

## Protocol for Participants with Diabetes Fasting and Medication Adjustment

Diabetes and impaired glucose intolerance (IGT) are increasingly common in the US population, likely related to increasing rates of obesity and inactivity. Diabetes and IGT are also prevalent in persons with HIV infection who are taking highly active antiretroviral therapy (HAART).

Once every 6-12 months, study participants are asked to fast for a prolonged period of time (5 hours or overnight). Participants who take insulin will need to make adjustments to their insulin regimens during a fast to avoid hypoglycemia, or low blood sugar. In addition, there are two classes of oral diabetes medications which promote hypoglycemia – the sulfonylureas and the meglitinides. All participants with diabetes who are using insulin or these oral hypoglycemic agents should check with their physicians or nurse practitioners for the correct adjustments to their medications during a prolonged fast. This Protocol provides some general recommendations on Medication Adjustments (pgs. 1 and 2), Diagnostic Criteria for Diabetes and IGT (pg. 3) and a list of Oral Diabetes Medications (pg. 4):

### Insulin Adjustments

#### Intermediate Acting Insulin (NPH or Lente) Alone or With Regular or Fast- Acting Insulin

- For 8:30 AM appt      **Do not eat or drink anything prior to clinic visit.** Do not take any regular or fast-acting insulin. Take ½ your usual morning intermediate-acting dose. If your fasting blood sugar in the morning tends to run low, you may want to cut back on your evening intermediate dose the night before your appt. Make sure that you eat after your appointment and cover with a sliding scale or usual dose of regular or fast-acting insulin.
- For 1:00 PM appt      **Eat usual breakfast, but no food or beverage after 8 AM\*.** Take ½ morning intermediate-acting insulin dose and usual regular or fast-acting insulin dose to cover breakfast.
- For 5:00 PM      **Eat usual breakfast and lunch, but no food or beverage after 12 noon\*.** Decrease morning dose of intermediate-acting insulin by ½. Take usual regular or fast-acting insulin after breakfast, but cut lunch-time regular or fast-acting insulin in half. Test blood sugar at 5:00 PM appointment. If >200, take usual dose of regular or fast-acting insulin.

#### Long Acting (Ultralente) Insulin Alone or With Regular or Fast Acting Insulin

- For 8:30 AM appt      **Do not eat or drink anything prior to clinic visit.** Take full dose in the morning. Do not take any regular or fast-acting insulin.
- For 1:00 PM appt      **Eat usual breakfast, but no food or beverage after 8 AM\*.** Take full dose of long acting insulin in the morning and usual regular or fast-acting insulin dose to cover breakfast.
- For 5:00 PM appt      **Eat usual breakfast and lunch, but no food or beverage after 12 noon\*.** Take full dose of long-acting insulin in the morning and usual fast-acting or regular insulin to cover breakfast and lunch.

## Protocol for Participants with Diabetes, continued

### Adjusting Oral Agents That Induce Hypoglycemia\*\*:Sulfonylureas and Meglitinides

- For 8:30 AM appt      **Do not eat or drink anything prior to clinic visit.** Omit morning dose of your sulfonylurea and/or meglitinide medication. Take full dose with first meal after your clinic appointment.
- For 1:00 PM appt      **Eat breakfast, but no food or beverage after 8 AM\***. With long-acting sulfonylureas (like Glucotrol XL or Amaryl) or intermediate-acting ones (like Diabeta, Micronase), take ½ morning dose with breakfast. If bid (twice a day) take full PM dose before evening meal, as usual.
- With short acting sulfonylureas (like Orinase), take full morning dose with breakfast. Take full dose with first meal after appointment.
- With meglitinides (like Prandin and Starlix), take full dose with breakfast. Take full dose with first meal after appointment.
- For 5:00 PM appt      **Eat usual breakfast and lunch, but no food or beverage after 12 noon\***. With all sulfonylureas, take full morning dose. If bid (twice a day), take full PM dose with evening meal (after your clinic visit).
- With meglitinides, like Prandin and Starlix, take full dose with breakfast, lunch and dinner.

**Give all participants with diabetes juice and crackers immediately after blood drawing. They can resume usual medication regimen for the rest of the day.**

*\* It is important to avoid skipping meals. For a 1:00 PM appointment, encourage the participant to eat breakfast before 8:00 AM to allow for the 5-hour fast. For a 5:00 PM appointment, encourage participant to eat lunch before 12 noon. This may mean eating these meals earlier than usual. If participant is unable to eat either breakfast or lunch as indicated above, further adjustments of insulin and/or oral agents may be necessary.*

*\*\* For all other oral agents, take as directed. See “Oral Diabetes Medications” on page 4..*

## Diagnostic Criteria

### Normal Blood Glucose

- Fasting < 110 mg/dl
- Results of a 2-hour, 75 gram Oral Glucose Tolerance Test (OGTT)\* <140 mg/dl.

### Diabetes:

- Fasting plasma glucose (FPG)  $\geq$ 126 mg/dl
- OR*
- Random plasma glucose (RPG)  $\geq$ 200 mg/dl and symptoms of diabetes: polyuria (frequent urination), polydipsia (excessive thirst), ketoacidosis, or unexplained weight loss.
- OR*
- Results of a 2-hour, 75 Gram Oral Glucose Tolerance Test (OGTT)  $\geq$ 200 mg/dl on greater than one occasion.

### Impaired Glucose Tolerance (IGT)

People with IGT have blood glucose levels that are higher than normal but not high enough to say they have diabetes. Diagnosis of IGT if:

- Fasting plasma glucose is 110-125 mg/dl.
- OR*
- Results of a 2-hour OGTT is 140-199 mg/dl.

**\*Oral Glucose Tolerance Test (OGTT):** After a fast of 8-12 hours, a person's blood glucose is measured before and 2 hours after drinking a glucose-containing solution. The OGTT includes measures of blood glucose after a fast and after a glucose challenge. Although the fasting test may be easier and less costly, the OGTT is more sensitive in identifying people with blood glucose problems that may first appear only after a glucose challenge.

## Oral Diabetes Medications

### Drug Classifications

All diabetes pills sold today in the United States are members of one of the following five classes of drugs: Sulfonylureas, Meglitinides, Biguanides, Thiazolidinediones, and Alpha-Glucosidase Inhibitors. These five classes of drugs work in different ways to lower blood glucose levels.

#### Sulfonylureas (brand names in parentheses):

- Chlorpropamide (Diabinese)
- Glipizide (Glucotrol, Glucotrol XL)
- Glyburide (Micronase, Glynase, Diabeta, PresTab))
- Glimepiride (Amaryl)
- Tolazamide (Tolinase)
- Tolbutamide (Orinase)

Sulfonylureas stimulate the beta cells of the pancreas to release insulin. For this reason, persons taking sulfonylureas are prone to hypoglycemia following prolonged periods without food or after exercise. These drugs are generally taken one to three times a day, before meals.

#### Meglitinides (brand names in parentheses):

- Repaglinide (Prandin)
- Nateglinide (Starlix)

Meglitinides are drugs that also stimulate the pancreas to release insulin. Persons taking meglitinides are also prone to hypoglycemia following prolonged periods without food or after exercise. They are generally taken before each of three meals.

#### Biguanides (brand names in parentheses):

- Metformin (Glucophage, Glucophage XR)

Metformin lowers blood glucose levels primarily by decreasing the amount of glucose produced by the liver. It also lowers blood glucose levels by improving how cells, particularly muscle cells, use insulin. Metformin rarely causes hypoglycemia when used alone. This medication is generally taken 2-3 times a day with meals.

#### Thiazolidinediones (brand names in parentheses):

- Rosiglitazone (Avandia)
- Pioglitazone (Actos)

Thiazolidinediones lower blood glucose by reducing glucose production in the liver and by helping insulin work better in muscle and fat cells. They rarely cause hypoglycemia when used alone. These medications are taken once or twice a day with food. Another drug in this class, Troglitazone (brand name Rezulin), was taken off the market due to reports of serious liver damage.

#### Alpha-glucosidase inhibitors (brand names in parentheses):

- Acarbose (Precose)
- Meglitol (Glyset)

Alpha-glucosidase inhibitors help the body lower blood glucose by blocking the breakdown and absorption of starches (from bread, potatoes, pasta, etc.) in the intestine. Their action slows the rise in blood glucose after a meal. They should be taken with the first bite of a meal. These drugs will not cause hypoglycemia when used alone but may cause gastrointestinal side effects such as gas and diarrhea.