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VOL. 36, NO. 3 - MARCH 4, 2013

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CHANGES IN TESTING FOR SCREENING AND DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS

ANNU KHAJURIA, PHD, FCACB, FACB; MARSHFIELD LABS MARIA A. MASCOLA, MD; MATERNAL & FETAL MEDICINE, OBSTETRICS AND GYNECOLOGY

Effective March 11, 2013, changes will be made to the reference ranges for the gestational diabetes screen and oral glucose tolerance test (OGTT). These changes are being made to conform to recommendations from the American College of Obstetrics and Gynecology (ACOG), and in response to national trends in the diagnosis of gestational diabetes.

Gestational diabetes is defined as carbohydrate intolerance that begins or is first recognized during pregnancy. It is a condition associated with increased risk to fetus and mother.

Numerous national and international organizations have issued specific guidelines with recommendations for screening and diagnosis. Two major organizations in the United States, the American Diabetes Association (ADA) and the American College of Obstetrics and Gynecology (ACOG), differ in their recommendations for screening:

- ADA recommends a one-step fasting 75g, 2hr OGTT as advocated by The International Association of the Diabetes and Pregnancy Study Groups (IADPSG).
- ACOG recommends a two-step approach with a non-fasting glucose screen and a fasting 100g, 3hr OGTT.

Currently, there is no compelling scientific evidence to prove that the one step approach leads to better maternal or newborn outcomes, nor

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is there consensus in the national community for one recommendation over the other. Therefore, until there is consensus, Marshfield Clinic's approach will be to adopt the ACOG recommendations for gestational diabetes screening and diagnosis as stated below.

AMERICAN COLLEGE OF OBSTETRICS AND GYNECOLOGY RECOMMENDATIONS:

"All pregnant women should be screened for gestational diabetes mellitus (GDM) – whether by patient history, clinical risk factors, or with a 50 g, onehour loading test at 24 to 28 weeks of gestation to determine blood glucose levels.

The diagnosis of GDM can be made based on the result of the 100 g, threehour oral glucose tolerance test. Either the plasma or serum glucose levels established by Carpenter and Coustan or the plasma levels designated by the National Diabetes Data Group are appropriate to use. A positive diagnosis requires that two or more upper thresholds be met or exceeded."

CURRENT TESTING

Currently, Marshfield Labs offers:

- Gestational Diabetes Screen with 1 hour 50 g oral glucose load. Current Reference value: <140 mg/dL
- Glucose Tolerance Test, OB 3 Hour 100 g & 75 g. Current Reference value:
 - Fasting <95 mg/dL; 1 Hour: <180 mg/dL; 2 Hour: <155 mg/dL; 3 Hour: <140 mg/dL (Carpenter & Coustan established thresholds.)
 - Fasting 70-99 mg/dL; 1 Hour: <190 mg/dL; 2 Hour: <165 mg/dL; 3 Hour: <145 mg/dL (Fasting values are non-diabetic fasting values; 1, 2 & 3 hr values are National Diabetes Data Group established thresholds.)

The \geq 140 mg/dL plasma/serum threshold has sensitivity of 80% and specificity of 90% for GDM. 10% of women with GDM have values between 130 mg/dL and 140 mg/dL. The sensitivity is increased to 90% with similar specificity if a threshold value of \geq 130 mg/dL is used but this is accompanied by an increase in diagnostic testing and overall cost of 12%. A screening cutoff value of \geq 135 mg/dL has been recommended, which provides an acceptable balance between detection rate and cost of testing.

TESTING CHANGES

- Gestational diabetes screen: Reference value will be changed to <135 mg/dL.
- Only 100g, 3 hour glucose tolerance test will be offered.

(75g, 3 hour glucose tolerance will *not* be an orderable test for gestational diabetes.)

- The reference threshold levels established by Carpenter and Coustan will be the diagnostic criteria for positive 100g, 3 hour glucose tolerance test. A positive diagnosis requires that two or more upper thresholds be met or exceeded.
 - Reference values: Fasting <95 mg/dL; 1 Hour: <180 mg/dL; 2 Hour: <155 mg/dL; 3 Hour: <140 mg/dL.

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QUESTIONS

For additional information or questions, contact: Annu Khajuria, PhD, FACAB, FACB; phone 1-800-222-5835.

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