## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Guideline

# Diabetes in pregnancy: management from preconception to the postnatal period

## **Draft for consultation, September 2020**

This guideline covers managing diabetes and its complications in women who are planning pregnancy or are already pregnant. The 2020 update covers flash and continuous glucose monitoring during pregnancy for women with type 1 diabetes.

This guideline will update NICE guideline NG3 (published February 2015).

#### Who is it for?

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- 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

#### What does it include?

This draft guideline contains:

- the draft recommendations
- · recommendations for research
- rationale and impact sections that explain why the committee made 2020 recommendations and how they might affect practice
- the guideline context.

Information about how the guideline was developed is on the <u>guideline's</u>

<u>page</u> on the NICE website. This includes the evidence reviews, the scope,
details of the committee and any declarations of interest.

#### New and updated recommendations

We have reviewed the evidence on flash and continuous glucose monitoring during pregnancy for women with type 1 diabetes. You are invited to comment on the new and updated recommendations. These are marked as **[2020]**.

You are also invited to comment on recommendations that we propose to delete from the 2015 guideline.

We have not reviewed the evidence for the recommendations shaded in grey, and cannot accept comments on them. In some cases, we have made minor wording changes for clarification.

See <u>update information</u> for a full explanation of what is being updated.

Full details of the evidence and the committee's discussion on the 2020 recommendations are in <u>the evidence reviews</u>. Evidence for the 2008 and 2015 recommendations is in the full version of the 2015 guideline.

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## 1 Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in <u>making decisions about your care</u>.

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.

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## Blood glucose and plasma glucose

- 4 'Blood glucose' is the more commonly used term. However, a lot of the
- 5 evidence this guideline is based on uses 'plasma' rather than 'blood' glucose.
- 6 Also, patient-held glucose meters and monitoring systems are calibrated to
- 7 plasma glucose equivalents. Because of this, in this guideline we use the term
- 8 '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

1 2		pregnancy and how pregnancy affects diabetes. The information should cover:
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16		<ul> <li>the role of diet, body weight and exercise</li> <li>the risks of hypoglycaemia and impaired awareness of hypoglycaemia during pregnancy</li> <li>how nausea and vomiting in pregnancy can affect blood glucose control</li> <li>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</li> <li>the need for diabetic retinopathy assessment before and during pregnancy</li> <li>the need for diabetic nephropathy assessment before pregnancy</li> <li>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</li> </ul>
17 18 19 20		<ul> <li>the possibility of that the baby may have health problems in the first 28 days, and may need admitting to a neonatal unit</li> <li>the risk of the baby developing obesity, diabetes and/or other health problems in later life. [2008]</li> </ul>
21	The impo	ortance of planning pregnancy and the role of
22	contrace	
<ul><li>23</li><li>24</li><li>25</li></ul>	1.1.4	Emphasise the importance of planning for pregnancy, as part of diabetes education from adolescence for women with diabetes.  [2008, amended 2015]
26 27 28 29	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]
30 31	1.1.6	Advise women with diabetes that they can use oral contraceptives.  [2015]

2	1.1.7	pregnant:
3 4		that the risks associated with diabetes in pregnancy will increase the longer they have had diabetes      to use contracention until they have good blood glucose central.
5		<ul> <li>to use contraception until they have good blood glucose control (assessed by <u>HbA1c levels</u> – see <u>recommendation 1.1.18</u>)</li> </ul>
7		<ul> <li>that blood glucose targets, glucose monitoring, medicines for</li> </ul>
8		treating diabetes (including insulin regimens) and medicines for
9		complications of diabetes will need to be reviewed before and
10		during pregnancy
11		that extra time and effort is needed to manage diabetes during
12		pregnancy, and that more frequent contact is needed with
13		healthcare professionals. [2015]
14	1.1.8	For women with diabetes who are planning a pregnancy, provide
15		information about the local arrangements for support, including
16		emergency contact numbers. [2015]
17	Diet, diet	tary supplements and body weight
18 19	1.1.9	Offer individualised dietary advice to women with diabetes who are planning a pregnancy. [2008]
20 21	1.1.10	For women with diabetes who are planning a pregnancy and who have a BMI above 27 kg/m², offer advice on how to lose weight, in
22		line with the NICE guideline on identifying, assessing and
23		managing obesity. See the NICE guideline on BMI for guidance on
24		using variations on the BMI cut-off, based on the risk for different
25		ethnic groups. [2008]
26	1.1.11	Advise women with diabetes who are planning a pregnancy to take
27		folic acid (5 mg/day) until 12 weeks of gestation to reduce the risk
28		of having a baby with a neural tube defect. [2008]

1	Monitori	ng blood glucose and ketones before pregnancy
2	1.1.12	Offer monthly measurement of HbA1c levels for women with
3		diabetes who are planning a pregnancy. [2008]
4	1.1.13	Offer blood glucose meters for self-monitoring to women with
5		diabetes who are planning a pregnancy. [2008]
6	1.1.14	If a woman with diabetes who is planning a pregnancy needs to
7		intensify blood glucose-lowering therapy, advise her to monitor her
8		blood glucose more often, to include fasting levels and a mixture of
9		pre-meal and post-meal levels. [2008]
10	1.1.15	Offer blood ketone testing strips and a meter to women with type 1
11		diabetes who are planning a pregnancy, and advise them to test for
12		ketonaemia if they become hyperglycaemic or unwell. [2015]
13	Target b	lood glucose and HbA1c levels before pregnancy
14	1.1.16	Agree individualised targets for self-monitoring of blood glucose
15		with women who have diabetes and are planning a pregnancy,
16		taking into account the risk of hypoglycaemia. [2008]
17	1.1.17	Advise women with type 1 diabetes who are planning a pregnancy
18		to aim for the normal capillary plasma glucose target ranges:
19		• a fasting plasma glucose level of 5 to 7 mmol/litre on waking and
20		• a plasma glucose level of 4 to 7 mmol/litre before meals at other
21		times of the day.
22		For more information, see the section on blood glucose targets in
23		the NICE guideline on type 1 diabetes in adults. [2015]
24	1.1.18	Advise women with diabetes who are planning a pregnancy to aim
25		to keep their HbA1c level below 48 mmol/mol (6.5%), if this is
26		achievable without causing problematic hypoglycaemia. [2015]

1 2 3	1.1.19	target is likely to reduce the risk of congenital malformations in the baby. [2015]
4	1.1.20	Strongly advise women with diabetes whose HbA1c level is above
5		86 mmol/mol (10%) not to get pregnant until their HbA1c level is
6		lower, because of the associated risks (see <u>recommendation</u>
7		<u>1.1.2</u> ). [2015]
8	Safety of	medicines for diabetes before and during pregnancy
9	1.1.21	Women with diabetes may be advised to use metformin as an
10		adjunct or alternative to insulin in the preconception period and
11		during pregnancy, when the likely benefits from improved blood
12		glucose control outweigh the potential for harm. Stop all other oral
13		blood glucose-lowering agents before pregnancy, and use insulin
14		instead.
15		
16		Note that this is an off-label use of metformin. See NICE's
17		information on prescribing medicines. [2008]
18	1.1.22	Be aware that the available evidence on rapid-acting insulin
19		analogues (aspart and lispro) does not show an adverse effect on
20		the pregnancy or the health of baby. [2008]
21	1.1.23	Use isophane insulin (also known as NPH insulin) as the first
22		choice for long-acting insulin during pregnancy. Consider
23		continuing treatment with long-acting insulin analogues (insulin
24		detemir or insulin glargine) for women with diabetes who have
25		established good blood glucose control before pregnancy.
26		
27		Note that this is an off-label use of long-acting insulin analogues.
28		See NICE's information on prescribing medicines. [2008, amended
29		2015]

1	Safety of medicines for complications of diabetes before and		
2	during p	regnancy	
3 4 5 6	1.1.24	Stop angiotensin-converting enzyme inhibitors and angiotensin 2 receptor antagonists before conception, or as soon as pregnancy is confirmed. Use alternative antihypertensive agents that are suitable for pregnant women. <b>[2008]</b>	
7 8	1.1.25	Stop statins before pregnancy, or as soon as pregnancy is confirmed. [2008]	
9	Making i	t easier for women to access preconception care	
10 11	1.1.26	From adolescence onwards, at every contact with women with diabetes:	
12 13 14 15 16		<ul> <li>healthcare professionals (including the diabetes care team)     should explain the benefits of preconception blood glucose     control</li> <li>the diabetes care team should record the plans women have for     pregnancy and conception. [2008]</li> </ul>	
17 18 19	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]	
20	Education	on and advice	
21 22 23 24 25 26	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 <a href="the education">the education</a> and information section in the NICE guideline on type 1 diabetes in adults, and <a href="the patient education section">the NICE guideline on type 2 diabetes in adults</a> . [2008]	
27 28	1.1.29	Offer preconception care and advice before stopping contraception for women with diabetes who are planning a pregnancy. [2008]	

1	Retinal a	assessment before pregnancy
2	1.1.30	For women with diabetes who are seeking preconception care,
3		offer a retinal assessment at their first appointment (unless they
4		have had a retinal assessment in the last 6 months). [2008,
5		amended 2020]
6	1.1.31	Advise women with diabetes who are planning a pregnancy to
7		defer rapid optimisation of blood glucose control until after they
8		have had retinal assessment and treatment. [2008]
9	Renal as	ssessment before pregnancy
10	1.1.32	Offer women with diabetes a renal assessment (including a
11		measure of albuminuria) before stopping contraception.
12	1.1.33	Consider referring women with diabetes to a nephrologist before
13		stopping contraception if:
1 /		- comun proctimino io 100 migromol/litro or pooro en
14		• serum creatinine is 120 micromol/litre or more <b>or</b>
15		the urinary albumin:creatinine ratio is greater than 30 mg/mmol
16		or  the estimated alamazular filtration rate (aCED) is less than
17 18		the estimated glomerular filtration rate (eGFR) is less than  45 ml/minute/1.73 m² [2009] amonded 2015]
10		45 ml/minute/1.73 m <sup>2</sup> . <b>[2008, amended 2015]</b>
19	1.2	Gestational diabetes
20	Risk ass	sessment, testing and diagnosis
21	Risk ass	essment
22	1.2.1	To help women make an informed decision about risk assessment
23		and testing for gestational diabetes, explain that:
24		<ul> <li>some women find that gestational diabetes can be controlled</li> </ul>
2 <del>4</del> 25		with changes in diet and exercise
26		<ul> <li>most women with gestational diabetes will need oral blood</li> </ul>
20 27		glucose-lowering agents or insulin
<del></del>		gggggg

1 2 3 4 5 6		<ul> <li>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</li> <li>women with gestational diabetes will need more monitoring, and may need more interventions during pregnancy and labour.</li> <li>[2015]</li> </ul>
7 8 9	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:
10 11 12 13 14 15 16 17		<ul> <li>BMI above 30 kg/m²</li> <li>previous macrosomic baby weighing 4.5 kg or more</li> <li>previous gestational diabetes</li> <li>family history of diabetes (first-degree relative with diabetes)</li> <li>an ethnicity with a high prevalence of diabetes.</li> </ul> Offer women with any of these risk factors testing for gestational diabetes (see recommendations 1.2.5 to 1.2.7). [2008, amended 2015]
19 20 21	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]
22	Glycosur	ia detected by routine antenatal testing
<ul><li>23</li><li>24</li><li>25</li></ul>	1.2.4	Consider further testing to exclude gestational diabetes in women who have the following reagent strip test results during routine antenatal care:
26 27		<ul> <li>glycosuria of 2+ or above on 1 occasion</li> <li>glycosuria of 1+ or above on 2 or more occasions. [2015]</li> </ul>

1	Testing	
2	1.2.5	Use the 2-hour 75 g oral glucose tolerance test (OGTT) to test for
3		gestational diabetes in women with risk factors (see
4		recommendation 1.2.2). <b>[2015]</b>
5	1.2.6	For women who have had gestational diabetes in a previous
6		pregnancy, offer:
7		early self-monitoring of blood glucose or
8		• a 75 g 2-hour OGTT as soon as possible after booking (whether
9		in the first or second trimester), and a further 75 g 2-hour OGTT
10		at 24 to 28 weeks if the results of the first OGTT are normal.
11		[2015]
12	1.2.7	Offer women with any of the other risk factors for gestational
13		diabetes (see recommendation 1.2.2) a 75 g 2-hour OGTT at 24 to
14		28 weeks. <b>[2015]</b>
15	Diagnosi	s
16	1.2.8	Diagnose gestational diabetes if the woman has either:
17		a fasting plasma glucose level of 5.6 mmol/litre or above or
18		• a 2-hour plasma glucose level of 7.8 mmol/litre or above. [2015]
19	1.2.9	When women are diagnosed with gestational diabetes:
20		offer a review with the joint diabetes and antenatal clinic within
21		1 week.
22		<ul> <li>tell their primary healthcare team (see also the section on</li> </ul>
23		continuity of care in the NICE guideline on patient experience in
24		adult NHS services). [2015]
25	Intervent	ions
26	1.2.10	Explain to women with gestational diabetes:

1		<ul> <li>the implications (both short and long term) of the diagnosis for</li> </ul>
2		her and her baby (including <u>UK government advice on driving</u>
3		with diabetes)
4		<ul> <li>that good blood glucose control throughout pregnancy will</li> </ul>
5		reduce the risk of fetal macrosomia, trauma during birth (for her
6		and her baby), induction of labour and/or caesarean section,
7		neonatal hypoglycaemia, and perinatal death
8		• that treatment includes changes in diet and exercise, and could
9		involve medicines. [2015]
10	1.2.11	Teach women with gestational diabetes how to self-monitor their
11		blood glucose. [2015]
12	1.2.12	Use the same capillary plasma glucose target levels for women
13		with gestational diabetes as for women with pre-existing diabetes
14		(see <u>recommendations 1.3.5 and 1.3.6</u> ). <b>[2015]</b>
15	1.2.13	Tailor blood glucose-lowering therapy to the blood glucose profile
16		and personal preferences of the woman with gestational diabetes.
17		[2015]
18	1.2.14	When women are diagnosed with gestational diabetes, offer advice
19		about changes in diet and exercise. [2015]
20	1.2.15	Advise women with gestational diabetes to eat a healthy diet during
21		pregnancy, and to switch from high to low glycaemic index food.
22		[2015]
23	1.2.16	Refer all women with gestational diabetes to a dietitian. [2015]
24	1.2.17	Advise women with gestational diabetes to exercise regularly (for
25		example, walking for 30 minutes after a meal). <b>[2015]</b>
26	1.2.18	For women with gestational diabetes who have a fasting plasma
27		glucose level below 7 mmol/litre at diagnosis, offer a trial of diet
28		and exercise changes. [2015]

1 2	1.2.19	If blood glucose targets are not met with diet and exercise changes within 1 to 2 weeks, offer metformin.
<ul><li>3</li><li>4</li><li>5</li></ul>		Note that this is an off-label use. See <u>NICE's information on prescribing medicines</u> . [2015]
6 7	1.2.20	If metformin is contraindicated or unacceptable to the woman, offer insulin. [2015]
8 9 10	1.2.21	If blood glucose targets are not met with diet and exercise changes plus metformin, offer insulin as well.
11 12		Note that this is an off-label use of metformin. See NICE's information on prescribing medicines. [2015]
13 14	1.2.22	For women with gestational diabetes who have a fasting plasma glucose level of 7.0 mmol/litre or above at diagnosis, offer:
15 16 17 18		<ul> <li>immediate treatment with insulin, with or without metformin and</li> <li>diet and exercise changes.</li> <li>Note that this is an off-label use of metformin. See <u>NICE's</u> information on prescribing medicines. [2015]</li> </ul>
20 21 22	1.2.23	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:
23 24 25 26 27		<ul> <li>immediate treatment with insulin, with or without metformin and</li> <li>diet and exercise changes.</li> <li>Note that this is an off-label use of metformin. See <u>NICE's</u> information on prescribing medicines. [2015].</li> </ul>
28	1.2.24	Consider glibenclamide for women with gestational diabetes if:

1 2		blood glucose targets are not met with metformin, and the woman declines insulin or
3		the woman cannot tolerate metformin.
5		Note that this is an off-label use for some brands of
6 7		glibenclamide. See <u>NICE's information on prescribing medicines</u> .  [2015]
8	1.3	Antenatal care for women with diabetes
9	See also	the NICE guideline on antenatal care for uncomplicated
10	pregnanci	i <mark>es</mark> .
11	Monitori	ng blood glucose
12	1.3.1	Advise pregnant women with type 1 diabetes to test their fasting,
13		pre-meal, 1-hour post-meal and bedtime blood glucose levels daily.
14		[2015]
15	1.3.2	Advise pregnant women with type 2 diabetes or gestational
16		diabetes who are on a multiple daily insulin injection regimen to test
17		their fasting, pre-meal, 1-hour post-meal and bedtime blood
18		glucose levels daily. [2015]
19	1.3.3	Advise pregnant women with type 2 diabetes or gestational
20		diabetes to test their fasting and 1-hour post-meal blood glucose
21		levels daily if they are:
22		<ul> <li>managing their diabetes with diet and exercise changes alone or</li> </ul>
23		• taking oral therapy (with or without diet and exercise changes) or
24		single-dose intermediate-acting or long-acting insulin. [2015]
25	Target b	lood glucose levels
26	1.3.4	Agree individualised targets for self-monitoring of blood glucose
27		with pregnant women with diabetes, taking into account the risk of
28		hypoglycaemia. [2008]

1 2 3	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:
4 5 6 7		<ul> <li>fasting: 5.3 mmol/litre</li> <li>and</li> <li>1 hour after meals: 7.8 mmol/litre or</li> <li>2 hours after meals: 6.4 mmol/litre. [2015]</li> </ul>
8 9 10	1.3.6	Advise pregnant women with diabetes who are taking insulin or glibenclamide to maintain their capillary plasma glucose level above 4 mmol/litre. [2015]
11	Monitori	ng HbA1c
12 13 14	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]
15 16 17	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]
18 19 20	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%). <b>[2015]</b>
21 22 23	1.3.10	Measure HbA1c levels when women are diagnosed with gestational diabetes, to identify women who may have pre-existing type 2 diabetes. <b>[2015]</b>
24 25 26	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]

1	Managing diabetes during pregnancy	
2	Insulin t	reatment and risks of hypoglycaemia
3	1.3.12	Consider rapid-acting insulin analogues (aspart and lispro) for
4		pregnant women with diabetes. Be aware that these insulin
5		analogues have advantages over soluble human insulin during
6		pregnancy. [2008]
7	1.3.13	Advise women with insulin-treated diabetes of the risks of
8		hypoglycaemia and impaired awareness of hypoglycaemia in
9		pregnancy, particularly in the first trimester. [2008]
10	1.3.14	Advise pregnant women with insulin-treated diabetes to always
11		have a fast-acting form of glucose available (for example, dextrose
12		tablets or glucose-containing drinks). [2008, amended 2015]
13	1.3.15	Provide glucagon to pregnant women with type 1 diabetes, for use
14		if needed. Explain to the woman and her partner or other family
15		members how to use it. [2008, amended 2015]
16	1.3.16	Offer continuous subcutaneous insulin infusion (CSII; also known
17		as insulin pump therapy) to pregnant women with insulin-treated
18		diabetes who:
19		are using multiple daily injections of insulin and
20		<ul> <li>do not achieve blood glucose control without significant disabling</li> </ul>
21		hypoglycaemia. [2008]
22	Flash ar	nd continuous glucose monitoring
23	1.3.17	For pregnant women with type 1 diabetes who cannot use flash
24		glucose monitoring because it is contraindicated or because of
25		hypersensitivities (such as an allergy to the adhesive used by the
26		system), offer continuous glucose monitoring. [2020]

1	1.3.18	For pregnant women with type 1 diabetes who are already using
2		continuous glucose monitoring (with or without an insulin pump),
3		continue with continuous glucose monitoring. [2020]
4	1.3.19	For pregnant women with type 1 diabetes who need predictive
5		alerts (for example, because of impaired hypoglycaemia awareness
6		or problematic nocturnal hypoglycaemia), offer continuous glucose
7		monitoring if there is no flash system with this feature. [2020]
8	1.3.20	If any of the criteria in recommendations 1.3.18 or 1.3.19 apply, but
9		a pregnant woman with type 1 diabetes prefers flash glucose
10		monitoring, offer this instead. [2020]
11	1.3.21	If none of the criteria in recommendations 1.3.17 to 1.3.19 apply,
12		offer pregnant women with type 1 diabetes the choice of flash or
13		continuous glucose monitoring while the costs of continuous
14		glucose monitoring are met centrally by NHS England and NHS
15		Improvement. [2020]
16	1.3.22	Consider continuous glucose monitoring for pregnant women who
17		are on insulin therapy but do not have type 1 diabetes, if:
18		<ul> <li>they have problematic severe hypoglycaemia (with or without</li> </ul>
19		impaired awareness of hypoglycaemia) <b>or</b>
20		they have unstable blood glucose levels (to minimise variability)
21		or
22		it would be useful to gain information about variability in blood
23		glucose levels. [2015, amended 2020]
24	1.3.23	For pregnant women who are using flash or continuous glucose
25		monitoring, a member of the joint diabetes and antenatal care team
26		with expertise in these systems should provide education and
27		support (including 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 <u>rationale and impact section on flash and continuous glucose monitoring</u>.

Full details of the evidence and the committee's discussion are in <u>evidence</u> review A: diabetes in pregnancy: management from preconception to the <u>postnatal period</u>.

1	Ketone te	esting and diabetic ketoacidosis
2	1.3.24	Offer blood ketone testing strips and a meter to pregnant women
3		with type 1 diabetes. Advise them to test for ketonaemia and to
4		seek urgent medical advice if they become hyperglycaemic or
5		unwell. <b>[2015]</b>
6	1.3.25	Advise pregnant women with type 2 diabetes or gestational
7		diabetes to seek urgent medical advice if they become
8		hyperglycaemic or unwell. [2015]
9	1.3.26	Test urgently for ketonaemia if a pregnant woman with any form of
10		diabetes presents with hyperglycaemia or is unwell. [2015]
11	1.3.27	Immediately admit pregnant women with suspected diabetic
12		ketoacidosis for <u>level 2 critical care</u> , where they can receive both
13		medical and obstetric care. [2008]
14	Retinal a	assessment during pregnancy
15	1.3.28	After pregnant women with pre-existing diabetes have had their first
16		antenatal clinic appointment:
17		offer retinal assessment by digital imaging with mydriasis using
18		tropicamide (unless they have had a retinal assessment in the
19		last 3 months)
20		if they have diabetic retinopathy, offer an additional retinal
21		assessment at 16 to 20 weeks

1 2		<ul><li>offer another retinal assessment at 28 weeks. [2008, amended</li><li>2015]</li></ul>
3 4 5	1.3.29	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]
6 7	1.3.30	Diabetic retinopathy should not be considered a contraindication to vaginal birth. [2008]
8	Renal as	sessment during pregnancy
9 10 11	1.3.31	Arrange a renal assessment at first contact during the pregnancy for women with pre-existing diabetes, if they have not had one in the last 3 months. [2008, amended 2015]
12 13	1.3.32	Consider referring pregnant women with diabetes to a nephrologist if:
14 15 16 17		<ul> <li>their serum creatinine is 120 micromol/litre or more or</li> <li>the urinary albumin:creatinine ratio is greater than 30 mg/mmol or</li> <li>total protein excretion exceeds 0.5 g/day. [2008, amended 2015]</li> </ul>
19	1.3.33	Do not use estimated glomerular filtration rate to measure kidney
20		function in pregnant women. [2008, amended 2015]
21 22 23	1.3.34	Consider thromboprophylaxis for pregnant women with nephrotic range proteinuria above 5 g/day (albumin:creatinine ratio greater than 220 mg/mmol). [2008, amended 2015]
24	Preventi	ng pre-eclampsia
25	1.3.35	For guidance on using antiplatelet agents to reduce the risk of
26 27		pre-eclampsia in pregnant women with diabetes, see <u>the section on</u> <a href="mailto:antiplatelet.agents">antiplatelet agents in the NICE guideline on hypertension in</a>
28		pregnancy. [2015]

1	Detecting	g congenital malformations
2	1.3.36	Offer women with diabetes an ultrasound scan at 20 weeks to
3		detect fetal structural abnormalities, including examination of the
4		fetal heart (4 chambers, outflow tracts and 3 vessels). [2008,
5		amended 2015]
6	Monitorii	ng fetal growth and wellbeing
7	1.3.37	Offer pregnant women with diabetes ultrasound monitoring of fetal
8		growth and amniotic fluid volume every 4 weeks from 28 to
9		36 weeks. <b>[2008]</b>
10	1.3.38	Routine monitoring of fetal wellbeing before 38 weeks is not
11		recommended in pregnant women with diabetes, unless there is a
12		risk of fetal growth restriction. This includes methods such as fetal
13		umbilical artery doppler recording, fetal heart rate recording and
14		biophysical profile testing. [2008, amended 2015]
15	1.3.39	Provide an individualised approach to monitoring fetal growth and
16		wellbeing for women with diabetes and a risk of fetal growth
17		restriction (macrovascular disease or nephropathy). [2008,
18		amended 2015]
19	Organisa	ation of antenatal care
20	1.3.40	Offer immediate contact with a joint diabetes and antenatal clinic to
21		pregnant women with diabetes. [2008]
22	1.3.41	Joint diabetes and antenatal clinics should be in contact with
23		women with diabetes every 1 to 2 weeks throughout pregnancy, for
24		blood glucose control assessment. [2008, amended 2015]
25	1.3.42	At antenatal appointments, provide care specifically for women with
26		diabetes, in addition to routine care for healthy pregnant women
27		(see the NICE guideline on antenatal care for uncomplicated
28		<u>pregnancies</u> ). Table 1 describes how care for women with diabetes
29		differs from routine antenatal care.

3

- 1 1.3.43 At each appointment, offer pregnant women with diabetes ongoing opportunities for information and education. [2008, amended 2015]
  - **Table 1 Timetable of antenatal appointments**

Appointment	Care for women with diabetes during pregnancy
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 one 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.
16 weeks	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.
20 weeks	Offer an ultrasound scan to detect fetal structural abnormalities, including examination of the fetal heart (4 chambers, outflow tracts and 3 vessels).
28 weeks	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.
32 weeks	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.

34 weeks	No differences in care for women with diabetes.
36 weeks	Offer ultrasound monitoring of fetal growth and amniotic fluid volume.
	Provide information and advice about:
	timing, mode and management of birth
	analgesia and anaesthesia
	changes to blood glucose-lowering therapy during and after birth
	care of the baby after birth
	starting to breastfeed and the effect of breastfeeding on blood glucose control
	contraception and follow-up.
37 <sup>+0</sup> weeks to 38 <sup>+6</sup> weeks	Offer induction of labour or (if indicated) caesarean section to women with type 1 or type 2 diabetes. Await spontaneous labour for other women.
38 weeks	Offer tests of fetal wellbeing.
39 weeks	Offer tests of fetal wellbeing.
	Advise women with uncomplicated gestational diabetes to give birth no later than 40 <sup>+6</sup> weeks.

1

#### Preterm labour in women with diabetes 2 3 1.3.44 Diabetes should not be considered a contraindication to tocolysis or to antenatal steroids for fetal lung maturation. [2008] 4 1.3.45 5 For women with insulin-treated diabetes who are taking steroids for 6 fetal lung maturation, give additional insulin according to an agreed 7 protocol and monitor the woman closely. [2008, amended 2015] 1.3.46 Do not use betamimetic medicines for tocolysis in women with 8 9 diabetes. [2008] 1.4 Intrapartum care 10 Timing and mode of birth 11 12 1.4.1 Discuss the timing and mode of birth with pregnant women with 13 diabetes during antenatal appointments, especially during the third 14 trimester. [2015]

1	1.4.2	Advise pregnant women with type 1 or type 2 diabetes and no other
2		complications to have an elective birth by induced labour or (if
3		indicated) caesarean section, between 37 <sup>+0</sup> and 38 <sup>+6</sup> weeks of
4		pregnancy. [2015]
5	1.4.3	Consider elective birth before 37 <sup>+0</sup> weeks for women with type 1 or
6		type 2 diabetes who have metabolic or other maternal or fetal
7		complications. [2015]
8	1.4.4	Advise women with gestational diabetes to give birth no later than
9		40 <sup>+6</sup> weeks. Offer elective birth by induced labour or (if indicated)
10		by caesarean section to women who have not given birth by this
11		time. [2015]
12	1.4.5	Consider elective birth before 40 <sup>+6</sup> weeks for women with
13		gestational diabetes who have maternal or fetal complications.
14		[2015]
15	1.4.6	Diabetes should not be considered a contraindication to vaginal
16		birth after a previous caesarean section. [2008]
17	1.4.7	For pregnant women with diabetes who have an
18		ultrasound-diagnosed macrosomic fetus, explain the risks and
19		benefits of vaginal birth, induction of labour and caesarean section.
20		[2008]
21	Anaesth	esia
22	1.4.8	For women with diabetes and comorbidities such as obesity or
23		autonomic neuropathy, offer an anaesthetic assessment in the third
24		trimester of pregnancy. [2008]
25	1.4.9	If the woman has general anaesthesia for the birth, monitor blood
26		glucose every 30 minutes from induction of general anaesthesia
27		until after the baby is born and the woman is fully conscious. [2008]

1	Blood gl	ucose control during labour and birth
2	1.4.10	Monitor capillary plasma glucose every hour during labour and birth
3		for women with diabetes, and maintain it between 4 and
4		7 mmol/litre. [2008, amended 2015]
5	1.4.11	Consider intravenous dextrose and insulin infusion from the onset
6		of established labour for women with type 1 diabetes. [2008]
7	1.4.12	Use intravenous dextrose and insulin infusion during labour and
8		birth for women with diabetes whose capillary plasma glucose is
9		not maintained between 4 and 7 mmol/litre. [2008, amended 2015]
10	1.5	Neonatal care
11	Initial as	sessment and criteria for admission to intensive or special
12	care	
13	1.5.1	Advise women with diabetes to give birth in hospitals where
14		advanced neonatal resuscitation skills are available 24 hours a day.
15		[2008]
16	1.5.2	Babies of women with diabetes should stay with their mothers,
17		unless there are complications or abnormal clinical signs that mean
18		the baby needs to be admitted to intensive or special care. [2008]
19	1.5.3	Carry out blood glucose testing routinely at 2 to 4 hours after birth
20		in babies of women with diabetes. Carry out blood tests for babies
21		with clinical signs of polycythaemia, hyperbilirubinaemia,
22		hypocalcaemia or hypomagnesaemia. [2008]
23	1.5.4	Perform an echocardiogram for babies of women with diabetes if
24		they show clinical signs associated with congenital heart disease or
25		cardiomyopathy, including heart murmur. Base the timing of the
26		examination on the clinical circumstances. [2008]
27	1.5.5	Admit babies of women with diabetes to the neonatal unit if they
28		have:

1		<ul> <li>hypoglycaemia associated with abnormal clinical signs</li> </ul>
2		respiratory distress
3		signs of cardiac decompensation from congenital heart disease
4		or cardiomyopathy
5		signs of neonatal encephalopathy
6		• signs of polycythaemia, and are likely to need partial exchange
7		transfusion
8		need for intravenous fluids
9		need for tube feeding (unless adequate support is available on
10		the postnatal ward)
11		• jaundice requiring intense phototherapy and frequent monitoring
12		of bilirubinaemia
13		• been born before 34 weeks (or between 34 and 36 weeks, if the
14		initial assessment of the baby and their feeding suggests this is
15		clinically appropriate). [2008]
16	1.5.6	Do not transfer babies of women with diabetes to community care
17		until:
18		they are at least 24 hours old <b>and</b>
19		you are satisfied that the baby is maintaining blood glucose
20		levels and is feeding well. [2008]
21	Preventi	ng and assessing neonatal hypoglycaemia
22	1.5.7	All maternity units should have a written policy for preventing,
23		detecting and managing hypoglycaemia in babies of women with
24		diabetes. [2008]
25	1.5.8	Test the blood glucose of babies of women with diabetes using a
26	1.5.0	quality-assured method validated for neonatal use (ward-based
27		glucose electrode or laboratory analysis). [2008]
		5
28	1.5.9	Women with diabetes should feed their babies:
29		as soon as possible after birth (within 30 minutes) and then

1 2 3		<ul> <li>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]</li> </ul>
4 5	1.5.10	Only use additional measures (such as tube feeding or intravenous dextrose) if:
6 7 8 9		<ul> <li>capillary plasma glucose values are below 2.0 mmol/litre on 2 consecutive readings despite maximal support for feeding or</li> <li>there are abnormal clinical signs or</li> <li>the baby will not effectively feed orally. [2008, amended 2015]</li> </ul>
10 11 12	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]
13	1.6	Postnatal care
14	Blood gl	ucose control, medicines and breastfeeding
15 16 17	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]
18 19 20 21	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]
22 23	1.6.3	Women who have been diagnosed with gestational diabetes should stop blood glucose-lowering therapy immediately after birth. [2008]
24 25 26 27 28	1.6.4	Women with pre-existing type 2 diabetes who are breastfeeding can resume or continue metformin and glibenclamide immediately after birth, but should avoid other oral blood glucose-lowering therapy while breastfeeding.

1		Note that this is an off-label use of metformin and some brands of		
2		glibenclamide. See <u>NICE's information on prescribing medicines</u> .		
3		[2008]		
4	1.6.5	Women with diabetes who are breastfeeding should continue to		
5		avoid any medicines for their diabetes complications that were		
6		stopped for safety reasons when they started planning the		
7		pregnancy. [2008]		
8	Informat	formation and follow up after birth		
9	Women v	with pre-existing diabetes		
10	1.6.6	Refer women with pre-existing diabetes back to their routine		
11		diabetes care arrangements. [2008]		
12	1.6.7	Remind women with diabetes of the importance of contraception		
13		and the need for preconception care when planning future		
14		pregnancies. [2008]		
15	Women o	Vomen diagnosed with gestational diabetes		
16	1.6.8	Before women who were diagnosed with gestational diabetes are		
17		transferred to community care, test their blood glucose to exclude		
18		persisting hyperglycaemia. [2008]		
19	1.6.9	Remind women who were diagnosed with gestational diabetes of		
20		the symptoms of hyperglycaemia. [2008]		
21	1.6.10	Explain to women who were diagnosed with gestational diabetes		
22		about the risks of recurrence in future pregnancies, and offer them		
23		diabetes testing when planning future pregnancies. [2008,		
24		amended 2015]		
25	1.6.11	For women who were diagnosed with gestational diabetes and		
26		whose blood glucose levels returned to normal after the birth:		
27		• offer lifestyle advice (including weight control, diet and exercise)		

1 2 3 4 5 6 7		<ul> <li>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)</li> <li>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</li> <li>do not routinely offer a 75 g 2-hour OGTT. [2015]</li> </ul>		
8 9	1.6.12	For women having a fasting plasma glucose test as the postnatal test:		
10 11 12 13 14 15 16 17 18 19 20 21 22 22 23 24 25 26 27		<ul> <li>Advise women with a fasting plasma glucose level below 6.0 mmol/litre that: <ul> <li>they have a low probability of having diabetes at the moment</li> <li>they should continue to follow the lifestyle advice (including weight control, diet and exercise) given after the birth</li> <li>they will need an annual test to check that their blood glucose levels are normal</li> <li>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).</li> </ul> </li> <li>Advise women with a fasting plasma glucose level between 6.0 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).</li> </ul>		
28 29 30		<ul> <li>Advise women with a fasting plasma glucose level of</li> <li>7.0 mmol/litre or above that they are likely to have type 2 diabetes, and offer them a test to confirm this. [2015]</li> </ul>		
2 1	1613	For women having an HhA1c test as the nostnatal test:		

1		Advise women with an HbA1c level below 39 mmol/mol (5.7%)	
2		that:	
3		<ul> <li>they have a low probability of having diabetes at the moment</li> </ul>	
4		<ul> <li>they should continue to follow the lifestyle advice (including</li> </ul>	
5		weight control, diet and exercise) given after the birth	
6		<ul> <li>they will need an annual test to check that their blood glucose</li> </ul>	
7		levels are normal	
8		<ul> <li>they have a moderate risk of developing type 2 diabetes, and</li> </ul>	
9		offer them advice and guidance in line with the NICE guideline	
10		on preventing type 2 diabetes (note that this guideline uses	
11		different risk thresholds, because it covers a different	
12		population).	
13		Advise women with an HbA1c level between 39 and	
14		47 mmol/mol (5.7% and 6.4%) that they are at high risk of	
15		developing type 2 diabetes, and offer them advice, guidance and	
16		interventions in line with the NICE guideline on preventing type 2	
17		<u>diabetes</u> (note that this guideline uses different risk thresholds,	
18		because it covers a different population).	
19		<ul> <li>Advise women with an HbA1c level of 48 mmol/mol (6.5%) or</li> </ul>	
20		above that they have type 2 diabetes, and refer them for further	
21		care. [2015]	
22	1.6.14	Offer an annual HbA1c test to women with gestational diabetes	
23		who have a negative postnatal test for diabetes. [2015]	
24	1.6.15	Offer women with gestational diabetes early self-monitoring of	
25		blood glucose or an OGTT in future pregnancies. Offer a	
26		subsequent OGTT if the first OGTT results in early pregnancy are	
27		normal (see recommendation 1.2.6). [2008, amended 2015]	

## 1 Terms used in this guideline

#### 2 Disabling hypoglycaemia

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

#### 6 HbA1c levels

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

#### 11 Level 2 critical care

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

## 15 Recommendations for research

- 16 The guideline committee has made the following recommendations for
- 17 research.

## 18 Key recommendations for research

#### 19 1 Preconception care for women with diabetes: insulin pump therapy

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

#### 24 Why this is important

- 25 Babies born to women with diabetes have a high risk of having congenital
- 26 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.
- 2 Insulin pump therapy and continuous glucose monitoring have been shown to
- 3 reduce both blood glucose levels and rates of hypoglycaemia in the
- 4 non-pregnant population, but it is uncertain if this holds true before conception
- 5 and in early pregnancy. There is therefore an urgent need to test the
- 6 effectiveness and acceptability of these technologies in women with diabetes
- 7 who are planning pregnancy. This would be best undertaken in a randomised
- 8 controlled trial of women with diabetes who are trying to conceive. Women
- 9 would be allocated to receive either conventional care (self-monitoring of
- 10 blood glucose and insulin adjustment) or insulin pump therapy and continuous
- 11 glucose monitoring.

#### 12 **2 Testing for gestational diabetes**

- 13 When should testing for gestational diabetes take place in the first or second
- 14 trimester?

#### 15 Why this is important

- 16 Conventionally, testing for gestational diabetes takes place in the second
- 17 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
- 20 incidence of type 2 diabetes) enter pregnancy with undiagnosed type 2
- 21 diabetes, but may not be tested for diabetes until the second trimester. This
- 22 exposes the woman and the fetus to risks resulting from early and prolonged
- 23 maternal hyperglycaemia. It is presumed that this is associated with increased
- 24 morbidity. UK population studies are needed to establish the incidence of
- 25 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
- 28 neonatal outcomes, including fetal hyperinsulinaemia.

#### 1 3 Barriers to achieving blood glucose targets before and during

- 2 pregnancy
- What are the barriers that women experience to achieving blood glucose
- 4 targets?

#### 5 Why this is important

- 6 It is vital for normal fetal development in the first trimester that women with
- 7 pre-existing diabetes achieve good blood glucose control both before and
- 8 during pregnancy. Good control also helps to prevent macrosomia and other
- 9 complications in the third trimester in women with pre-existing or gestational
- 10 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
- 16 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
- 19 pregnancy for women with pre-existing diabetes and women with gestational
- 20 diabetes.

#### 4 Risk of fetal death for women with diabetes

- How can fetuses at risk of intrauterine death be identified in women with
- 23 diabetes?

24

#### Why this is important

- 25 Unexpected intrauterine death remains a significant contributor to perinatal
- 26 mortality in pregnant women with diabetes. Conventional tests of fetal
- wellbeing (umbilical artery doppler ultrasound, cardiotocography and other
- 28 biophysical tests) have been shown to have poor sensitivity for predicting
- 29 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

- 1 randomised controlled trials that are sufficiently powered are needed to
- 2 determine whether these approaches are clinically and cost effective.

#### **5 Postnatal treatment for women diagnosed with gestational diabetes**

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

#### Why this is important

7

- 8 Gestational diabetes is one of the strongest risk factors for the subsequent
- 9 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
- 13 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
- 18 feasible in practice. However, it would be possible to have a
- 19 quasi-randomised study comparing 2 populations of women with similar
- demographic profiles who had gestational diabetes. One population would be
- 21 encouraged at their annual check to follow a specific diet and exercise regime
- 22 and those in the other population would not. The incidence of the
- development of type 2 diabetes in the 2 groups at 5, 10 and 20 years would
- be compared.

25

#### Other recommendations for research

#### 26 Glucose monitoring for women planning a pregnancy

- 27 In women with type 1 diabetes who are planning to become pregnant, what is
- the most effective method of glucose monitoring to improve maternal and
- 29 infant outcomes:
- continuous glucose monitoring

- flash glucose monitoring
- intermittent capillary blood glucose monitoring?

For a short explanation of why the committee made this recommendation, see the <u>rationale section on glucose monitoring for women planning a pregnancy</u>.

Full details of the evidence and the committee's discussion are in <u>evidence</u> review A: diabetes in pregnancy: management from preconception to the postnatal period.

## 3 Flash glucose monitoring for pregnant women

- 4 In women with type 1 diabetes who are already pregnant, what is the most
- 5 effective method of glucose monitoring to improve maternal and infant
- 6 outcomes:
- 7 continuous glucose monitoring
- 8 flash glucose monitoring?

For a short explanation of why the committee made this recommendation, see the <u>rationale section on flash glucose monitoring for pregnant women</u>.

Full details of the evidence and the committee's discussion are in <u>evidence</u> review A: diabetes in pregnancy: management from preconception to the postnatal period.

#### 9

10

## Rationale and impact

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

## 13 Continuous glucose monitoring

14 Recommendations 1.3.17 to 1.3.23

#### 1 Why the committee made the recommendations

- 2 There was evidence comparing continuous glucose monitoring with flash and
- 3 with intermittent capillary glucose monitoring, for pregnant women with type 1
- 4 diabetes.
- 5 When compared with intermittent capillary glucose monitoring, continuous
- 6 glucose monitoring resulted in:
- 7 more women achieving their blood glucose targets
- fewer caesarean sections
- fewer neonatal intensive care unit (NICU) admissions.
- When flash and continuous glucose monitoring were compared, there was no
- clear difference between the 2 monitoring systems in maternal and neonatal
- 12 outcomes.
- 13 Health economic modelling found that flash clearly has the lowest overall cost
- of the 3 options, when taking into account the benefits it provides. However, it
- is much less certain that flash provides the most benefit (a finding that is in
- line with the clinical evidence). Continuous glucose monitoring may provide
- more benefits, although this would be at a higher cost.
- 18 Based on these findings, the committee used their experience to highlight
- 19 situations where continuous glucose monitoring would provide enough benefit
- 20 to justify the extra cost. They recommended offering a choice of flash or
- 21 continuous glucose monitoring because in these situations the costs and
- benefits of the 2 systems are likely to be similar, and some women prefer
- 23 flash or have trouble using continuous glucose monitoring systems.
- 24 For women who are less likely to see extra benefits from continuous glucose
- 25 monitoring, the committee recommended that a choice of flash or continuous
- 26 glucose monitoring is offered while the cost of continuous glucose monitoring
- is met centrally by NHS England and NHS Improvement.
- 28 The committee believed that education and support are important for pregnant
- women using flash and continuous glucose monitoring, to ensure they get the

- full benefit. Therefore, they updated and expanded the 2015 recommendation
- 2 on providing support.
- 3 The current evidence base comparing flash with continuous glucose
- 4 monitoring in pregnant women with type 1 diabetes consists of 1 retrospective
- 5 cohort study. The committee agreed that more evidence is needed comparing
- 6 flash and continuous glucose monitoring, so they made a <u>research</u>
- 7 <u>recommendation</u> to address this.
- 8 The committee also reviewed the evidence for women who are planning a
- 9 pregnancy. One study compared continuous glucose monitoring and
- intermittent capillary glucose monitoring, but it did not show a difference
- between these systems for important outcomes (such as achieving blood
- 12 glucose targets). There was no evidence for flash glucose monitoring. Based
- on this lack of evidence, the committee did not make new recommendations
- 14 for women who are planning a pregnancy. Instead, they recommended further
- 15 research in this area.

#### 16 How the recommendations might affect practice

- 17 Use of continuous glucose monitoring varies across the country, but most
- centres offer flash and/or continuous glucose monitoring 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.

#### 21 Return to recommendations

## Context

22

- 23 Approximately 700,000 women give birth in England and Wales each year,
- 24 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
- 27 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
- 29 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
- 2 population and more pregnancies in older women.
- 3 Diabetes in pregnancy is associated with risks to the woman and to the
- 4 developing fetus. Miscarriage, pre-eclampsia and preterm labour are more
- 5 common in women with pre-existing diabetes. In addition, diabetic retinopathy
- 6 can worsen rapidly during pregnancy. Stillbirth, congenital malformations,
- 7 macrosomia, birth injury, perinatal mortality and postnatal adaptation
- 8 problems (such as hypoglycaemia) are more common in babies born to
- 9 women with pre-existing diabetes.
- 10 This guideline contains recommendations for managing diabetes and its
- complications in women who are planning pregnancy and those who are
- 12 already pregnant. The guideline focuses on areas where additional or different
- care should be offered to women with diabetes and their newborn babies.
- 14 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
- 18 transferred from paediatric to adult services.

## 19 Finding more information and resources

- To find out what NICE has said on topics related to this guideline, see our web
- 21 pages on fertility, pregnancy and childbirth and diabetes.
- 22 For details of the guideline committee, see the committee member list.

## 23 Update information

#### 24 **December 2020**

- New recommendations have been added on flash and continuous glucose
- 26 monitoring during pregnancy for women with type 1 diabetes.
- 27 Recommendations are marked [2020] if the evidence has been reviewed.

- 1 Recommendations on diabetic retinopathy have been amended to bring them
- 2 in line with the diabetic eye screening programme. The evidence for these
- 3 recommendations has not been reviewed, and they are marked [2008,
- 4 amended 2020].
- 5 Recommendations that have been deleted, or changed without an
- 6 evidence review
- We propose to delete some recommendations from the 2015 guideline.
- 8 Table 2 sets out these recommendations and includes details of replacement
- 9 recommendations. If there is no replacement recommendation, an explanation
- 10 for the proposed deletion is given.
- For recommendations shaded in grey and ending [2008, amended 2020] or
- 12 **[2015, amended 2020]**, we have made changes that could affect the intent
- without reviewing the evidence. Yellow shading is used to highlight these
- changes, and reasons for the changes are given in <u>table 3</u>.
- For recommendations shaded in grey and ending [2008], [2015] or [2008,
- amended 2015], we have not reviewed the evidence. In some cases, minor
- changes have been made for example, to update links, or bring the
- language and style up to date without changing the intent of the
- 19 recommendation.
- 20 See also the previous NICE guideline and supporting documents.

#### 21 Table 2 Recommendations that have been deleted

Recommendation in 2015 guideline	Comment	
1.1.32	This recommendation has been deleted to avoid overlap with the NHS Diabetic Eye Screening Programme.	
1.3.17	This recommendation has been deleted because the committee highlighted that practice and technology has changed along with the increased use of flash glucose monitoring since 2015 recommendations,	
1.3.26	This recommendation has been deleted to avoid overlap with the NHS Diabetic Eye Screening Programme.	

1

#### 2 Table 3 Amended recommendation wording (change to intent) without

#### 3 an evidence review

Recommendation in 2015 guideline	Recommendation in current guideline	Reason for change
1.1.3	1.1.3	Minor amendments to wording of the recommendation to provide further clarity.
1.1.31	1.1.30	Minor amendments to wording to avoid overlap with the NHS Diabetic Eye Screening Programme.
1.3.24	1.3.25	Minor amendments to wording of the recommendation to provide further clarity.

4

5

## February 2015

- 6 This guideline is an update of NICE guideline CG63 (March 2008) and
- 7 replaces it.
- 8 We have made some changes without an evidence review:
- 9 • Recommendation 1.1.23 was updated to better reflect the summaries of 10 product characteristics for insulin detemir and insulin glargine, and the 11 possibility of disrupted glucose control for women who switch to isophane
- insulin during pregnancy. 12
- 13 Recommendation 1.1.34 was updated to use the same thresholds and 14 terminology as the NICE guideline on chronic kidney disease.
- 15 • Recommendation 1.2.2 was updated to remove mention of specific family 16 origins, because the original list was not exhaustive and potentially missed 17 out some groups.
- 18 • Recommendation 1.3.14 was updated to match current clinical practice.

- Recommendation 1.3.28 was updated to reflect the increased risk of pre-
- 2 eclampsia in women with moderately increased albuminuria, and to use the
- 3 same thresholds and terminology as the NICE guideline on chronic kidney
- 4 disease.
- Recommendation 1.3.30 and table 1 were updated to address.
- 6 inconsistencies in the guideline on when the fetal heart examination should
- 7 take place.
- Recommendation 1.3.32 was updated to clarify which types of monitoring
- 9 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.
- 13 These recommendations are marked [2008, amended 2015].
- 14 Recommendations marked [2008] last had an evidence review in 2008. In
- some cases, minor changes have been made to the wording to bring the
- language and style up to date, without changing the meaning.

## 17 Minor changes since publication

- 18 August 2018: Footnotes were added to recommendation 1.1.10 to clarify BMI
- in different ethnic groups, and to recommendation 1.2.11 to provide a link to
- the Driver and Vehicle Licensing Agency (DVLA). The footnotes on
- 21 glibenclamide and on thresholds for defining risk of developing type 2
- 22 diabetes were updated.
- 23 **December 2015:** Recommendation 1.1.29 and related NICE guidance section
- were amended to refer to the updated <u>NICE guideline on type 2 diabetes in</u>
- 25 <u>adults</u>. Footnote numbering corrected.
- October 2015: Title changed from 'Diabetes in pregnancy: management of
- 27 diabetes and its complications from preconception to the postnatal period' to
- 28 'Diabetes in pregnancy: management from preconception to the postnatal
- 29 period' for clarity and consistency with other guidance on this topic.

- 1 August 2015: Changes have been made for consistency with other NICE
- 2 guidelines. Recommendation 1.1.17 now includes plasma glucose target
- 3 levels taken from the NICE guideline on type 1 diabetes in adults.
- 4 Recommendation 1.1.29 cross-refers to recommendations about education in
- 5 the NICE guidelines on type 1 diabetes in adults and type 2 diabetes in adults.
- 6 Recommendations 1.1.34 and 1.3.28 have been amended to ensure
- 7 consistency with the terminology used in the NICE guideline on chronic kidney
- 8 disease.
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