education and support (including advising women about sources of out-of-hours support). [2020]

For a short explanation of why the committee made the 2020 recommendations and how they might affect practice, see the rationale and impact section on continuous glucose monitoring.

Full details of the evidence and the committee's discussion are in evidence review A: continuous glucose monitoring.

Ketone testing and diabetic ketoacidosis

1.3.21 Offer blood ketone testing strips and a meter to pregnant women with type 1 diabetes. Advise them to test for ketonaemia and to seek urgent medical advice if they become hyperglycaemic or unwell. [2015]

1.3.22 Advise pregnant women with type 2 diabetes or gestational diabetes to seek urgent medical advice if they become hyperglycaemic or unwell. [2015]

1.3.23 Test urgently for ketonaemia if a pregnant woman with any form of diabetes presents with hyperglycaemia or is unwell. [2015]

1.3.24 Immediately admit pregnant women with suspected diabetic ketoacidosis for level 2 critical care, where they can receive both medical and obstetric care. [2008]
Retinal assessment during pregnancy

1.3.25 After pregnant women with pre-existing diabetes have had their first antenatal clinic appointment:

- offer retinal assessment by digital imaging with mydriasis using tropicamide (unless they have had a retinal assessment in the last 3 months)
- if they have diabetic retinopathy, offer an additional retinal assessment at 16 to 20 weeks
- offer another retinal assessment at 28 weeks. [2008, amended 2015]

1.3.26 Diabetic retinopathy should not be considered a contraindication to rapid optimisation of blood glucose control in women who present with a high HbA1c in early pregnancy. [2008]

1.3.27 Diabetic retinopathy should not be considered a contraindication to vaginal birth. [2008]

Renal assessment during pregnancy

1.3.28 Arrange a renal assessment at first contact during the pregnancy for women with pre-existing diabetes, if they have not had 1 in the last 3 months. [2008, amended 2015]

1.3.29 Consider referring pregnant women with diabetes to a nephrologist if:

- their serum creatinine is 120 micromol/litre or more or
- the urinary albumin:creatinine ratio is greater than 30 mg/mmol or
- total protein excretion exceeds 0.5 g/day. [2008, amended 2015]

1.3.30 Do not use eGFR to measure kidney function in pregnant women. [2008, amended 2015]

1.3.31 Consider thromboprophylaxis for pregnant women with nephrotic range proteinuria above 5 g/day (albumin:creatinine ratio greater than 220 mg/mmol). [2008, amended 2015]
Preventing pre-eclampsia

1.3.32 For guidance on using antiplatelet agents to reduce the risk of pre-eclampsia in pregnant women with diabetes, see the section on antiplatelet agents in the NICE guideline on hypertension in pregnancy. [2015]

Detecting congenital malformations

1.3.33 Offer women with diabetes an ultrasound scan at 20 weeks to detect fetal structural abnormalities, including examination of the fetal heart (4 chambers, outflow tracts and 3 vessels). [2008, amended 2015]

Monitoring fetal growth and wellbeing

1.3.34 Offer pregnant women with diabetes ultrasound monitoring of fetal growth and amniotic fluid volume every 4 weeks from 28 to 36 weeks. [2008]

1.3.35 Routine monitoring of fetal wellbeing before 38 weeks is not recommended in pregnant women with diabetes, unless there is a risk of fetal growth restriction. This includes methods such as fetal umbilical artery doppler recording, fetal heart rate recording and biophysical profile testing. [2008, amended 2015]

1.3.36 Provide an individualised approach to monitoring fetal growth and wellbeing for women with diabetes and a risk of fetal growth restriction (macrovascular disease or nephropathy). [2008, amended 2015]

Organisation of antenatal care

1.3.37 Offer immediate contact with a joint diabetes and antenatal clinic to pregnant women with diabetes. [2008]

1.3.38 Joint diabetes and antenatal clinics should be in contact with women with diabetes every 1 to 2 weeks throughout pregnancy, for blood glucose control assessment. [2008, amended 2015]
1.3.39 At antenatal appointments, provide care specifically for women with diabetes, in addition to routine care for healthy pregnant women (see the NICE guideline on antenatal care for uncomplicated pregnancies). Table 1 describes how care for women with diabetes differs from routine antenatal care. [2008, amended 2015]

1.3.40 At each appointment, offer pregnant women with diabetes ongoing opportunities for information and education. [2008, amended 2015]
Table 1 Timetable of antenatal appointments

<table>
<thead>
<tr>
<th>Appointment</th>
<th>Care for women with diabetes during pregnancy</th>
</tr>
</thead>
</table>
| Booking appointment (joint diabetes and antenatal care) – ideally by 10 weeks | Discuss how diabetes will affect the pregnancy, birth and early parenting (such as breastfeeding and initial care of the baby). If the woman has not had preconception care:  
• give information, education and advice  
• take a clinical history to establish the extent of diabetes-related complications (including neuropathy and vascular disease), and review medicines for diabetes and its complications. If the woman has had preconception care, continue to provide information, education and advice on achieving optimal blood glucose control (including dietary advice). Offer retinal assessment for women with pre-existing diabetes unless the woman has been assessed in the last 3 months. Offer a renal assessment for women with pre-existing diabetes, if they have not had 1 in the last 3 months. Arrange contact with the joint diabetes and antenatal clinic every 1 to 2 weeks throughout pregnancy for all women with diabetes. Measure HbA1c levels for women with pre-existing diabetes to determine the level of risk for the pregnancy. Offer self-monitoring of blood glucose or a 75-g 2-hour oral glucose tolerance test (OGTT) as soon as possible for women with previous gestational diabetes who book in the first trimester. Confirm the viability of the pregnancy and gestational age at 7 to 9 weeks. |
<table>
<thead>
<tr>
<th>Appointment</th>
<th>Care for women with diabetes during pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 weeks</td>
<td>Offer retinal assessment at 16 to 20 weeks to women with pre-existing diabetes who had diabetic retinopathy at their first antenatal clinic visit. Offer self-monitoring of blood glucose or a 75-g 2-hour OGTT as soon as possible for women with previous gestational diabetes who book in the second trimester.</td>
</tr>
<tr>
<td>20 weeks</td>
<td>Offer an ultrasound scan to detect fetal structural abnormalities, including examination of the fetal heart (4 chambers, outflow tracts and 3 vessels).</td>
</tr>
<tr>
<td>28 weeks</td>
<td>Offer ultrasound monitoring of fetal growth and amniotic fluid volume. Offer retinal assessment to all women with pre-existing diabetes. Women diagnosed with gestational diabetes as a result of routine antenatal testing at 24 to 28 weeks enter the care pathway.</td>
</tr>
<tr>
<td>32 weeks</td>
<td>Offer ultrasound monitoring of fetal growth and amniotic fluid volume. Offer nulliparous women all routine investigations normally scheduled for 31 weeks in routine antenatal care.</td>
</tr>
<tr>
<td>34 weeks</td>
<td>No differences in care for women with diabetes.</td>
</tr>
<tr>
<td>Appointment</td>
<td>Care for women with diabetes during pregnancy</td>
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<tr>
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<tr>
<td>36 weeks</td>
<td>Offer ultrasound monitoring of fetal growth and amniotic fluid volume. Provide information and advice about:</td>
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<tr>
<td></td>
<td>• timing, mode and management of birth</td>
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<tr>
<td></td>
<td>• analgesia and anaesthesia</td>
</tr>
<tr>
<td></td>
<td>• changes to blood glucose-lowering therapy during and after birth</td>
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<tr>
<td></td>
<td>• care of the baby after birth</td>
</tr>
<tr>
<td></td>
<td>• starting to breastfeed and the effect of breastfeeding on blood glucose control</td>
</tr>
<tr>
<td></td>
<td>• contraception and follow-up.</td>
</tr>
<tr>
<td>37 weeks to 38</td>
<td>Offer induction of labour or (if indicated) caesarean section to women with type 1 or type 2 diabetes. Await spontaneous</td>
</tr>
<tr>
<td>weeks plus 6 days</td>
<td>labour for other women.</td>
</tr>
<tr>
<td>38 weeks</td>
<td>Offer tests of fetal wellbeing.</td>
</tr>
<tr>
<td>39 weeks</td>
<td>Offer tests of fetal wellbeing. Advise women with uncomplicated gestational diabetes to give birth no later than 40 weeks plus 6 days.</td>
</tr>
</tbody>
</table>

**Preterm labour in women with diabetes**

1.3.41 Diabetes should not be considered a contraindication to tocolysis or to antenatal steroids for fetal lung maturation. [2008]

1.3.42 For women with insulin-treated diabetes who are taking steroids for fetal lung maturation, give additional insulin according to an agreed protocol and monitor the woman closely. [2008, amended 2015]

1.3.43 Do not use betamimetic medicines for tocolysis in women with diabetes. [2008]
1.4 Intrapartum care

Timing and mode of birth

1.4.1 Discuss the timing and mode of birth with pregnant women with diabetes during antenatal appointments, especially during the third trimester. [2015]

1.4.2 Advise pregnant women with type 1 or type 2 diabetes and no other complications to have an elective birth by induced labour or (if indicated) caesarean section, between 37 weeks and 38 weeks plus 6 days of pregnancy. [2015]

1.4.3 Consider elective birth before 37 weeks for women with type 1 or type 2 diabetes who have metabolic or other maternal or fetal complications. [2015]

1.4.4 Advise women with gestational diabetes to give birth no later than 40 weeks plus 6 days. Offer elective birth by induced labour or (if indicated) by caesarean section to women who have not given birth by this time. [2015]

1.4.5 Consider elective birth before 40 weeks plus 6 days for women with gestational diabetes who have maternal or fetal complications. [2015]

1.4.6 Diabetes should not be considered a contraindication to vaginal birth after a previous caesarean section. [2008]

1.4.7 For pregnant women with diabetes who have an ultrasound-diagnosed macrosomic fetus, explain the risks and benefits of vaginal birth, induction of labour and caesarean section. [2008]

Anaesthesia

1.4.8 For women with diabetes and comorbidities such as obesity or autonomic neuropathy, offer an anaesthetic assessment in the third trimester of pregnancy. [2008]
1.4.9 If the woman has general anaesthesia for the birth, monitor blood glucose every 30 minutes from induction of general anaesthesia until after the baby is born and the woman is fully conscious. [2008]

Blood glucose control during labour and birth

1.4.10 Monitor capillary plasma glucose every hour during labour and birth for women with diabetes, and maintain it between 4 mmol/litre and 7 mmol/litre. [2008, amended 2015]

1.4.11 Consider intravenous dextrose and insulin infusion from the onset of established labour for women with type 1 diabetes. [2008]

1.4.12 Use intravenous dextrose and insulin infusion during labour and birth for women with diabetes whose capillary plasma glucose is not maintained between 4 mmol/litre and 7 mmol/litre. [2008, amended 2015]

1.5 Neonatal care

Initial assessment and criteria for admission to intensive or special care

1.5.1 Advise women with diabetes to give birth in hospitals where advanced neonatal resuscitation skills are available 24 hours a day. [2008]

1.5.2 Babies of women with diabetes should stay with their mothers, unless there are complications or abnormal clinical signs that mean the baby needs to be admitted to intensive or special care. [2008]

1.5.3 Carry out blood glucose testing routinely at 2 to 4 hours after birth in babies of women with diabetes. Carry out blood tests for babies with clinical signs of polycythaemia, hyperbilirubinaemia, hypocalcaemia or hypomagnesaemia. [2008]

1.5.4 Perform an echocardiogram for babies of women with diabetes if they show clinical signs associated with congenital heart disease or cardiomyopathy, including heart murmur. Base the timing of the
1.5.5 Admit babies of women with diabetes to the neonatal unit if they have:

- hypoglycaemia associated with abnormal clinical signs
- respiratory distress
- signs of cardiac decompensation from 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 the initial assessment of the baby and their feeding suggests this is clinically appropriate). [2008]

1.5.6 Do not transfer babies of women with diabetes to community care until:

- they are at least 24 hours old and
- you are satisfied that the baby is maintaining blood glucose levels and is feeding well. [2008]

Preventing and assessing neonatal hypoglycaemia

1.5.7 All maternity units should have a written policy for preventing, detecting and managing hypoglycaemia in babies of women with diabetes. [2008]

1.5.8 Test the blood glucose of babies of women with diabetes using a quality-assured method validated for neonatal use (ward-based glucose
1.5.9 Women with diabetes should feed their babies:

- as soon as possible after birth (within 30 minutes) and then
- at frequent intervals (every 2 to 3 hours) until feeding maintains their pre-feed capillary plasma glucose levels at a minimum of 2.0 mmol/litre. [2008, amended 2015]

1.5.10 Only use additional measures (such as tube feeding or intravenous dextrose) if:

- capillary plasma glucose values are below 2.0 mmol/litre on 2 consecutive readings despite maximal support for feeding or
- there are abnormal clinical signs or
- the baby will not effectively feed orally. [2008, amended 2015]

1.5.11 For babies with clinical signs of hypoglycaemia, test blood glucose levels and provide intravenous dextrose as soon as possible. [2008, amended 2015]

1.6 Postnatal care

Blood glucose control, medicines and breastfeeding

1.6.1 Women with insulin-treated pre-existing diabetes should reduce their insulin immediately after birth and monitor their blood glucose levels to find the appropriate dose. [2008]

1.6.2 Explain to women with insulin-treated pre-existing diabetes that they are at increased risk of hypoglycaemia in the postnatal period (especially when breastfeeding), and advise them to have a meal or snack available before or during feeds. [2008]

1.6.3 Women who have been diagnosed with gestational diabetes should stop blood glucose-lowering therapy immediately after birth. [2008]
1.6.4 Women with pre-existing type 2 diabetes who are breastfeeding can resume or continue metformin immediately after birth, but should avoid other oral blood glucose-lowering therapy while breastfeeding.

Note that this is an off-label use of metformin. See NICE’s information on prescribing medicines. [2008, amended 2020]

1.6.5 Women with diabetes who are breastfeeding should continue to avoid any medicines for their diabetes complications that were stopped for safety reasons when they started planning the pregnancy. [2008]

**Information and follow-up after birth**

**Women with pre-existing diabetes**

1.6.6 Refer women with pre-existing diabetes back to their routine diabetes care arrangements. [2008]

1.6.7 Remind women with diabetes of the importance of contraception and the need for preconception care when planning future pregnancies. [2008]

**Women diagnosed with gestational diabetes**

1.6.8 Before women who were diagnosed with gestational diabetes are transferred to community care, test their blood glucose to exclude persisting hyperglycaemia. [2008]

1.6.9 Remind women who were diagnosed with gestational diabetes of the symptoms of hyperglycaemia. [2008]

1.6.10 Explain to women who were diagnosed with gestational diabetes about the risks of recurrence in future pregnancies, and offer them diabetes testing when planning future pregnancies. [2008, amended 2015]

1.6.11 For women who were diagnosed with gestational diabetes and whose blood glucose levels returned to normal after the birth:

- offer lifestyle advice (including weight control, diet and exercise)
• offer a fasting plasma glucose test 6 to 13 weeks after the birth to exclude diabetes (for practical reasons this might take place at the 6-week postnatal check)

• after 13 weeks offer a fasting plasma glucose test if this has not been done earlier, or an HbA1c test if a fasting plasma glucose test is not possible

• do not routinely offer a 75-g 2-hour OGTT

• offer a referral into the NHS Diabetes Prevention Programme if eligible based on the results of the fasting plasma glucose test or HbA1c test. [2015, amended 2020]

1.6.12 For women having a fasting plasma glucose test as the postnatal test:

• Advise women with a fasting plasma glucose level below 6.0 mmol/litre that:
  – they have a low probability of having diabetes at the moment
  – they should continue to follow the lifestyle advice (including weight control, diet and exercise) given after the birth
  – they will need an annual test to check that their blood glucose levels are normal
  – they have a moderate risk of developing type 2 diabetes, and offer them advice and guidance in line with the NICE guideline on preventing type 2 diabetes (note that this guideline uses different risk thresholds, because it covers a different population).

• Advise women with a fasting plasma glucose level between 6.0 mmol/litre and 6.9 mmol/litre that they are at high risk of developing type 2 diabetes, and offer them advice, guidance and interventions in line with the NICE guideline on preventing type 2 diabetes (note that this guideline uses different risk thresholds, because it covers a different population).

• Advise women with a fasting plasma glucose level of 7.0 mmol/litre or above that they are likely to have type 2 diabetes, and offer them a test to confirm this. [2015]

1.6.13 For women having an HbA1c test as the postnatal test:
• Advise women with an HbA1c level below 39 mmol/mol (5.7%) that:
  – they have a low probability of having diabetes at the moment
  – they should continue to follow the lifestyle advice (including weight control, diet and exercise) given after the birth
  – they will need an annual test to check that their blood glucose levels are normal
  – they have a moderate risk of developing type 2 diabetes, and offer them advice and guidance in line with the NICE guideline on preventing type 2 diabetes (note that this guideline uses different risk thresholds, because it covers a different population).

• Advise women with an HbA1c level between 39 mmol/mol and 47 mmol/mol (5.7% and 6.4%) that they are at high risk of developing type 2 diabetes, and offer them advice, guidance and interventions in line with the NICE guideline on preventing type 2 diabetes (note that this guideline uses different risk thresholds, because it covers a different population).

• Advise women with an HbA1c level of 48 mmol/mol (6.5%) or above that they have type 2 diabetes, and refer them for further care. [2015]

1.6.14 Offer an annual HbA1c test to women with gestational diabetes who have a negative postnatal test for diabetes. [2015]

1.6.15 Offer women with gestational diabetes early self-monitoring of blood glucose or an OGTT in future pregnancies. Offer a subsequent OGTT if the first OGTT results in early pregnancy are normal (see recommendation 1.2.6). [2008, amended 2015]

Terms used in this guideline

Continuous glucose monitoring

This covers both real–time (rtCGM) and intermittently scanned (isCGM, commonly referred to as ‘flash’) continuous glucose monitoring.
Disabling hypoglycaemia

Repeated and unpredicted hypoglycaemia, requiring third-party assistance, that results in continuing anxiety about recurrence and is associated with significant adverse effect on quality of life.

HbA1c levels

HbA1c values are reported in mmol/mol, using the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) standardised HbA1c test. The equivalent values in %, using the Diabetes Control and Complications Trial (DCCT)-aligned HbA1c test, are reported in parentheses.

Level 2 critical care

Care for patients who need detailed observation or intervention, including support for a single failing organ system, postoperative care, and patients 'stepping down' from higher levels of care.
Recommendations for research

The guideline committee has made the following recommendations for research.

**Key recommendations for research**

1. **Preconception care for women with diabetes: insulin pump therapy and real-time continuous glucose monitoring**

   What are the roles of insulin pump therapy (continuous subcutaneous insulin infusion) and real-time continuous glucose monitoring (rtCGM) in helping women with diabetes to achieve blood glucose targets before pregnancy?

   **Why this is important**

   Babies born to women with diabetes have a high risk of having congenital malformations and this risk is greater if blood glucose control is poor around the time of conception. However, lowering the risk to that of women without diabetes would require normalisation of blood glucose levels, and this is difficult to achieve without increasing the risk of serious hypoglycaemia. Insulin pump therapy and rtCGM have been shown to reduce both blood glucose levels and rates of hypoglycaemia in the non-pregnant population, but it is uncertain if this holds true before conception and in early pregnancy. There is therefore an urgent need to test the effectiveness and acceptability of these technologies in women with diabetes who are planning pregnancy. This would be best undertaken in a randomised controlled trial of women with diabetes who are trying to conceive. Women would be allocated to receive either conventional care (self-monitoring of blood glucose and insulin adjustment) or insulin pump therapy and rtCGM.

2. **Testing for gestational diabetes**

   When should testing for gestational diabetes take place – in the first or second trimester?

   **Why this is important**

   Conventionally, testing for gestational diabetes takes place in the second trimester.
Intervention has been shown to improve outcomes for women diagnosed with gestational diabetes. However, maternal age and obesity are increasing, and some women (especially those from populations with a high incidence of type 2 diabetes) enter pregnancy with undiagnosed type 2 diabetes, but may not be tested for diabetes until the second trimester. This exposes the woman and the fetus to risks resulting from early and prolonged maternal hyperglycaemia. It is presumed that this is associated with increased morbidity. UK population studies are needed to establish the incidence of glucose intolerance in women in the first trimester. Well-designed randomised controlled trials are needed to establish if testing, diagnosis and intervention in the first rather than the second trimester improves maternal, fetal and neonatal outcomes, including fetal hyperinsulinaemia.

3 Barriers to achieving blood glucose targets before and during pregnancy

What are the barriers that women experience to achieving blood glucose targets?

Why this is important

It is vital for normal fetal development in the first trimester that women with pre-existing diabetes achieve good blood glucose control both before and during pregnancy. Good control also helps to prevent macrosomia and other complications in the third trimester in women with pre-existing or gestational diabetes. Whereas many women manage to achieve blood glucose targets, a proportion of women continue to find it difficult to do so. A number of factors could be involved, such as health beliefs, a poor understanding of the importance of good blood glucose control, an inability to be able to comply with a demanding regimen of blood glucose testing up to 7 times a day, and the need to adjust insulin dosage. A better understanding of the barriers in this cohort of women is needed so that healthcare professionals can work to overcome them. Robust qualitative studies are needed to explore these barriers, with the aim of improving blood glucose control and fetal outcomes in pregnancy for women with pre-existing diabetes and women with gestational diabetes.

4 Risk of fetal death for women with diabetes

How can fetuses at risk of intrauterine death be identified in women with diabetes?
Why this is important

Unexpected intrauterine death remains a significant contributor to perinatal mortality in pregnant women with diabetes. Conventional tests of fetal wellbeing (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 erythropoietin in the amniotic fluid and MRI 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.

5 Postnatal treatment for women diagnosed with gestational diabetes

Are there effective long-term pharmacological interventions to prevent the onset of type 2 diabetes that can be recommended postnatally for women who have been diagnosed with gestational diabetes?

Why this is important

Gestational diabetes is one of the strongest risk factors for the subsequent development of type 2 diabetes: up to 50% of women diagnosed with gestational diabetes develop type 2 diabetes within 5 years of the birth. There are some data suggesting that changes in diet and exercise, with or without metformin, can prevent type 2 diabetes developing in non-pregnant middle-aged people with glucose intolerance, but there are no studies specifically in women with a past history of gestational diabetes. There is thus an urgent need to investigate what interventions may delay or prevent type 2 diabetes developing in this high-risk population of women. Undertaking a formal randomised controlled trial involving long-term outcomes is often not feasible in practice. However, it would be possible to have a quasi-randomised study comparing 2 populations of women with similar demographic profiles who had gestational diabetes. One population would be encouraged at their annual check to follow a specific diet and exercise regime and those in the other population would not. The incidence of the development of type 2 diabetes in the 2 groups at 5 years, 10 years and 20 years would be compared.
Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice.

Continuous glucose monitoring

Recommendations 1.3.17 to 1.3.20

Why the committee made the recommendations

There was evidence comparing real-time continuous glucose monitoring (rtCGM) with intermittently scanned CGM (isCGM) and with intermittent capillary glucose monitoring, for pregnant women with type 1 diabetes.

When compared with intermittent capillary glucose monitoring, rtCGM resulted in:

- more women achieving their blood glucose targets
- fewer caesarean sections
- fewer neonatal intensive care unit (NICU) admissions.

One retrospective study was identified that compared isCGM with rtCGM. This study showed no clear difference between the 2 monitoring systems in maternal and neonatal outcomes.

Health economic modelling found that isCGM clearly has the lowest overall cost of the 3 options. It is much less certain that isCGM provides the most benefit (a finding that is in line with the clinical evidence). The committee were concerned by the very low quality of the evidence for isCGM, the accuracy of isCGM (particularly in the hypoglycaemic range) and the number of finger-pricks that would still be needed to use isCGM safely.

The committee agreed that all the uncertainties in the evidence would be likely to lead to the benefits of isCGM being overestimated. Therefore, they could not be confident that isCGM represents a better use of NHS resources than rtCGM, which had been shown in high-quality evidence to have better outcomes than intermittent capillary glucose
monitoring and a 94% chance of being cheaper in the probabilistic sensitivity analysis.

Based on these findings, the committee recommended that rtCGM should be offered to all women with type 1 diabetes to help women meet their pregnancy blood glucose targets and improve neonatal outcomes.

The committee also noted that some women may be unable to use rtCGM or may prefer using isCGM instead. In these situations they recommended offering isCGM.

The committee amended the 2015 recommendation on considering rtCGM for pregnant women who are on insulin therapy but do not have type 1 diabetes because they wanted to identify specific scenarios in which rtCGM could be considered.

The committee believed that education and support are important for pregnant women using continuous glucose monitoring (CGM), to ensure they get the full benefit. Therefore, they updated and expanded the 2015 recommendation on providing support.

**How the recommendations might affect practice**

Use of CGM varies across the country, but most centres offer isCGM and/or rtCGM to pregnant women with type 1 diabetes (in accordance with the NHS long-term plan). Because of this, the recommendations are unlikely to cause a major shift in practice.
Context

Approximately 700,000 women give birth in England and Wales each year, and up to 5% of these women have either pre-existing diabetes or gestational diabetes. Of women who have diabetes during pregnancy, it is estimated that approximately 87.5% have gestational diabetes (which may or may not resolve after pregnancy), 7.5% have type 1 diabetes and the remaining 5% have type 2 diabetes. The prevalence of type 1 diabetes, and especially type 2 diabetes, has increased in recent years. The incidence of gestational diabetes is also increasing as a result of higher rates of obesity in the general population and more pregnancies in older women.

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 guideline contains recommendations for managing diabetes and its complications in women who are planning pregnancy and those who are already pregnant. The guideline 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 and women with 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.
Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the NICE webpage on diabetes.

For full details of the evidence and the guideline committee's discussions, see the evidence reviews. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.
Update information

December 2020: We have reviewed the evidence and made new recommendations on continuous glucose monitoring (CGM) and intermittently scanned CGM (flash) during pregnancy for women with type 1 diabetes. These recommendations are marked [2020].

We have also made some changes without an evidence review:

- we have made minor amendments to recommendation 1.1.3 for clarity
- we have updated recommendation 1.1.12 to clarify timing of measurement
- we have added out-of-hours support to recommendation 1.3.20
- we have made minor amendments to recommendation 1.3.25 to clarify the actions
- we have updated recommendations on retinal assessment before pregnancy in line with the diabetic eye screening programme
- we have removed glibenclamide from the guideline (including from recommendations 1.3.6 and 1.6.4) because it has been discontinued
- we have added referral to the NHS Diabetes Prevention Programme to recommendation 1.6.11.

These recommendations are marked [2008, amended 2020] or [2015, amended 2020].

In some other recommendations, minor changes have been made to the wording to bring the language and style up to date, without changing the meaning.

We added text at the beginning of the section on insulin treatment and hypoglycaemia to highlight a Medicines and Healthcare products Regulatory Agency safety update reminding patients to rotate insulin injection sites within the same body region to avoid cutaneous amyloidosis.

February 2015: We made the following changes without an evidence review:
• Recommendation 1.1.23 was updated to better reflect the summaries of product characteristics for insulin detemir and insulin glargine, and the possibility of disrupted glucose control for women who switch to isophane insulin during pregnancy.

• Recommendation 1.1.33 was updated to use the same thresholds and terminology as the NICE guideline on chronic kidney disease

• Recommendation 1.2.2 was updated to remove mention of specific family origins, because the original list was not exhaustive and potentially missed out some groups.

• Recommendation 1.3.14 was updated to match current clinical practice

• Recommendations 1.3.28 to 1.3.31 were updated to clarify renal assessment during pregnancy.

• Recommendation 1.3.33 and table 1 were updated to address inconsistencies in the guideline on when the fetal heart examination should take place.

• Recommendation 1.3.35 was updated to clarify which types of monitoring are being referred to.

• Recommendations 1.6.10 and 1.6.15 were updated to remove mention of women with 'ongoing impaired glucose regulation'; because this group need support from their diabetes team rather than just self-monitoring.

These recommendations are marked [2008, amended 2015].

Minor changes since publication

March 2022: We have removed 2 research recommendations on continuous glucose monitoring, because new research has been carried out in this area. We have also removed the off-label notes from recommendations 1.1.21, 1.2.19, and 1.2.21 to 1.2.23, in line with its summary of product characteristics, and changed the terminology for continuous glucose monitoring to align this guideline with the NICE guidelines on type 1 diabetes in adults, diabetes (type 1 and type 2) in children and young people and type 2 diabetes in adults.

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