

ADDENDUM I

DIABETES SCREENING AND DIAGNOSIS RECOMMENDATIONS

TESTING CRITERIA FOR DIAGNOSIS OF DIABETES MELLITUS

The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus of the American Diabetes Association (*Diabetes Care* 36:S11-S66, 2013) stated that diabetes can be provisionally diagnosed with any one of the four criteria listed below.

1. HbA1c \geq 6.5% or,*
2. A fasting plasma glucose of \geq 126 mg/dL (after no caloric intake for at least 8 hours) or,*
3. An oral glucose tolerance test (OGTT) (75 gram dose) of \geq 200 mg/dL for the two hour sample. Oral glucose tolerance testing is not necessary if patient has a fasting plasma glucose level of \geq 126 mg/dL or,*
4. A random plasma glucose of \geq 200 mg/dL (taken at any time of day without regard to time of last meal) with classic diabetes symptoms: increased urination, increased thirst and unexplained weight loss.

* In the absence of unequivocal hyperglycemia, criteria 1-3 should be confirmed by repeat testing.

Impaired Glucose Metabolism (pre-diabetes)

The Committee defined a fasting plasma glucose value of 99 mg/dL as the upper limit of normal blood glucose. The Committee also recognized two categories of impaired glucose metabolism that are considered risk factors for future diabetes and cardiovascular disease.

1. Impaired Fasting Glucose (IFG) is when fasting plasma glucose is between 100 and 125 mg/dL.
2. Impaired Glucose Tolerance (IGT) is when 2-hour sample results of the oral glucose tolerance test are between 140 and 199 mg/dL.
3. HbA1c 5.7 - 6.4%.

Summarized Interpretation of Oral Glucose Tolerance Test (OGTT)

2 hour postload glucose of < 140 mg/dL = NORMAL GLUCOSE TOLERANCE

2 hour postload glucose between 140 mg/dL and 199 mg/dL = IMPAIRED GLUCOSE TOLERANCE

2 hour postload glucose \geq 200 mg/dL = PROVISIONAL DIAGNOSIS OF DIABETES (Must be confirmed on a subsequent day by any of the above criteria for diagnosis of Diabetes Mellitus.)

AMERICAN DIABETES ASSOCIATION RECOMMENDATIONS

TABLE 1: Criteria for testing for diabetes in asymptomatic adult individuals
<p>1. Testing for diabetes should be considered in all adults who are overweight (BMI ≥ 25 kg/m^{2*}) and have additional risk factors, as follows:</p> <ul style="list-style-type: none"> • physical inactivity • first-degree relative with diabetes • high-risk race/ethnicity (e.g., African American, Latino, Native American, Asian American, Pacific Islander) • women who delivered a baby weighing >9 lb or have been diagnosed with GDM • hypertension ($\geq 140/90$ mmHg or on therapy for hypertension) • HDL cholesterol level <35 mg/dL (0.90 mmol/l and/or a triglyceride level >250 mg/dL (2.82 mmol/l)) • Women with polycystic ovary syndrome • HbA1c $\geq 5.7\%$, IGT, or IFG on previous testing • other clinical conditions associated with insulin resistance (e.g. severe obesity, acanthosis nigricans) • history of CVD <p>2. In the absence of the above criteria, testing for diabetes should begin at age 45 years.</p> <p>3. If results are normal, testing should be repeated at least at 3-year intervals, with consideration of more frequent testing depending on initial results (e.g., those with prediabetes should be tested yearly) and risk status.</p>

*At-risk BMI may be lower in some ethnic groups.

TABLE 2: Testing for Type 2 diabetes in asymptomatic children*
<p>Criteria:</p> <ul style="list-style-type: none"> • overweight (BMI >85th percentile for age and sex, weight for height >85th percentile, or weight >120% of ideal for height) <p>Plus any two of the following risk factors:</p> <ul style="list-style-type: none"> • family history of type 2 diabetes in first-or second-degree relative • race/ethnicity (Native American, African American, Latino, Asian American, Pacific Islander) • signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, polycystic ovary syndrome, or small-for-gestational-age birth weight) • Maternal history of diabetes or GDM during the child's gestation. <p>Age of initiation: age 10 years or at onset of puberty, if puberty occurs at a younger age Frequency: every 3 years</p>

*Persons aged 18 years and younger.

SCREEN AND DIAGNOSTIC TESTING FOR GESTATIONAL DIABETES MELLITUS (GDM)

The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study, a large-scale (~25,000 pregnant women) multinational epidemiological study, demonstrated that risk of adverse maternal, fetal, and neonatal outcomes continuously increased as a function of maternal glycemia at 24-28 weeks, even within ranges previously considered normal for pregnancy.

ADDENDUM I (continued)

After deliberations in 2008-2009, the International association of Diabetes and Pregnancy Study Groups (IADPSG), an international consensus group with representatives from multiple obstetrical and diabetes organizations, including ADA, developed revised recommendations for diagnosing GDM. The group recommended that all women not known to have prior diabetes undergo a 75g OGTT at 24-28 weeks of gestation. Additionally, the group developed diagnostic cut points for fasting, 1 hour and 2 hour plasma glucose measurements that conveyed an odds ratio for adverse outcomes of at least 1.75 compared with women with the mean glucose levels in the HAPO study (**not supported by ACOG**).

The American Diabetes Association's (**ADA Recommendation**) Position Statement on Gestational Diabetes Mellitus (*Diabetes Care* 36:S11-S66, 2013) recommends:

- Screen for undiagnosed type 2 diabetes at the first prenatal visit in those with risk factors, using standard diagnostic criteria.
- In pregnant women not previously known to have diabetes, screen for GDM at 24-28 weeks of gestation, using a 75g 2 hour OGTT and their diagnostic cut points in Table 3.
- Screen women with GDM for persistent diabetes at 6-12 weeks postpartum, using the OGTT and non-pregnancy diagnostic criteria.
- Women with history of GDM should have lifelong screening for the development of diabetes or prediabetes at least every 3 years.
- Women with history of GDM found to have prediabetes should receive lifestyle interventions or Metformin to prevent diabetes.

Fasting	92 mg/dL
One Hour	180 mg/dL
Two Hour	153 mg/dL

* The OGTT should be performed in the morning after an overnight fast of at least 8 hours.

These new criteria will significantly increase the prevalence of GDM, primarily because only one abnormal value, not two, is sufficient to make the diagnosis.

The American College of Obstetricians and Gynecologists (**ACOG Recommendation**) announced in 2011 that they continue to recommend use of prior diagnostic criteria for GDM as follows: (ACOG Committee Opinion Number 504, September 2011).

- All pregnant women should be screened for GDM, whether by patient history, clinical risk factors, or a 50g, 1 hour loading test to determine blood glucose levels.
- The diagnosis of GDM can be made based on the result of the 100g, 3 hour oral glucose tolerance test (OGTT), for which there is evidence that treatment improves outcome. Either the plasma or serum level established by Carpenter and Coustan or the plasma glucose level designated by the National Diabetes Data Group are appropriate to use (see Table 4). A positive diagnosis requires that two or more thresholds be met or exceeded.
- Diagnosis of GDM based on the one step screening and diagnosis test (75g glucose load) outlined in the International Association of Diabetes and Pregnancy Study Group (IADPSG) guidelines is not recommended at this time because there is no evidence that diagnosis using this criteria leads to clinically significant improvements in maternal and newborn outcomes and would lead to a significant increase in health care costs.

One-Step Approach: Perform a diagnostic oral glucose tolerance test (OGTT). The test should be done in the morning after an overnight fast of at least 8 hours. Two or more of the following venous plasma concentrations must be met or exceeded for a positive diagnosis:

TABLE 4	Specimen*	Plasma or Serum Glucose Level - Carpenter and Coustan Conversion	Plasma Glucose Level - National Diabetes Data Group Conversion
	Fasting	95 mg/dL	105 mg/dL
	One Hour	180 mg/dL	190 mg/dL
	Two Hour	155 mg/dL	165 mg/dL
	Three Hour	140 mg/dL	145 mg/dL

Diagnostic criteria for the 100g OGTT are derived from the work of O'Sullivan and Mahan, modified by Carpenter and Coustan, and shown in TABLE 4.

Two-Step Approach: Perform an initial screening for GDM by measuring plasma or serum glucose concentration 1 hour after a 50 gram oral glucose load. The patient need not be fasting. A diagnostic oral glucose tolerance test (see one step approach above) should be performed on the women that exceeded the glucose threshold value on the 1 hour screening test. A glucose threshold of >139 mg/dL on the 1 hour screening test identifies approximately 80% of women with GDM, and the yield is further increased to 90% by using a screening threshold of >129 mg/dL.