

Gestational Diabetes Screening and Treatment Guideline

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Guidelines are systematically developed statements to assist patients and providers in choosing appropriate health care for specific clinical conditions. While guidelines are useful aids to assist providers in determining appropriate practices for many patients with specific clinical problems or prevention issues, guidelines are not meant to replace the clinical judgment of the individual provider or establish a standard of care. The recommendations contained in the guidelines may not be appropriate for use in all circumstances. The inclusion of a recommendation in a guideline does not imply coverage. A decision to adopt any particular recommendation must be made by the provider in light of the circumstances presented by the individual patient.

Major Changes as of April 2018

New	Previous
2-step gestational diabetes (GDM) screening test	1-step GDM screening test
Follow Canadian Diabetes Association blood glucose cutoffs for diagnosis: <ul style="list-style-type: none"> • Fasting \geq 95 mg/dL or • 1-hour \geq 180 mg/dL or • 2-hour \geq 162 mg/dL 	Follow American Diabetes Association blood glucose cutoffs for diagnosis: <ul style="list-style-type: none"> • Fasting \geq 92 mg/dL or • 1-hour \geq 180 mg/dL or • 2-hour \geq 153 mg/dL
Targets for blood glucose control: <ul style="list-style-type: none"> • Fasting $<$ 95 mg/dL • 1 hour postprandial $<$ 140 mg/dL 	Targets for blood glucose control: <ul style="list-style-type: none"> • Fasting $<$ 90 mg/dL • 1 hour postprandial $<$ 120 mg/dL
For women on insulin with good glucose control, consider induction during week 39.	For women on insulin, consider induction at 39 weeks and no later than 41 weeks.
For women on insulin with poor glucose control, consider induction during week 38.	
For women on insulin for GDM, ultrasound to estimate fetal weight is recommended between weeks 30 and 32.	Ultrasound to estimate fetal weight was not recommended.

Screening Recommendations and Tests

Table 1. Recommendations for screening for previously undiagnosed diabetes and for gestational diabetes ¹			
Screen for	Eligible population	Recommended frequency	Recommended tests
Previously undiagnosed diabetes	All pregnant women ¹	Initial OB visit with nurse	HbA1c (as part of OB lab panel) If HbA1c screen is negative but diabetes is suspected due to symptoms, BMI, or ultrasound findings, a provocative test is recommended (2-step oral glucose tolerance test).
Gestational diabetes	Pregnant women at high risk for gestational diabetes ²	Consider screening earlier than 24–28 weeks gestation.	2-step oral glucose tolerance test
	Pregnant women not at high risk for gestational diabetes ²	Screen at 24–28 weeks gestation.	
¹ It is reasonable to exclude screening for previously undiagnosed diabetes if the woman is at low risk for diabetes and gestational diabetes. This would include women who are Caucasian, young (age $<$ 25), thin, and with no personal or family history of diabetes.			
² Women at increased risk of diabetes or gestational diabetes include those with a history of gestational diabetes; BMI $>$ 30; previous macrosomic baby (weighing \geq 4.5 kg); first-degree relative with diabetes; ethnicity with high prevalence of diabetes (Hispanic, American Indian, African American, South Asian); or polycystic ovarian syndrome (PCOS).			

Diagnosis

Diagnosis	Recommended tests	Positive result parameters
Previously undiagnosed diabetes	HbA1c Confirm the diagnosis with a second test on a different day. The second test can be HbA1c, fasting plasma glucose or random plasma glucose. For more information about the diagnostic process, see the Type 2 Diabetes Guideline .	≥ 6.5%
Gestational diabetes at 24–28 weeks	2-step oral glucose tolerance test Step 1 is nonfasting 1-hour 50 mg glucose tolerance test. <ul style="list-style-type: none">○ 1-hour result < 135 mg/dL is considered normal. No more testing required.○ 1-hour result between 135 mg/dL and 200 mg/dL is considered abnormal and the patient needs to move on to step 2.○ 1-hour result ≥ 200 mg/dL is considered diagnostic of GDM and does not require any further diagnostic tests. Step 2 is fasting 2-hour 75 mg glucose tolerance test. The patient is diagnosed with GDM if any one of these three values is abnormal: <ul style="list-style-type: none">○ Fasting ≥ 95 mg/dL○ 1-hour ≥ 180 mg/dL○ 2-hour ≥ 162 mg/dL	

Treatment

Goals

Maintaining glycemic control will lead to improved pregnancy outcomes, including decreases in macrosomia, clinical neonatal hypoglycemia, and cesarean section rates.

Lifestyle modifications/non-pharmacologic options

Most women who have gestational diabetes can successfully control their blood glucose with diet and exercise. Initiate a trial of lifestyle modifications and provide information about diet and exercise.

Diet and nutrition

- Give simple messages about nutrition: decrease simple sugars, rely more on complex carbohydrates, and increase lean protein and vegetable consumption.
- Diet recommendations for women with gestational diabetes are different from those for non-pregnant women with diabetes, in that the diet for GDM includes both more protein and more fat.
- Among women with gestational diabetes, 75–80% can achieve normoglycemia through dietary changes.

Calorie distribution

Opinions regarding the optimal distribution of calories vary. Most programs suggest three meals and three snacks; however, in overweight and obese women the snacks are often eliminated. Listed below are recommendations for caloric distribution:

- Breakfast: 10% of total caloric allotment (Carbohydrate intake at breakfast is limited since insulin resistance is greatest in the morning.)
- Lunch: 30% of calories
- Dinner: 30% of calories

- Snacks: 30% of calories

Recommended overall total caloric distribution:

- Carbohydrate: 33–40%
- Protein: about 20%
- Fat: about 40%

Exercise

Moderate exercise is recommended by the American Diabetes Association (ADA):

- All women, including those who are pregnant, are encouraged to exercise 1 hour daily.
- The current intensity and type of exercise should be modified for obvious safety issues (e.g., activities involving balance, direct contact sports).

Pharmacologic options

Patient home glucose monitoring

Following the diagnosis of gestational diabetes, ask the patient to begin home glucose monitoring as outlined in Table 3. Ask her to report the results after 1 week of monitoring and every 2–3 weeks thereafter until she delivers. Let the patient know that she will be informed if any changes to her treatment are needed based on those results.

Glucose monitoring time	Goal
Fasting	Average < 95 mg/dL
Before lunch Before evening meal	Average < 95 mg/dL
1 hour after all meals	Average < 140 mg/dL

If the patient is maintaining good glucose control, consider decreasing her home monitoring to twice a day: fasting and 1 hour after the biggest meal.

However, the patient should return to the full Table 3 schedule:

- If, at any time, her average readings are not below target, and
- Periodically throughout pregnancy as her dietary needs change.

Initiation of pharmacologic treatment

Pharmacologic treatment is initiated if lifestyle measures are inadequate for reaching target blood glucose.

The glucose level for which pharmacotherapy's benefits clearly outweigh its disadvantages or harms has not been clearly established. The Hyperglycemia and Adverse Pregnancy Outcome trial (HAPO), a large observational trial, demonstrated that a fasting glucose level of > 105 mg/dL is associated with a five-fold increase in the risk of macrosomia compared to a fasting glucose level of < 75 mg/dL (25% versus 5%) (HAPO Study Cooperative Research Group 2008). Lower glucose levels were associated with better primary outcomes, but there were no obvious thresholds at which the risks increased. Since the HAPO trial, more organizations are recommending lower glucose targets.

This guideline recommends initiating pharmacologic treatment if, **during the previous week**, the patient's average readings are:

- Fasting plasma glucose \geq 95 mg/dL, **or**
- 1-hour postprandial glucose \geq 140 mg/dL

There is no direct evidence on which to establish treatment thresholds; therefore, if the patient would prefer a higher threshold before initiating pharmacotherapy—after a conversation about the risks of

gestational diabetes and the benefits of tight glucose control has occurred—a higher target can be negotiated between the patient and her clinician.

Table 4. Recommended anti-hyperglycemic medications		
Population	Line	Medication
All women with gestational diabetes not controlled by diet and exercise	1 st	Insulin
Women with gestational diabetes not controlled by diet and exercise and unwilling to take insulin <i>See “Prescribing notes.”</i>	1 st	Metformin
	2 nd	Glyburide
Women taking metformin prior to pregnancy for the management of polycystic ovarian syndrome (PCOS)	<i>See “Prescribing notes.”</i>	

Prescribing notes for Table 4

Oral anti-hyperglycemic agents

Currently, the use of oral anti-hyperglycemic agents has not been approved by the FDA for treatment of gestational diabetes. Reserve oral diabetes agents for women who fail nutritional therapy and cannot or refuse to take insulin. If oral diabetes agents are used, patients should be clearly informed that these drugs cross the placenta and may have unknown risks to the fetus.

Metformin

There is insufficient evidence on which to base recommendations for continuing metformin during pregnancy for the management of PCOS. The harms of discontinuation include possible increased risk of miscarriage. If metformin is stopped, monitor glucose with the goal of FPG < 95 mg/dL and 1-hour postprandial < 140 mg/dL.

- If the patient received clear instructions from her prescribing specialist about what to do if she became pregnant while on metformin, she should continue following that advice.
- For those who did not receive clear advice, the decision about tapering or changing medications should be individualized between the patient and her physician. It is likely that a transition to insulin would be accompanied by a tapering of metformin as plasma glucose levels are monitored.

Table 5. Insulin dosing recommendations			
Long-acting insulin analogs (insulin glargine, insulin detemir) are not recommended, as they have not been studied extensively in pregnancy.			
Step 1: Control fasting hyperglycemia by initiating insulin therapy with NPH. (Goal: average weekly fasting blood glucose < 95 mg/dL—see Table 3.)			
Medication	Frequency	Starting dose	Modified dose
NPH	The entire dose is taken at bedtime.	0.2 units/kg	Every 4 days; if 4-day average is ≥ 95 mg/dL, increase dose by 2 units until 4-day average fasting blood glucose is < 95 mg/dL.
Step 2: After controlling fasting hyperglycemia, control postprandial readings with insulin aspart. (Goal: average weekly postprandial readings < 140 mg/dL—see Table 3.)			
Medication	Frequency	Starting dose	Modified dose
Insulin aspart	If for any meal the 1-hour postprandial reading is <i>persistently</i> ≥ 140 mg/dL, add insulin aspart to be taken at that meal.	1 unit aspart per 10 g carbohydrate	Increase aspart to 2 units per 15 g carbohydrate until 1-hour postprandial reading is < 140 mg/dL.
Step 3: If control is still not adequate, contact the Diabetes Team for advice on additional adjustments.			

Table 6. Oral medication options for glycemic control for women who will not take insulin			
Eligible population	Medication	Starting dose	Titration
Pregnant women unable or unwilling to take insulin	Metformin See "Prescribing notes."	250 mg once daily	500 mg b.i.d. to 850 mg t.i.d.
	Glyburide See "Prescribing notes."	2.5–5.0 mg daily at first meal	2.5 mg once daily to 7.5 mg b.i.d.
Pregnant women above goal on oral medication	Switch to insulin.	—	—

Prescribing notes for Table 6

Metformin

Metformin should be titrated as tolerated. A reasonable initial titration schedule is:

- a) 500 mg ½ tab (250 mg) PO once daily x 7 days;
- b) 500 mg 1 tab PO once daily x 7 days;
- c) 500 mg 1 tab PO b.i.d.

If a patient does not experience any GI side effects after 2–3 days, the dose may be titrated to goal more quickly.

If a patient develops GI side effects, reduce the dose and reassess. Consider a more conservative titration schedule starting with 500 mg ¼ tab (125 mg) PO once daily; alternatively, consider prescribing the XR formulation for patients who cannot tolerate ideal dose with regular release formulation. Some patients (young, obese, and without GI side effects) may tolerate metformin up to 3,000 mg daily; consider consultation with a diabetes expert.

Glyburide

While the maximum dose is glyburide 10 mg b.i.d., the medication's effectiveness has been found to plateau at 5.0–7.5 mg b.i.d.

Additional Testing/Monitoring

Antenatal monitoring

There is no evidence on which to base the optimal timing for delivery, ultrasound for fetal weight and amniotic fluid index, or for non-stress testing, so the following recommendations are based on community standards and expert opinion.

	GDM diet controlled/GDM A1	GDM med/insulin controlled/GDM A2	GDM poorly controlled
Non-stress test	Not standard practice	Start at 32–34 weeks/ twice weekly	Start at 32–34 weeks/ twice weekly
Ultrasound for fetal weight (estimated fetal weight)	Not standard practice	Start at 30–32 weeks/ Consider repeat in 4–6 weeks	Start at 30–32 weeks/ Consider repeat in 4–6 weeks
Amniotic fluid index/ maximum vertical pocket	Not standard practice	Start at 32–34 weeks/ once weekly	Start at 32–34 weeks/ once weekly
Induction of labor	Consider between 40w0d and 40w6d	Consider between 39w0d and 39w6d	Consider between 38w0d and 38w6d

Ketone checking is *not* recommended as an antenatal test.

Follow-up after delivery

Gestational diabetes is a risk factor for type 2 diabetes. While only about 5% of women who have gestational diabetes develop type 2 diabetes within 6 months of delivery, about 60% will develop type 2 diabetes within 10 years (Hartling 2012). Encourage a healthy diet, exercise, and weight control to prevent type 2 diabetes.

Eligible population	Test	Frequency/timing
All women with gestational diabetes (place order at 4-week postpartum visit)	HbA1c	3 months postpartum
All women with a history of gestational diabetes	HbA1c	Annually

Referral

- Family medicine providers or ARNP midwives should consult with an obstetrician if the estimated fetal weight is $\geq 4,500$ g, or if the non-stress test or amniotic fluid index is abnormal.
- Obstetricians should consider a consult with Maternal Fetal Medicine if early induction of labor is being considered (at 38 weeks gestation or earlier).
- Women with gestational diabetes (regardless of whether they are taking insulin) do not need to be managed by an obstetrician unless specific issues arise.

Evidence Summary

The Gestational Diabetes Guideline was developed using an evidence-based process, including systematic literature search, critical appraisal, and evidence synthesis.

As part of our improvement process, the Kaiser Permanente Washington guideline team is working towards developing new clinical guidelines and updating the current guidelines every 2–3 years. To achieve this goal, we are adapting evidence-based recommendations from high-quality national and international external guidelines, if available and appropriate. The external guidelines should meet several quality standards to be considered for adaptation. They must: be developed by a multidisciplinary team with no or minimal conflicts of interest; be evidence-based; address a population that is reasonably similar to our population; and be transparent about the frequency of updates and the date the current version was completed. An additional evidence review is performed to answer questions not addressed by the external guidelines and to update the evidence with more recently published studies.

Key questions addressed in the KPWA guideline

1. Does the use of the 1-step diagnostic test versus the 2-step approach for screening and diagnosis of gestational diabetes (GDM) lead to improvements in maternal, perinatal, or neonatal health outcomes?
2. What is the optimal blood glucose cutoff value for diagnosing pregnant women with GDM and for identifying those at risk for fetal overgrowth?
3. What is the optimal target for glycemic control in pregnant women with GDM?
4. What are the appropriate measures for antenatal fetal surveillance in pregnancies complicated by GDM?
5. What are the most appropriate timing and mode of delivery for women with GDM with or without good glycemic control? Does early induction of labor improve fetal outcomes?

External guidelines meeting KPWA criteria for adaptation/adoption

2017	American Diabetes Association: Standards of Medical Care in Diabetes.
2017	American College of Obstetrics and Gynecology Practice Bulletin No. 180: Gestational Diabetes Mellitus.
2017	National Institute for Health and Health Care Excellence (NICE). Gestational Diabetes: Risk Assessment, Testing, Diagnosis and Management.
2016	Canadian Diabetes Association (CDA). Clinical Practice Guideline: Diabetes in Pregnancy.
2015	Kaiser Permanente Colorado Clinical Practice Resource: Gestational Diabetes Diagnosis and Management.

Key questions 1 and 2

Does the use of the 1-step diagnostic test versus the 2-step approach for screening and diagnosis of gestational diabetes (GDM) lead to improvements in maternal, perinatal, or neonatal health outcomes?

What is the optimal blood glucose cutoff value for diagnosing pregnant women with GDM and for identifying those at risk for fetal overgrowth?

A review of the recommendations of different professional societies and organizations (in the United States, Canada, and European countries) shows that there is no consensus on the strategies for screening pregnant women for GDM, the diagnostic criteria used for its identification, or the threshold at which treatment of GDM will reduce the risks of adverse perinatal outcomes. There are variations in recommendations of who to screen (universal versus selective screening for high-risk women), the preferred screening/diagnostic method (e.g., 1- versus 2-step testing), glucose load (75 versus 100g), test duration, glucose cutoff values, and how many increased glucose values (one or more) are required to diagnose GDM. Several diagnostic criteria are being used, but none has been universally recommended for use in all antenatal practices.

A literature search for more recently published studies did not provide additional evidence to determine the optimal strategy for the screening and diagnosis of GDM. The results of one randomized controlled trial (RCT) and several observational studies suggest that using the 1-step testing approach increases the number of women diagnosed with GDM. However, there are no published RCTs to date that examined the impact of the 1-step test versus the 2-step test for screening/diagnosing pregnant women on maternal, perinatal, or neonatal health outcomes.

In a review article, Gupta and colleagues (2015) presented arguments for and against adopting the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria as well as the 1-step versus 2-step methods for testing for GDM. They explained that the diagnostic criteria proposed by O'Sullivan in 1964 and modified by Carpenter and Coustan were based on maternal risk of developing type 2 diabetes, while the IADPSG criteria aim at linking the level of glycaemia to pregnancy and fetal outcomes. IADPSG recommendations were based on HAPO study results, which showed a linear association between glucose levels at fasting, 1 hour, and 2 hours after an oral glucose tolerance test (OGTT) and predefined fetal and pregnancy outcomes. The diagnostic threshold was arbitrary and decided by the IADPSG consensus panel.

The following table (source: Gupta 2015) summarizes the advantages and disadvantages of both the 1-step and 2-step approaches:

	One-step testing for GDM	Two-step testing for GDM
Method	75- or 100-g OGTT is done in all patients, without the preliminary step by the glucose challenge test (GCT)	50-g GCT followed by 100-g, 3-hour OGTT. Those who screen positive are followed-up by an oral 100-g glucose tolerance test
Advantages	<ul style="list-style-type: none"> • Simple to follow • Easily diagnosed 	<ul style="list-style-type: none"> • Fewer false positives • Avoids OGTT in more than 75% of women
Disadvantages	<ul style="list-style-type: none"> • Poor reproducibility • All women need to come in the fasting state 	<ul style="list-style-type: none"> • Missed diagnosis: 75% sensitivity with 84% specificity as compared with single-step 100-g OGTT • Delay in initiating treatment even in those who test positive • Requires patients to make two visits for testing

Key question 3

What is the optimal target for glycemic control in pregnant women with GDM?

The following targets for glycemic control are recommended by most of professional organizations and societies:

Status	Target
Fasting	≤ 95 mg/dL (5.3 mmol/L)
1-hour postprandial	≤140 mg/dL (7.8 mmol/L)
2-hour postprandial	≤120 mg/dL (6.7 mmol/L)

There are no published trials to date that compared the effect of the different glucose targets on maternal or newborn health outcomes.

Key question 4

What are the appropriate measures for antenatal fetal surveillance in pregnancies complicated by GDM?

- Overall, the guidelines of the different societies/organizations agree that women whose GDM is well controlled without the use of medication, in the absence of other pregnancy complications or risk factors for poor pregnancy outcomes, may not need antenatal fetal monitoring. Fetal surveillance may be beneficial for those with poor glycemic control or who are treated medically with insulin or oral agents.
- There is insufficient published evidence or consensus on the optimal strategy for fetal surveillance in pregnancies complicated by GDM.
- There is insufficient evidence to determine the optimal timing and frequency of fetal antenatal assessment in women with GDM for whom such assessment is recommended.
- A review article by Garrison (2015) indicates that a sonographically estimated fetal weight > 4000 g (8 lb 13 oz) is only modestly predictive of an actual fetal weight > 4000 g, with a positive likelihood ratio of 5.7 (95% CI, 4.3–7.6) and a negative likelihood ratio of 0.48 (98% CI, 0.38–0.60). He also noted that a clinical estimate using Leopold maneuvers and fundus height measurement are as predictive as ultrasonography for fetuses weighing > 4000 g. Garrison's statements, however, were based on earlier studies, and might not be applicable to the current state of ultrasound technology.

Key question 5

What are the most appropriate timing and mode of delivery for women with GDM with or without good glycemic control? Does early induction of labor improve fetal outcomes?

- The recommendations of the published guidelines on timing of delivery of pregnancies complicated by GDM are inconsistent.
- There is insufficient published evidence from valid, well-conducted RCTs to allow weighing the potential benefits and harms of routine induction of labor in women with GDM.
- There is moderate-quality evidence from RCTs with limitations and from observational studies suggesting that elective induction of labor in low-risk pregnant women with GDM or women with impending macrosomia may reduce the risk of shoulder dystocia without increasing the rate of cesarean section.
 - The GINEXMAL RCT (Alberico 2017), which compared induction of labor (at 38 weeks 0 days and 39 weeks 0 days gestation) versus expectant management in GDM pregnancies, shows no significant differences between the two study arms in the incidence of caesarean section, maternal outcomes, and the majority of neonatal outcomes. However, the trial had a lack of statistical power among other limitations.
 - The Boulvain 2015 open-label RCT (10% of the women had GDM) suggests that induction of labor (within 3 days between 37 weeks 0 days and 38 weeks 6 days gestation) in low-risk GDM pregnancies and pregnancies with large-for-date fetuses (impending macrosomia) may decrease the rate of shoulder dystocia and does not increase the rate of cesarean delivery.
 - The Melamed observational study (2016) suggests that induction of labor at 38 or 39 weeks gestation in women with low-risk GDM is associated with a lower risk of caesarean section compared to expectant management. Induction of labor at 38 weeks was, however, associated with an increased risk of neonatal intensive care unit admission.

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Guideline Development Process and Team

Development process

To develop the Gestational Diabetes Screening and Treatment Guideline, the guideline team adapted recommendations from external developed evidence-based guidelines and/or recommendations organizations that establish community standards. The guideline team reviewed additional evidence in several areas. For details, see Evidence Summary and References.

This edition of the guideline was approved for publication by the Guideline Oversight Group in April 2018.

Team

The Gestational Diabetes Screening and Treatment Guideline development team included representatives from Clinical Improvement & Prevention, endocrinology, family medicine, laboratory medicine, obstetrics/gynecology, residency, and women's health.

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Disclosure of conflict of interest

Kaiser Permanente requires that team members participating on a guideline team disclose and resolve all potential conflicts of interest that arise from financial relationships between a guideline team member or guideline team member's spouse or partner and any commercial interests or proprietary entity that provides or produces health care-related products and/or services relevant to the content of the guideline.

Team members listed above have disclosed that their participation on the Gestational Diabetes Guideline team includes no promotion of any commercial products or services, and that they have no relationships with commercial entities to report.