PURPOSE:

Hyperglycemia is the hallmark of diabetes mellitus. The common underlying defect is a deficiency of insulin secretion or action, which leads to the development of hyperglycemia. Hyperglycemic disorders can be classified as:

1) **Type 1 Diabetes:** Characterized by beta cell destruction, usually leading to absolute insulin deficiency. It has two forms: *Immune-Mediated Diabetes Mellitus* which results from a cellular mediated autoimmune destruction of the beta cells of the pancreas; and *Idiopathic Diabetes Mellitus* which refers to forms of the disease that have no known etiologies.

2) **Type 2 diabetes:** The most common form of diabetes mellitus (80-90% of patients). Most individuals with Type 2 DM have plasma insulin concentrations that are higher than normal but not sufficient to maintain a normal blood glucose concentration - relative deficiency of insulin activity.

3) **Impaired glucose tolerance (IGT):** These individuals have a slightly abnormal glucose tolerance but not sufficiently abnormal to be diagnostic of diabetes mellitus. They have a greater than normal risk for developing diabetes mellitus.

4) **Gestational diabetes mellitus (GDM):** Gestational diabetes is diagnosed when an abnormal glucose concentration is found for the first time during pregnancy. Early diagnosis is important so that the patient can be monitored and treatment can be instituted when necessary.

In the oral glucose tolerance test measurements of plasma or serum glucose are made before and after glucose is given orally. This test is most helpful in the following situations:

1) Diagnosis of gestational diabetes mellitus
2) Further evaluation of an individual with a borderline elevation of fasting or postprandial plasma glucose.

PATIENT PREPARATION:

The test should be performed in the AM after 3 days of unrestricted diet and activity and after a 10-16 hour fast. Water is permitted during the fasting period but coffee and smoking are not allowed.

For three days prior to the test omit medications known to affect glucose tolerance (e.g. thiazides, diphenylhydantoin, propranolol, corticosteroids, estrogens, salicylates and diuretics). Oral contraceptives should be omitted for one complete cycle prior to the test.

The presence of anorexia or any other condition precluding adequate food intake automatically invalidates the test.

Inactivity, such as bed rest, has been reported to reduce glucose tolerance. A glucose tolerance test thus should not be performed in non-ambulatory patients.

The test should not be done if the patient has had an illness during the prior two weeks.
SPECIMEN:

Blood should be drawn for glucose levels at each of the prescribed times. 0.5 ml serum or heparinized plasma accepted, store refrigerated. Minimum sample volume is 100 ul plasma or serum.

Urine samples do not need to be collected. Insulin levels may be requested by the physician. Serum for insulin assays should then be drawn along with each glucose sample.

REAGENTS AND EQUIPMENT:

SP Brand Orange 75 and 100 gm Glucose Tolerance Beverage: Contains 75 or 100 g dextrose (D-Glucose)(Source of Dextrose: Corn), citric acid, flavoring, 0.05% sodium benzoate and 0.01% propylparahydroxybenzoate as preservative. Do not freeze. Store at room temperature. Stable until expiration date on bottle.

PROCEDURE:

1. Collect a fasting blood sample. Determine the fasting glucose. If the fasting glucose is within the range 75-125 mg/dl, proceed with the test. If the fasting glucose is >125 mg/dL, NPL should call the ordering physician and obtain their decision whether to proceed with the test or cancel it. NOTE: If the ordering physician is not available, contact a pathologist before proceeding with the test.

2. For an adult, give 75 grams of glucose tolerance beverage.

3. For a child, give 1.75 grams of glucose per kg body weight.* Convert the child’s weight from lbs to kg by dividing the number of pounds by 2.2. Multiply this value by 1.75 grams to determine the dosage in grams of glucose. To convert dosage in grams to dosage in ml apply the following formula:

   \[ \text{Dosage in ml (see note)} = \frac{296 \text{ ml}}{100 \text{ gm}} \times \text{Dosage in grams} \]

NOTE: this formula applies to the 100 gm size of glucose beverage

*This calculation should be used if the child is less than 94 pounds. If they are 94 pounds or more, give the adult dose (75 grams).

4. Administer the glucose tolerance beverage in a single dose over 5 minutes. Begin timing the tolerance as soon as the patient has finished drinking.

5. Draw a blood sample for glucose at 2 hours.
6. If nausea, fainting, sweating or other autonomic nervous system over-activity occurs, draw a specimen for glucose immediately, discontinue the procedure and notify a pathologist.

7. The glucose tolerance test may be extended to 3, 4 or 5 hours if specifically requested by the physician. Each additional glucose must be test-requested in the LIS as an individual glucose with a comment added stating the number of hours post dose (e.g. “3 hours post-dose”.)

REPORTING RESULTS:

The test code for a glucose tolerance test is GTOL.

Enter all glucose results into the computer. Add a comment stating the dosage of glucose (in grams) given to the patient, e.g. "75 grams glucose administered".

Classification of Glucose Results (American Diabetes Association 1999 Revised Criteria)

Patients may be classified into 3 categories based on the 2-hour postload glucose:

<table>
<thead>
<tr>
<th>2-hr Postload Glucose</th>
<th>Patient Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;140 mg/dl</td>
<td>Normal glucose tolerance</td>
</tr>
<tr>
<td>≥140 mg/dl or &lt;200 mg/dl</td>
<td>Impaired glucose tolerance</td>
</tr>
<tr>
<td>≥200 mg/dl</td>
<td>Provisional diabetes mellitus</td>
</tr>
</tbody>
</table>

NOTE: The ADA has defined 3 criteria for the diagnosis of diabetes:

- Symptoms of diabetes plus a random plasma glucose ≥200 mg/dl
- Fasting plasma glucose of ≥126 mg/dl
- Oral glucose tolerance test value of >200 mg/dl at 2 hours after an appropriate glucose dose (e.g. 75 gm glucose in adults)

Diabetes can be diagnosed by a positive result for any one of these 3 criteria, followed by a confirming positive finding on a subsequent day. Any combination of these findings may be used, but the preferred diagnostic test is the fasting plasma glucose (FPG). An FPG of >100 mg/dl but <126 mg/dl is defined as “Impaired Fasting Glucose”.

Glucose tolerance CHEM213.doc
SCREEN FOR GESTATIONAL DIABETES

PRINCIPLE:

Screening for gestational diabetes should be performed between 24 and 28 weeks of gestational age if the patient falls into any of the following groups: 1) a strong family history of diabetes mellitus; 2) ≥25 years of age; 3) <25 years of age and obese; 4) member of an ethnic/racial group with a high prevalence of diabetes, e.g. Hispanic, Native American, Asian, African or Pacific Islander.

PATIENT PREPARATION:

Fasting is not required. During the one hour testing period the patient may drink water, but should not eat or drink anything else.

SPECIMEN:

Draw blood one hour following administration of the glucose challenge. Heparinized plasma or serum accepted, 0.5 ml refrigerated. Urine samples are not required.

REAGENTS AND EQUIPMENT:

SP Brand Orange 100 gm Glucose Tolerance Beverage: Contains 100 g dextrose (D-Glucose)(Source of Dextrose: Corn), citric acid, flavoring, 0.05% sodium benzoate and 0.01% propylparahydroxybenzoate as preservative. Do not freeze. Store at room temperature. Stable until expiration date on bottle.

PROCEDURE:

1. Administer an oral 50 gm glucose load to the patient (148 ml of the 100 gram glucose tolerance beverage).

2. One hour later draw a blood sample for glucose.

REPORTING RESULTS:

The test code is GLUP1. Add the comment "50 grams glucose administered."

The following interpretive comment, which is based on 2007 ADA criteria, will be appended to the result: “A glucose threshold value >140 mg/dl identifies approximately
80% of women with GDM. The yield is further increased to 90% by using a cutoff of >130 mg/dl.”

**ORAL GLUCOSE TOLERANCE TEST FOR GESTATIONAL DIABETES MELLITUS**

**PATIENT PREPARATION:**

This test should be performed in the morning after the patient has had 3 days of unrestricted diet and activity and after a 10-16 hour fast. All medications known to affect glucose tolerance should be omitted. This test may be ordered by the physician if the gestational screen is abnormal.

**SPECIMEN:**

Blood specimens should be drawn at the times specified in the procedure. 0.5 mL serum or heparinized plasma is acceptable. Store refrigerated. Minimum sample volume is 100 ul plasma or serum.

**REAGENT:**

SP Brand Orange 100 gm Glucose Tolerance Beverage: Contains 100 g dextrose (D-Glucose)(Source of Dextrose: Corn), citric acid, flavoring, 0.05% sodium benzoate and 0.01% propylparahydroxybenzoate as preservative. Do not freeze. Store at room temperature. Stable until expiration date on bottle.

**PROCEDURE:**

1. Draw a fasting blood glucose. See NOTES

2. Administer 100 gm of the glucose tolerance beverage to the patient (296 ml of the 100 gram glucose tolerance beverage).

3. Draw blood for glucose determinations at 1 hour, 2 hours and 3 hours.

**NOTES:**

1. The 3-hour glucose tolerance for Gestational Diabetes should only be ordered if results of a previous 1-hour, 50-gram glucose challenge (GLUP1) were abnormal.
2. If the result of the previous GLUP1 for the patient was <200 mg/dL, it is not necessary to wait for the fasting glucose result before administering the glucola.

3. If the result of the previous GLUP1 for the patient was \( \geq 200 \) mg/dL, do not administer the glucose tolerance beverage until the fasting glucose is complete. If the fasting result is <200 mg/dL, proceed with the test. If the fasting glucose is \( \geq 200 \), the 100-gram tolerance test should be cancelled.

REPORTING RESULTS:

The test code for this test is GTOLP.

The 2007 ADA criteria for diagnosis of gestational diabetes mellitus are:

If any two of the four plasma glucose levels (fasting, 1, 2 and 3 hr) are elevated above the levels in the following table, a diagnosis of gestational diabetes may be made.

<table>
<thead>
<tr>
<th>Time</th>
<th>Glucose Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting</td>
<td>95 mg/dL</td>
</tr>
<tr>
<td>1 hour</td>
<td>180 mg/dL</td>
</tr>
<tr>
<td>2 hour</td>
<td>155 mg/dL</td>
</tr>
<tr>
<td>3 hour</td>
<td>140 mg/dL</td>
</tr>
</tbody>
</table>

REFERENCES:


