

# DIABETES

## DIABETES

### GOALS AND OBJECTIVES

#### Course Description

“Diabetes” is a home study continuing education course for rehabilitation professionals. The course presents updated information about diabetes including sections on etiology, symptomology, diagnosis, treatment, risk factors, associated disorders, and research.

#### Course Rationale

The information presented in this course is applicable for rehabilitation professionals in all settings. A greater understanding of diabetes will enable therapists and assistant to provide more effective and efficient rehabilitative care to individuals affected by this condition.

#### Course Goals and Objectives

Upon completion of this course, the therapist or assistant will be able to:

1. Differentiate between the different types of diabetic disorders
2. Identify the etiology of diabetes
3. Identify current research findings
4. Recognize how diabetes is diagnosed
5. Identify and understand each of the treatments for diabetes
6. Identify effective diabetes management
7. List risk factors associated with diabetes.
8. Recognize the relationship between diabetes and other specific associated medical conditions.
9. Recognize how diabetes affects specific populations

#### Course Instructor

Michael Niss, DPT

#### Target Audience

Physical therapists, physical therapist assistants, occupational therapists, and occupational therapist assistants

#### Course Educational Level

This course is applicable for introductory learners.

#### Course Prerequisites

None

#### Criteria for issuance of Continuing Education Credits

A documented score of 70% or greater on the written post-test.

#### Continuing Education Credits

Four (4) hours of continuing education credit (4 NBCOT PDUs/4 contact hours)  
AOTA - .4 AOTA CEU, Category 1: Domain of OT – Client Factors, Context

#### Determination of Continuing Education Contact Hours

“Diabetes” has been established to be a 4 hour continuing education program. This determination is based on the standard for home-based self-study courses of approximately 12 pages of text (12 pt font) per hour. The complete instructional text for this course is 48 pages (excluding References and Post-Test)

# DIABETES

## Diabetes Course Outline

	page	
Goals and Objectives	1	start hour 1
Course Outline	2	
Diabetes Overview	3	
Types of Diabetes	3-4	
Risk Factors	5-6	
Diagnosing Diabetes	6-7	
Diabetes Management	7-9	
Medication	9-10	
Treating Insulin Resistance	11-12	
Alternative Therapies	12	end hour 1
Medical Problems Associated with Diabetes	13-33	start hour 2
Diabetic Retinopathy	13-14	
Gastroparesis	14-15	
Hypoglycemia	15-16	
Kidney Disease	17-20	
Diabetic Neuropathies	20-24	end hour 2
Foot Problems and LE Amputations	24-33	start hour 3
Diabetes and Children	33-34	
Diabetes and African Americans	35-36	end hour 3
Diabetes and Native Americans	37-40	start hour 4
Diabetes and Hispanics	41-43	
Diabetes Research	43-48	
Resources	49	
References	50-51	
Post-Test	52-53	end hour 4

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# DIABETES

## Diabetes Overview

Diabetes is widely recognized as one of the leading causes of death and disability in the United States. It is associated with long-term complications that affect almost every part of the body. The disease often leads to blindness, heart and blood vessel disease, strokes, kidney failure, amputations, and nerve damage. Uncontrolled diabetes can complicate pregnancy, and birth defects are more common in babies born to women with diabetes.

In 2002, diabetes cost the United States \$132 billion. Indirect costs, including disability payments, time lost from work, and premature death, totaled \$40.2 billion; direct medical costs for diabetes care, including hospitalizations, medical care, and treatment supplies, totaled \$91.8 billion.

## Types of Diabetes

The three main types of diabetes are

- Type 1 diabetes
- Type 2 diabetes
- Gestational diabetes

An American Diabetes Association expert committee recently recommended a change in the names of the two main types of diabetes because the former names caused confusion. The type of diabetes that was known as Type I, juvenile-onset diabetes, or insulin-dependent diabetes mellitus (IDDM) is now **type 1 diabetes**. The type of diabetes that was known as Type II, noninsulin-dependent diabetes mellitus (NIDDM), or adult-onset diabetes is now **type 2 diabetes**. The new names reflect an effort to move away from basing the names on treatment or age at onset.

### Type 1 diabetes

Type 1 diabetes is an autoimmune disease. An autoimmune disease results when the body's system for fighting infection (the immune system) turns against a part of the body. In diabetes, the immune system attacks the insulin-producing beta cells in the pancreas and destroys them. The pancreas then produces little or no insulin. Someone with type 1 diabetes needs to take insulin daily to live.

At present, scientists do not know exactly what causes the body's immune system to attack the beta cells, but they believe that autoimmune, genetic, and environmental factors, possibly viruses, are involved. Type 1 diabetes accounts for about 5 to 10 percent of diagnosed diabetes in the United States.

Type 1 diabetes develops most often in children and young adults, but the disorder can appear at any age. Symptoms of type 1 diabetes usually develop over a short period, although beta cell destruction can begin years earlier.

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# DIABETES

Symptoms include increased thirst and urination, constant hunger, weight loss, blurred vision, and extreme fatigue. If not diagnosed and treated with insulin, a person can lapse into a life-threatening diabetic coma, also known as diabetic ketoacidosis.

## **Type 2 diabetes**

Most people with type 2 diabetes have two problems: the pancreas may not produce enough insulin, and fat, muscle, and liver cells cannot use it effectively. This means that glucose builds up in the blood, overflows into the urine, and passes out of the body--without fulfilling its role as the body's main source of fuel. The most common form of diabetes is type 2 diabetes. About 90 to 95 percent of people with diabetes have type 2. This form of diabetes usually develops in adults age 40 and older and is most common in adults over age 55. About 80 percent of people with type 2 diabetes are overweight. Type 2 diabetes is often part of a metabolic syndrome that includes obesity, elevated blood pressure, and high levels of blood lipids. Unfortunately, as more children and adolescents become overweight, type 2 diabetes is becoming more common in young people.

When type 2 diabetes is diagnosed, the pancreas is usually producing enough insulin, but, for unknown reasons, the body cannot use the insulin effectively, a condition called insulin resistance. After several years, insulin production decreases. The result is the same as for type 1 diabetes--glucose builds up in the blood and the body cannot make efficient use of its main source of fuel.

The symptoms of type 2 diabetes develop gradually. They are not as sudden in onset as in type 1 diabetes. Some people have no symptoms. Symptoms may include fatigue or nausea, frequent urination, unusual thirst, weight loss, blurred vision, frequent infections, and slow healing of wounds or sores.

## **Gestational Diabetes**

Gestational diabetes develops only during pregnancy. Like type 2 diabetes, it occurs more often in African Americans, American Indians, Hispanic Americans, and people with a family history of diabetes. Though it usually disappears after delivery, the mother is at increased risk of getting type 2 diabetes later in life.

## **Prediabetes**

Pre-diabetes, also called impaired glucose tolerance (IGT) or impaired fasting glucose (IFG), is a condition in which your blood glucose (blood sugar) levels are higher than normal but not high enough for a diagnosis of diabetes. Having pre-diabetes puts you at higher risk for developing type 2 diabetes. If you have pre-diabetes, you are also at increased risk for developing heart disease.

About 16 million people between the ages of 40 and 74 in the United States have pre-diabetes. Most of them are likely to develop type 2 diabetes within 10 years, unless they take steps to prevent or delay diabetes.

# DIABETES

## Risk Factors

Type 1 diabetes occurs equally among males and females, but is more common in whites than in nonwhites. Data from the World Health Organization's Multinational Project for Childhood Diabetes indicate that type 1 diabetes is rare in most African, American Indian, and Asian populations. However, some northern European countries, including Finland and Sweden, have high rates of type 1 diabetes. The reasons for these differences are not known.

Type 2 diabetes is more common in older people, especially in people who are overweight, and occurs more often in African Americans, American Indians, Asian and Pacific Islander Americans, and Hispanic Americans. On average, non-Hispanic African Americans are twice as likely to have diabetes as non-Hispanic whites of the same age. Hispanic Americans are nearly twice as likely to have diabetes as non-Hispanic whites. American Indians have the highest rates of diabetes in the world. Among the Pima Indians living in Arizona, for example, half of all adults have type 2 diabetes. American Indians and Alaska Natives are 2.6 times as likely to have diabetes as non-Hispanic whites. Although prevalence data for diabetes among Asian Americans and Pacific Islanders is limited, some groups, such as Native Hawaiians, are 2.5 times more likely to have diabetes as white residents of Hawaii.

The prevalence of diabetes in the United States is likely to increase for several reasons. First, a large segment of the population is aging. Also, Hispanic Americans and other minority groups make up the fastest-growing segment of the U.S. population. Finally, Americans are increasingly overweight and sedentary. According to recent estimates, the prevalence of diabetes in the United States is predicted to be 8.9 percent of the population by 2025.

You are more likely to develop type 2 diabetes if

- you are overweight
- you are 45 years old or older
- you have a parent, brother, or sister with diabetes
- your family background is African American, American Indian, Asian American, Hispanic American/Latino, or Pacific Islander
- you have had gestational diabetes or gave birth to at least one baby weighing more than 9 pounds
- your blood pressure is 140/90 or higher, or you have been told that you have high blood pressure
- your HDL cholesterol is 35 or lower, or your triglyceride level is 250 or higher
- you are fairly inactive, or you exercise fewer than three times a week

Because insulin resistance tends to run in families, we know that genes are partly responsible. Excess weight also contributes to insulin resistance because too

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# DIABETES

much fat interferes with muscles' ability to use insulin. Lack of exercise further reduces muscles' ability to use insulin.

Many people with insulin resistance and high blood glucose have excess weight around the waist, high LDL (bad) blood cholesterol levels, low HDL (good) cholesterol levels, high levels of triglycerides (another fat in the blood), and high blood pressure, all conditions that also put the heart at risk. This combination of problems is referred to as the metabolic syndrome, or the insulin resistance syndrome (formerly called Syndrome X).

Metabolic syndrome is the term researchers give to the presence of any three of the following conditions:

- excess weight around the waist (waist measurement of more than 40 inches for men and more than 35 inches for women)
- high levels of triglycerides (150 mg/dL or higher)
- low levels of HDL, or "good," cholesterol (below 40 mg/dL for men and below 50 mg/dL for women)
- high blood pressure (130/85 mm Hg or higher)
- high fasting blood glucose levels (110 mg/dL or higher)

## Diagnosing Diabetes

### Criteria for Diagnosis of Type 1 or Type 2

A new lower fasting plasma glucose (FPG) value is now recommended to diagnose diabetes. The new FPG value is 126 milligrams per deciliter (mg/dL) or greater, rather than 140 mg/dL or greater. This recommendation was based on a review of the results of more than 15 years of research. This research showed that a fasting blood glucose of 126 mg/dL or greater is associated with an increased risk of diabetes complications affecting the eyes, nerves, and kidneys. When diagnosis was based on a blood glucose value of 140 mg/dL or greater, these complications often developed before the diagnosis of diabetes. The experts believe that earlier diagnosis and treatment can prevent or delay the costly and burdensome complications of diabetes.

The prior criteria for diagnosing diabetes relied heavily on performing an oral glucose tolerance test (OGTT). In this test, the person must come in fasting, drink a glucose syrup, and have a blood sample taken 2 hours later. This complicated procedure made detection and diagnosis of diabetes a difficult and cumbersome process, and the expert committee recommended that it be eliminated from clinical use. The change to using fasting plasma glucose for determining the presence of diabetes will make detection and diagnosis of

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## DIABETES

diabetes more routine. The fasting value can be easily obtained during routine physician visits, in clinics at the place of employment, and other situations. Currently, about 5 to 6 million adults in the United States have diabetes but do not know it. The simpler testing method of measuring fasting glucose should help identify these people so they can benefit from treatment sooner.

Diabetes can be detected by any of three positive tests. To confirm the diagnosis, there must be a second positive test on a different day.

- A casual plasma glucose level (taken at any time of day) of 200 mg/dL or greater when the symptoms of diabetes are present.
- A fasting plasma glucose value of 126 mg/dL or greater.
- An OGTT value in the blood of 200 mg/dl or greater measured at the 2 hour interval.

The fasting plasma glucose test is the preferred test for diagnosing type 1 or type 2 diabetes.

### **Gestational Diabetes**

Gestational diabetes is diagnosed based on plasma glucose values measured during the OGTT. Glucose levels are normally lower during pregnancy, so the threshold values for diagnosis of diabetes in pregnancy are lower. If a woman has two plasma glucose values meeting or exceeding any of the following numbers, she has gestational diabetes: a fasting plasma glucose level of 95 mg/dL, a 1-hour level of 180 mg/dL, a 2-hour level of 155 mg/dL, or a 3-hour level of 140 mg/dL.

### **Insulin Resistance**

Insulin resistance and pre-diabetes usually have no symptoms. You may have one or both conditions for several years without noticing anything. If you have a severe form of insulin resistance, you may get dark patches of skin, usually on the back of your neck. Sometimes people get a dark ring around their neck. Other possible sites for these dark patches include elbows, knees, knuckles, and armpits. This condition is called acanthosis nigricans.

## **Diabetes Management**

Healthy eating, physical activity, and blood glucose testing are the basic management tools for type 2 diabetes. In addition, many people with type 2 diabetes require oral medication and insulin to control their blood glucose levels.

People with diabetes must take responsibility for their day-to-day care. Much of the daily care involves keeping blood glucose levels from going too low or too high. When blood glucose levels drop too low from certain diabetes medicines--a condition known as hypoglycemia--a person can become nervous, shaky, and

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## DIABETES

confused. Judgment can be impaired. If blood glucose falls too low, a person can faint.

A major study, the Diabetes Control and Complications Trial (DCCT), sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), showed that keeping blood glucose levels as close to normal as safely possible reduces the risk of developing major complications of type 1 diabetes.

The 10-year study, included 1,441 people with type 1 diabetes. The study compared the effect of two treatment approaches--intensive management and standard management--on the development and progression of eye, kidney, and nerve complications of diabetes. Intensive treatment aimed at keeping hemoglobin A-1-c as close to normal (6 percent) as possible. Hemoglobin A-1-c reflects average blood sugar over a 2- to 3-month period. Researchers found that study participants who maintained lower levels of blood glucose through intensive management had significantly lower rates of these complications. More recently, a follow-up study of DCCT participants showed that the ability of intensive control to lower the complications of diabetes persists up to 4 years after the trial ended.

The United Kingdom Prospective Diabetes Study showed that intensive control of blood glucose and blood pressure reduced the risk of blindness, kidney disease, stroke, and heart attack in people with type 2 diabetes.

<b>Normal and target blood glucose ranges (mg/dL)</b>	
<b>Normal blood glucose levels in people who do not have diabetes</b>	
Upon waking (fasting)	70 to 110
After meals	70 to 140
<b>Target blood glucose levels in people who have diabetes</b>	
Before meals	90 to 130
1 to 2 hours after the start of a meal	less than 180
Hypoglycemia (low blood glucose)	70 or below

# DIABETES

## **Non-Invasive Glucose Monitoring**

Over the years, scientists have been trying to find noninvasive ways for people with diabetes to measure their blood glucose. Most methods of monitoring blood glucose require a blood sample, usually obtained by using an automatic lancing device on a finger. Some meters use a blood sample from a less sensitive area, such as the upper arm, forearm, or thigh. Some devices use a beam of light instead of a lancet to pierce the skin.

In March 2001, the U.S. Food and Drug Administration (FDA) approved a noninvasive blood glucose monitoring device for adults with diabetes. Noninvasive monitoring means checking blood glucose levels without puncturing the skin for a blood sample. The GlucoWatch Biographer, manufactured by Cygnus Inc., was approved to detect glucose level trends and patterns in adults age 18 and older with diabetes. It must be used along with conventional blood glucose monitoring of blood samples. The device, which looks like a wristwatch, pulls body fluid from the skin using small electric currents. It checks blood glucose levels every 20 minutes.

## **Medication**

### **Insulin**

Before the discovery of insulin in 1921, everyone with type 1 diabetes died within a few years after diagnosis. Although insulin is not considered a cure, its discovery was the first major breakthrough in diabetes treatment.

Today, healthy eating, physical activity, and insulin via injection or an insulin pump are the basic therapies for type 1 diabetes. The amount of insulin must be balanced with food intake and daily activities.

Most people who take insulin to manage diabetes inject the insulin with a needle and syringe that delivers insulin just under the skin. Several other devices for taking insulin are available, and new approaches are under development.

*Insulin pens* can be helpful if you want the convenience of carrying insulin with you in a discreet way. An insulin pen is a device that looks like a pen with a cartridge. Some pens use replaceable cartridges of insulin; other pen models are totally disposable. A fine, short needle, similar to the needle on an insulin syringe, is on the tip of the pen. Users turn a dial to select the desired dose of insulin and press a plunger on the end to deliver the insulin just under the skin.

*Insulin jet injectors* send a fine spray of insulin through the skin by a high-pressure air mechanism instead of needles.

## DIABETES

*External insulin pumps* connect to narrow, flexible plastic tubing that ends with a needle inserted just under the skin near the abdomen. The insulin pump is about the size of a deck of cards, weighs about 3 ounces, and can be worn on a belt or in a pocket. Users set the pump to give a steady trickle or "basal" amount of insulin continuously throughout the day. Most pumps today have the option for setting several basal rates. Pumps release "bolus" doses of insulin (several units at a time) at meals and at times when blood sugar is too high based on the users' programming. Frequent blood glucose monitoring is essential to determine insulin dosages and to ensure that insulin is delivered.

### **Approaches under development**

*Implantable insulin pumps* are surgically implanted, usually on the left side of the abdomen. The pump is disk shaped and weighs about 6 to 8 ounces. It delivers a basal dose of insulin continuously. Users deliver bolus insulin doses with a remote control unit that prompts the pump to give the specified amount of insulin.

An advantage of this method is that, like insulin produced naturally from the pancreas, the insulin from the pump goes directly to the liver to prevent excess sugar production there.

*The insulin patch*, placed on the skin, gives a continuous low dose of insulin. To adjust insulin doses before meals, users can pull off a tab on the patch to release insulin. The problem with the patch is that insulin does not get through the skin easily.

*The inhaled insulin delivery system*, provides insulin as a dry powder inhaled through the mouth directly into the lungs where it passes into the bloodstream. This aerosol delivery system is about the size of a flashlight and uses rapid-acting insulin.

### **Other Medications**

Two classes of drugs can improve response to insulin and are used by prescription for type 2 diabetes--biguanides and thiazolidinediones. Other medicines used for diabetes act by other mechanisms. Alpha-glucosidase inhibitors restrict or delay the absorption of carbohydrates after eating, resulting in a slower rise of blood glucose levels. Sulfonylureas and meglitinides increase insulin production.

The DPP showed that the diabetes drug metformin, a biguanide, reduced the risk of diabetes in those with pre-diabetes but was much less successful than losing weight and increasing activity. In another study, treatment with troglitazone, a thiazolidinedione later withdrawn from the market following reports of liver toxicity, delayed or prevented type 2 diabetes in Hispanic women with a history of gestational diabetes. Acarbose, an alpha-glucosidase inhibitor, has been effective in delaying development of type 2 diabetes. Additional studies using other diabetes medicines and some types of blood pressure medicines to prevent

# DIABETES

diabetes are under way. No drug has been approved by the Food and Drug Administration (FDA) specifically for insulin resistance or pre-diabetes.

## Treating Insulin Resistance

### Exercise

In people with diabetes, regular exercise can lower blood glucose, improve insulin sensitivity, raise HDL cholesterol, improve blood flow and heart muscle strength, enhance fibrinolysis, control weight, increase muscle mass, and provide an overall sense of well-being. Because of these effects, regular exercise may also delay the onset of neuropathy and atherosclerosis.

People who have had type 1 diabetes for more than 10 years, or type 2 diabetes for more than 5 years, should be screened for medical risk prior to beginning an exercise program. While the presence of neuropathy does not rule out exercise, care should be taken not to worsen soft tissue and joint injury or cause foot ulcers or bone injury. Stretching muscles before exercise is important to prevent ligament strain. Swimming or bicycling are recommended forms of exercise because they avoid abrasion to the feet. Attention to the construction and fit of footwear is essential.

Physical activity and weight loss make the body respond better to insulin. By losing weight and being more physically active, you may avoid developing type 2 diabetes.

### Diet and Nutrition

People who follow a low-fat, low-calorie diet and who increase activities such as walking briskly or riding a bike for 30 minutes, five times a week, have a far smaller risk of developing diabetes than people who do not exercise regularly. The DPP also reinforced the importance of a low-calorie, low-fat diet. Following a low-calorie, low-fat diet can provide two benefits. If you are overweight, one benefit is that limiting your calorie and fat intake can help you lose weight. DPP participants who lost weight were far less likely to develop diabetes than others in the study who remained at an unhealthy weight. Increasing your activity and following a low-calorie, low-fat diet can also improve your blood pressure and cholesterol levels and has many other health benefits.

Scientists have established some numbers to help people set goals that will reduce their risk of developing glucose metabolism problems.

### Weight

Body mass index (BMI) is a measure used to evaluate body weight relative to height.

# DIABETES

## **Blood pressure**

For the general population, blood pressure below 130/85 is considered normal, although people whose blood pressure is slightly elevated and who have no additional risk factors for heart disease may be advised to make lifestyle changes--that is, diet and exercise--rather than take blood pressure medicines. People who have diabetes, however, should take whatever steps necessary, including lifestyle changes and medicine, to reach a blood pressure goal of below 130/80.

## **Cholesterol**

Cholesterol is usually reported with three values: low density lipoprotein (LDL) cholesterol, high density lipoprotein (HDL) cholesterol, and total cholesterol. LDL cholesterol is sometimes called "bad" cholesterol, while HDL cholesterol is called "good" cholesterol. To lower the risk of cardiovascular problems if you have diabetes, you should try to keep the LDL cholesterol below 100 and the total cholesterol below 200.

## **Smoking**

In addition to increasing the risk of cancer and cardiovascular disease, smoking contributes to insulin resistance.

## **Alternative Therapies**

### **Vanadium**

Vanadium is a compound found in tiny amounts in plants and animals. Early studies showed that vanadium normalized blood glucose levels in animals with type 1 and type 2 diabetes. A recent study found that when people with diabetes were given vanadium, they developed a modest increase in insulin sensitivity and were able to decrease their insulin requirements. Currently researchers want to understand how vanadium works in the body, discover potential side effects, and establish safe dosages.

### **Chromium**

The benefit of added chromium for diabetes has been studied and debated for several years. Several studies report that chromium supplementation may improve diabetes control. Chromium is needed to make glucose tolerance factor, which helps insulin improve its action. Because of insufficient information on the use of chromium to treat diabetes, no recommendations for supplementation yet exist.

### **Magnesium**

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# DIABETES

Although the relationship between magnesium and diabetes has been studied for decades, it is not yet fully understood. Studies suggest that a deficiency in magnesium may worsen the blood sugar control in type 2 diabetes. Scientists believe that a deficiency of magnesium interrupts insulin secretion in the pancreas and increases insulin resistance in the body's tissues. Evidence suggests that a deficiency of magnesium may contribute to certain diabetes complications.

## **Medical Problems Associated with Diabetes**

### **Diabetic Retinopathy**

Diabetic retinopathy occurs when diabetes damages the tiny blood vessels in the retina. At this point, most people do not notice any changes in their vision.

Some people develop a condition called macular edema. It occurs when the damaged blood vessels leak fluid and lipids onto the macula, the part of the retina that lets us see detail. The fluid makes the macula swell, blurring vision.

As the disease progresses, it enters its advanced, or proliferative, stage. Fragile, new blood vessels grow along the retina and in the clear, gel-like vitreous that fills the inside of the eye. Without timely treatment, these new blood vessels can bleed, cloud vision, and destroy the retina.

All people with diabetes are at risk--those with Type I diabetes (juvenile onset) and those with Type II diabetes (adult onset). During pregnancy, diabetic retinopathy may also be a problem for women with diabetes. It is recommended that all pregnant women with diabetes have dilated eye examinations each trimester to protect their vision.

Diabetic retinopathy often has no early warning signs. At some point, though, you may have macular edema. It blurs vision, making it hard to do things like read and drive. In some cases, your vision will get better or worse during the day.

As new blood vessels form at the back of the eye, they can bleed (hemorrhage) and blur vision. The first time this happens it may not be very severe. In most cases, it will leave just a few specks of blood, or spots, floating in your vision. They often go away after a few hours.

These spots are often followed within a few days or weeks by a much greater leakage of blood. The blood will blur your vision. In extreme cases, a person will only be able to tell light from dark in that eye. It may take the blood anywhere from a few days to months or even years to clear from the inside of your eye. In some cases, the blood will not clear. You should be aware that large hemorrhages tend to happen more than once, often during sleep.

## DIABETES

Diabetic retinopathy is detected during an eye examination that includes:

**Visual acuity test:** This eye chart test measures how well you see at various distances.

**Pupil dilation:** The eye care professional places drops into the eye to widen the pupil. This allows him or her to see more of the retina and look for signs of diabetic retinopathy. After the examination, close-up vision may remain blurred for several hours.

**Ophthalmoscopy:** This is an examination of the retina in which the eye care professional: (1) looks through a device with a special magnifying lens that provides a narrow view of the retina, or (2) wearing a headset with a bright light, looks through a special magnifying glass and gains a wide view of the retina.

**Tonometry:** A standard test that determines the fluid pressure inside the eye. Elevated pressure is a possible sign of glaucoma, another common eye problem in people with diabetes.

Eye care professionals look at the retina for early signs of the disease, such as: (1) leaking blood vessels, (2) retinal swelling, such as macular edema, (3) pale, fatty deposits on the retina--signs of leaking blood vessels, (4) damaged nerve tissue, and (5) any changes in the blood vessels.

Should your doctor suspect that you need treatment for macular edema, he or she may ask you to have a test called fluorescein angiography.

In this test, a special dye is injected into your arm. Pictures are then taken as the dye passes through the blood vessels in the retina. This test allows the doctor to find the leaking blood vessels.

There are two treatments for diabetic retinopathy. They are very effective in reducing vision loss from this disease. In fact, even people with advanced retinopathy have a 90 percent chance of keeping their vision when they get treatment before the retina is severely damaged.

These two treatments are laser surgery and vitrectomy. It is important to note that although these treatments are very successful, they do not cure diabetic retinopathy.

### **Gastroparesis**

Gastroparesis, also called delayed gastric emptying, is a disorder in which the stomach takes too long to empty its contents. It often occurs in people with type 1 diabetes or type 2 diabetes.

Gastroparesis happens when nerves to the stomach are damaged or stop working. The vagus nerve controls the movement of food through the digestive

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## DIABETES

tract. If the vagus nerve is damaged, the muscles of the stomach and intestines do not work normally, and the movement of food is slowed or stopped. Diabetes can damage the vagus nerve if blood glucose levels remain high over a long period of time. High blood glucose causes chemical changes in nerves and damages the blood vessels that carry oxygen and nutrients to the nerves.

### Signs and Symptoms of Gastroparesis

- heartburn
- nausea
- vomiting of undigested food
- an early feeling of fullness when eating
- weight loss
- abdominal bloating
- erratic blood glucose levels
- lack of appetite
- gastroesophageal reflux
- spasms of the stomach wall

These symptoms may be mild or severe, depending on the person. If food lingers too long in the stomach, it can cause problems like bacterial overgrowth from the fermentation of food. Also, the food can harden into solid masses called bezoars that may cause nausea, vomiting, and obstruction in the stomach. Bezoars can be dangerous if they block the passage of food into the small intestine.

Gastroparesis can make diabetes worse by adding to the difficulty of controlling blood glucose. When food that has been delayed in the stomach finally enters the small intestine and is absorbed, blood glucose levels rise. Since gastroparesis makes stomach emptying unpredictable, a person's blood glucose levels can be erratic and difficult to control.

### **Hypoglycemia**

Hypoglycemia, also called low blood sugar, occurs when your blood glucose (blood sugar) level drops too low to provide enough energy for your body's activities. In adults or children older than 10 years, hypoglycemia is uncommon except as a side effect of diabetes treatment, but it can result from other medications or diseases, hormone or enzyme deficiencies, or tumors.

Glucose, a form of sugar, is an important fuel for your body. Carbohydrates are the main dietary sources of glucose. Rice, potatoes, bread, tortillas, cereal, milk, fruit, and sweets are all carbohydrate-rich foods.

After a meal, glucose molecules are absorbed into your bloodstream and carried to the cells, where they are used for energy. Insulin, a hormone produced by your

## DIABETES

pancreas, helps glucose enter cells. If you take in more glucose than your body needs at the time, your body stores the extra glucose in your liver and muscles in a form called glycogen. Your body can use the stored glucose whenever it is needed for energy between meals. Extra glucose can also be converted to fat and stored in fat cells.

When blood glucose begins to fall, glucagon, another hormone produced by the pancreas, signals the liver to break down glycogen and release glucose, causing blood glucose levels to rise toward a normal level. If you have diabetes, this glucagon response to hypoglycemia may be impaired, making it harder for your glucose levels to return to the normal range.

Symptoms of hypoglycemia include

- hunger
- nervousness and shakiness
- perspiration
- dizziness or light-headedness
- sleepiness
- confusion
- difficulty speaking
- feeling anxious or weak

Hypoglycemia can also happen while you are sleeping. You might

- cry out or have nightmares
- find that your pajamas or sheets are damp from perspiration
- feel tired, irritable, or confused upon waking

Usually hypoglycemia is mild and can easily be treated by eating or drinking something with carbohydrate. But left untreated, hypoglycemia can lead to loss of consciousness. Although hypoglycemia can happen suddenly, it can usually be treated quickly, bringing your blood glucose level back to normal.

### **Causes of Hypoglycemia**

In people taking certain blood-glucose lowering medications, blood glucose can fall too low for a number of reasons:

- meals or snacks that are too small, delayed, or skipped
- excessive doses of insulin or some diabetes medications, including sulfonylureas and meglitinides (Alpha-glucosidase inhibitors, biguanides, and thiazolidinediones alone should not cause hypoglycemia but can when used with other diabetes medicines.)
- increased activity or exercise
- excessive drinking of alcohol

# DIABETES

## Diabetes and Kidney Disease

Diabetes is the most common cause of kidney failure, accounting for more than 40 percent of new cases. Even when drugs and diet are able to control diabetes, the disease can lead to nephropathy and kidney failure. Most people with diabetes do not develop nephropathy that is severe enough to cause kidney failure. About 16 million people in the United States have diabetes, and about 100,000 people have kidney failure as a result of diabetes.

People with kidney failure undergo either dialysis, which substitutes for some of the filtering functions of the kidneys, or transplantation to receive a healthy donor kidney. Most U.S. citizens who develop kidney failure are eligible for federally funded care. In 1997, the Federal Government spent about \$11.8 billion on care for patients with kidney failure.

African Americans, American Indians, and Hispanic Americans develop diabetes, nephropathy, and kidney failure at rates higher than average. Scientists have not been able to explain these higher rates. Nor can they explain fully the interplay of factors leading to diabetic nephropathy--factors including heredity, diet, and other medical conditions, such as high blood pressure. They have found that high blood pressure and high levels of blood glucose increase the risk that a person with diabetes will progress to kidney failure.

The deterioration that characterizes kidney disease of diabetes takes place in and around the glomeruli, the blood-filtering units of the kidneys. Early in the disease, the filtering efficiency diminishes, and important proteins in the blood are lost in the urine. Medical professionals gauge the presence and extent of early kidney disease by measuring protein in the urine. Later in the disease, the kidneys lose their ability to remove waste products, such as creatinine and urea, from the blood. Measuring these waste products in the blood gives an indication of how far kidney disease has progressed.

Symptoms related to kidney failure usually occur only in late stages of the disease, when kidney function has diminished to less than 10 to 25 percent of normal capacity. For many years before that point, kidney disease of diabetes is a silent process.

### Five Stages of Kidney Failure

Scientists have described five stages in the progression to kidney failure in people with diabetes.

*Stage I.* The flow of blood through the kidneys, and therefore through the glomeruli, increases--this is called hyperfiltration--and the kidneys are larger than normal. Some people remain in stage I indefinitely; others advance to stage II after many years.

## DIABETES

*Stage II.* The rate of filtration remains elevated or at near-normal levels, and the glomeruli begin to show damage. Small amounts of a blood protein known as albumin leak into the urine--a condition known as microalbuminuria. In its earliest stages, microalbuminuria may not be detected on each evaluation. But as the rate of albumin loss increases from 20 to 200 micrograms per minute, the finding of microalbuminuria becomes more constant. (Normal losses of albumin are less than 5 micrograms per minute.) A special test is required to detect microalbuminuria. People with type 1 and type 2 diabetes may remain in stage II for many years, especially if they have good control of their blood pressure and blood glucose levels.

*Stage III.* The loss of albumin and other proteins in the urine exceeds 200 micrograms per minute. It now can be detected during routine urine tests. Because such tests often involve dipping indicator strips into the urine, they are referred to as "dipstick methods." Stage III sometimes is referred to as "dipstick-positive proteinuria" (or "clinical albuminuria" or "overt diabetic nephropathy"). Some patients develop high blood pressure. The glomeruli suffer increased damage. The kidneys progressively lose the ability to filter waste, and blood levels of creatinine and urea-nitrogen rise. People with type 1 and type 2 diabetes may remain at stage III for many years.

*Stage IV.* This is referred to as "advanced clinical nephropathy." The glomerular filtration rate decreases to less than 75 milliliters per minute, large amounts of protein pass into the urine, and high blood pressure almost always occurs. Levels of creatinine and urea-nitrogen in the blood rise further.

*Stage V.* The final stage is kidney failure. The glomerular filtration rate drops to less than 10 milliliters per minute. Symptoms of kidney failure become apparent.

These stages describe the progression of kidney disease for most people with type 1 diabetes who develop kidney failure. For people with type 1, the average length of time required to progress from onset of kidney disease to stage IV is 17 years. The average length of time to progress to kidney failure is 23 years. Progression to kidney failure may occur more rapidly (5-10 years) in people with untreated high blood pressure. If proteinuria does not develop within 25 years, the risk of developing advanced kidney disease begins to decrease. Type 1 diabetes accounts for only 5 to 10 percent of all diagnosed cases of diabetes, but type 1 accounts for 30 percent of the cases of kidney failure caused by diabetes.

### **Treating Kidney Disease in Diabetics**

Scientists have made great progress in developing methods that slow the onset and progression of kidney disease in people with diabetes.

**Medications** - Drugs used to lower blood pressure (antihypertensive drugs) can slow the progression of kidney disease significantly. One kind

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## DIABETES

of drug, angiotensin-converting enzyme (ACE) inhibitors, has proven effective in preventing progression to stages IV and V. Diuretics, beta-blockers, adrenergic nervous system modulators, and calcium channel blockers also may enhance blood pressure control in patients with diabetes mellitus.

An example of an effective ACE inhibitor is captopril, which doctors commonly prescribe for treating kidney disease of diabetes. The benefits of captopril extend beyond its ability to lower blood pressure: it may directly protect the kidney's glomeruli. ACE inhibitors have lowered proteinuria and slowed deterioration even in diabetic patients who did not have high blood pressure.

Any medicine that helps patients achieve a blood pressure target of 125/75 or lower provides benefits. Patients with even mild hypertension or persistent microalbuminuria should consult a physician about the use of antihypertensive medicines.

**Low-Protein Diets** - A diet containing reduced amounts of protein may benefit people with kidney disease of diabetes. In people with diabetes, excessive consumption of protein may be harmful. Experts recommend that most patients with stage III or stage IV nephropathy consume limited amounts of protein.

**Intensive Management of Blood Glucose** - A third treatment, known as intensive management of blood glucose or glycemic control, has shown great promise for people with type 1 and type 2 diabetes, especially for those in early stages of nephropathy.

Intensive management is a treatment regimen that aims to keep blood glucose levels close to normal. The regimen includes frequently testing blood glucose, administering insulin frequently throughout the day on the basis of food intake and exercise, following a diet and exercise plan, and frequently consulting a health care team. Some people use an insulin pump to supply insulin throughout the day.

A number of studies have pointed to the beneficial effects of intensive management. Two such studies, funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health, are the Diabetes Control and Complications Trial (DCCT) and a trial led by researchers at the University of Minnesota Medical School. A third study, conducted in the United Kingdom, is the U.K. Prospective Diabetes Study (UKPDS).

The DCCT involved 1,441 participants who had type 1 diabetes. Researchers found a 50 percent decrease in both development and

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## DIABETES

progression of early diabetic kidney disease (stages I and II) in participants who followed an intensive regimen for controlling blood glucose levels. The intensively managed patients had average blood glucose levels of 150 milligrams per deciliter--about 80 milligrams per deciliter lower than the levels observed in the conventionally managed patients.

In the Minnesota Medical School trial, researchers examined kidney tissues of people with long-standing diabetes who received healthy kidney transplants. After 5 years, patients who followed an intensive regimen developed significantly fewer lesions in their glomeruli than did patients not following an intensive regimen. This result, along with findings of the DCCT and studies performed in Scandinavia, suggests that any program resulting in sustained lowering of blood glucose levels will be beneficial to patients in the early stages of diabetic nephropathy.

**Kidney Transplant** - When people with diabetes experience kidney failure, they must undergo either dialysis or a kidney transplant. As recently as the 1970s, medical experts commonly excluded people with diabetes from dialysis and transplantation, in part because the experts felt damage caused by diabetes would offset benefits of the treatments. Today, because of better control of diabetes and improved rates of survival following treatment, doctors do not hesitate to offer dialysis and kidney transplantation to people with diabetes.

Currently, the survival of kidneys transplanted into patients with diabetes is about the same as survival of transplants in people without diabetes. Dialysis for people with diabetes also works well in the short run. Even so, people with diabetes who receive transplants or dialysis experience higher morbidity and mortality because of coexisting complications of the diabetes--such as damage to the heart, eyes, and nerves.

### Diabetic Neuropathies

Diabetic neuropathies are a family of nerve disorders caused by diabetes. People with diabetes can, over time, have damage to nerves throughout the body. Neuropathies lead to numbness and sometimes pain and weakness in the hands, arms, feet, and legs. Problems may also occur in every organ system, including the digestive tract, heart, and sex organs. People with diabetes can develop nerve problems at any time, but the longer a person has diabetes, the greater the risk.

An estimated 50 percent of those with diabetes have some form of neuropathy, but not all with neuropathy have symptoms. The highest rates of neuropathy are among people who have had the disease for at least 25 years.

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# DIABETES

Diabetic neuropathy also appears to be more common in people who have had problems controlling their blood glucose levels, in those with high levels of blood fat and blood pressure, in overweight people, and in people over the age of 40. The most common type is peripheral neuropathy, also called distal symmetric neuropathy, which affects the arms and legs.

## Causes

The causes are probably different for different varieties of diabetic neuropathy. Researchers are studying the effect of glucose on nerves to find out exactly how prolonged exposure to high glucose causes neuropathy. Nerve damage is likely due to a combination of factors:

- metabolic factors, such as high blood glucose, long duration of diabetes, possibly low levels of insulin, and abnormal blood fat levels
- neurovascular factors, leading to damage to the blood vessels that carry oxygen and nutrients to the nerves
- autoimmune factors that cause inflammation in nerves
- mechanical injury to nerves, such as carpal tunnel syndrome
- inherited traits that increase susceptibility to nerve disease
- lifestyle factors such as smoking or alcohol use

## Symptoms

Symptoms depend on the type of neuropathy and which nerves are affected. Some people have no symptoms at all. For others, numbness, tingling, or pain in the feet is often the first sign. A person can experience both pain and numbness. Often, symptoms are minor at first, and since most nerve damage occurs over several years, mild cases may go unnoticed for a long time. Symptoms may involve the sensory or motor nervous system, as well as the involuntary (autonomic) nervous system. In some people, mainly those with focal neuropathy, the onset of pain may be sudden and severe.

Symptoms may include

- numbness, tingling, or pain in the toes, feet, legs, hands, arms, and fingers
- wasting of the muscles of the feet or hands
- indigestion, nausea, or vomiting
- diarrhea or constipation
- dizziness or faintness due to a drop in postural blood pressure
- problems with urination
- erectile dysfunction (impotence) or vaginal dryness
- weakness

## Types of Diabetic Neuropathy

Diabetic neuropathies can be classified as peripheral, autonomic, proximal, and focal. Each affects different parts of the body in different ways.

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## DIABETES

- Peripheral neuropathy causes either pain or loss of feeling in the toes, feet, legs, hands, and arms.
- Autonomic neuropathy causes changes in digestion, bowel and bladder function, sexual response, and perspiration. It can also affect the nerves that serve the heart and control blood pressure. Autonomic neuropathy can also cause hypoglycemia (low blood sugar) unawareness, a condition in which people no longer experience the warning signs of hypoglycemia.
- Proximal neuropathy causes pain in the thighs, hips, or buttocks and leads to weakness in the legs
- Focal neuropathy results in the sudden weakness of one nerve, or a group of nerves, causing muscle weakness or pain. Any nerve in the body may be affected.

### **Peripheral Neuropathy**

This type of neuropathy damages nerves in the arms and legs. The feet and legs are likely to be affected before the hands and arms. Many people with diabetes have signs of neuropathy upon examination but have no symptoms at all.

Symptoms of peripheral neuropathy may include

- numbness or insensitivity to pain or temperature
- a tingling, burning, or prickling sensation
- sharp pains or cramps
- extreme sensitivity to touch, even a light touch
- loss of balance and coordination

These symptoms are often worse at night.

Peripheral neuropathy may also cause muscle weakness and loss of reflexes, especially at the ankle, leading to changes in gait (walking). Foot deformities, such as hammertoes and the collapse of the midfoot, may occur. Blisters and sores may appear on numb areas of the foot because pressure or injury goes unnoticed. If foot injuries are not treated promptly, the infection may spread to the bone, and the foot may then have to be amputated. Some experts estimate that half of all such amputations are preventable if minor problems are caught and treated in time.

### **Autonomic Neuropathy**

Autonomic neuropathy affects the nerves that control the heart, regulate blood pressure, and control blood glucose levels. It also affects other internal organs, causing problems with digestion, respiratory function, urination, sexual response, and vision. In addition, the system that restores blood glucose levels to normal after a hypoglycemic episode may be affected, resulting in loss of the warning signs of hypoglycemia such as sweating and palpitations.

**Glucose Regulation** - Normally, symptoms such as shakiness occur as blood glucose levels drop below 70 mg/dL. In people with autonomic neuropathy, symptoms may not occur, making hypoglycemia difficult to recognize. However, other problems can also cause hypoglycemia unawareness so this does not always indicate nerve damage.

## DIABETES

**Heart and Circulatory System** - Damage to nerves in the cardiovascular system interferes with the body's ability to adjust blood pressure and heart rate. As a result, blood pressure may drop sharply after sitting or standing, causing a person to feel light-headed--or even to faint. Damage to the nerves that control heart rate can mean that it stays high, instead of rising and falling in response to normal body functions and exercise.

**Digestive System** - Nerve damage to the esophagus may make swallowing difficult, while nerve damage to the bowels can cause constipation alternating with frequent, uncontrolled diarrhea, especially at night. Problems with the digestive system may lead to weight loss.

**Urinary Tract and Sex Organs** - Autonomic neuropathy most often affects the organs that control urination and sexual function. Nerve damage can prevent the bladder from emptying completely, allowing bacteria to grow in the bladder and kidneys and causing urinary tract infections. When the nerves of the bladder are damaged, urinary incontinence may result because a person may not be able to sense when the bladder is full or control the muscles that release urine. Neuropathy can also gradually decrease sexual response in men and women, although the sex drive is unchanged. A man may be unable to have erections or may reach sexual climax without ejaculating normally. A woman may have difficulty with lubrication, arousal, or orgasm.

**Sweat Glands** - Autonomic neuropathy can affect the nerves that control sweating. When nerve damage prevents the sweat glands from working properly, the body cannot regulate its temperature properly. Nerve damage can also cause profuse sweating at night or while eating.

**Eyes** - Finally, autonomic neuropathy can affect the pupils of the eyes, making them less responsive to changes in light. As a result, a person may not be able to see well when the light is turned on in a dark room or may have trouble driving at night.

### **Proximal Neuropathy**

Proximal neuropathy, sometimes called lumbosacral plexus neuropathy, femoral neuropathy, or diabetic amyotrophy, starts with pain in either the thighs, hips, buttocks, or legs, usually on one side of the body. This type of neuropathy is more common in those with type 2 diabetes and in older people. It causes weakness in the legs, manifested by an inability to go from a sitting to a standing position without help. Treatment for weakness or pain is usually needed. The length of the recovery period varies, depending on the type of nerve damage.

# DIABETES

## **Focal Neuropathy**

Occasionally, diabetic neuropathy appears suddenly and affects specific nerves, most often in the head, torso, or leg. Focal neuropathy may cause

- inability to focus the eye
- double vision
- aching behind one eye
- paralysis on one side of the face (Bell's palsy)
- severe pain in the lower back or pelvis
- pain in the front of a thigh
- pain in the chest, stomach, or flank
- pain on the outside of the shin or inside the foot
- chest or abdominal pain that is sometimes mistaken for heart disease, heart attack, or appendicitis

Focal neuropathy is painful and unpredictable and occurs most often in older people. However, it tends to improve by itself over weeks or months and does not cause long-term damage.

People with diabetes also tend to develop nerve compressions, also called entrapment syndromes. One of the most common is carpal tunnel syndrome, which causes numbness and tingling of the hand and sometimes muscle weakness or pain. Other nerves susceptible to entrapment may cause pain on the outside of the shin or the inside of the foot.

## **Foot Problems and Lower Extremity Amputations**

Foot disease is the most common complication of diabetes leading to hospitalization. Foot disease accounts for 6 percent of hospital discharges listing diabetes and lower extremity ulcers, with an average hospital stay of 14.7 days. The total annual cost associated with diabetes foot disease is estimated to be more than \$1 billion. This cost does not include surgeons' fees, rehabilitation costs, prostheses, time lost from work, and disability payments.

Diabetes foot disease is a major burden for both the individual and the health care system and may increase as the population ages. Fifteen percent of all patients with diabetes in a population-based study experienced ulcers or sores on the foot or ankle. The prevalence increased with age, especially in patients who were age 30 or under at diagnosis of diabetes.

After an amputation, the chance of another amputation of the same extremity or of the opposite extremity within 5 years is as high as 50 percent. The 5-year mortality rate after lower extremity amputation ranges from 39 to 68 percent .

An analysis of a statewide California hospital discharge database indicated that the age-adjusted incidence of diabetes-related lower extremity amputations per 10,000 people with diabetes was 95.3 in African Americans, 56.0 in non-Hispanic

## DIABETES

whites, and 44.4 in Hispanics. Amputations were 1.72 and 2.17 times more likely in African Americans compared with non-Hispanic whites and Hispanics, respectively. Hispanics had a higher proportion of amputations (82.7 percent) associated with diabetes as opposed to other causes of amputation, than did African Americans (61.6 percent) or non-Hispanic whites (56.8 percent).

Amputation rates in San Antonio, TX, were 66.5 per 10,000 for whites, 120.1 per 10,000 for Mexican Americans, and 181.2 per 10,000 for African Americans . The incidence of amputations for Native Americans living on the Gila River Indian Reservation was 24.1 per 1,000 person-years compared to 6.5 per 1,000 person-years for the overall U.S. population with diabetes . Increased awareness and identification of diabetes-related foot disease is especially important in these high-risk minority groups.

### **Risk Factors for Lower Extremity Amputation (LEA)**

Peripheral neuropathy, peripheral vascular disease, and prior foot ulcer are independently associated with risk of LEA . A study of Pima Indians with diabetes confirmed this finding and included the presence of foot deformity as another independent risk factor. The presence of plantar callus also is highly predictive of subsequent ulceration in patients with diabetic neuropathy and is more predictive of ulceration than increased plantar foot pressures. Hyperglycemia is an additional risk factor. In a Finnish study researchers determined risk factors for amputation in 1,044 middle-aged patients with type 2 diabetes who were followed for up to 7 years. Because the incidence of amputation was similar in both sexes (5.6 percent men and 5.3 percent women), all statistical analyses were carried out combining men and women. This study found that high fasting plasma glucose levels at baseline, high HbA1c, and the duration of diabetes were independently associated with a twofold risk of amputation. Signs of peripheral neuropathy, bilateral absence of vibration sense, and bilateral absence of Achilles tendon reflexes were two times more frequent in patients with amputation than in patients without amputation.

### **Causal Pathways for Lower Extremity Amputations (LEA)**

A study conducted at the Seattle Veterans Affairs Medical Center examined the causal pathways for LEA in patients with diabetes and identified the most common sequences of events. Seventy-three percent of the amputations in study subjects were a result of the causal sequence of minor trauma, cutaneous ulceration, and wound-healing failure. Estimates of the cumulative proportions of various causes indicated that 86 percent of amputations were attributed to initial minor trauma causing tissue injury.

### **Precipitating or Pivotal Events**

## DIABETES

In the causal pathway study noted above, foot trauma was caused by shoe-related repetitive pressure leading to cutaneous ulceration in 36 percent of all cases, accidental cuts or wounds in 8 percent, thermal trauma (frostbite or burns) in 8 percent, and decubitus ulceration in 8 percent. Similarly, another study found that in one-third of diabetic amputees with peripheral arterial disease, the initial lesion was self-induced. The most common cause of self-injury was ill-fitting new shoes; the second most common cause was cutting toenails improperly. Other investigators identified external precipitating factors in 84 percent of study patients with foot ulcers. The most common factors were ill-fitting shoes/socks, acute mechanical trauma, stress ulcer, and paronychia.

### **Screening for Patients at Risk**

Examination of the feet by people with diabetes and health care providers is the most basic preventive action to be taken. In a National Health Interview Survey (NHIS), 52 percent of all people with diabetes stated that they checked their feet at least daily, but 22 percent stated that they never checked their feet. More self-exams were reported by insulin treated individuals than those who did not use insulin.

Almost 53 percent of patients with diabetes reported no foot exam by a health professional within the past six months. In a nationwide survey, primary care physicians reported performing semi-annual foot examinations for 66 percent of patients with type 1 diabetes and for 52 percent of patients with type 2 diabetes. A review of Indian Health Service medical records showed that close to 50 percent of patients with diabetes had documentation of an annual foot examination.

### **Screening Tools to Identify High-Risk Feet**

The importance of identifying individuals at risk for foot ulceration and LEA and the need for preventive foot care practices for both the provider and the patient have been noted. Several simple screening tools have been developed to identify people at high risk. These tools include a patient report and a clinical examination to quantify loss of peripheral sensation, foot deformities, peripheral vascular disease, and prior foot ulcers. Use of these measures has been shown to predict subsequent ulceration and amputation.

In one study, during annual patient examinations, researchers recorded the presence of a foot deformity, history of lower extremity ulceration or amputation, and the ability to perceive the Semmes-Weinstein 5.07 10-gram monofilament at eight sites on the plantar surface of each foot. Based on the findings, subjects were classified as sensate or insensate and placed in one of four risk categories. Insensitivity to the monofilament occurred in 68 (19 percent) of the patients screened. Over a 32-month follow-up period, 41 of these patients developed ulcerations and 14 amputations occurred.

# DIABETES

Identifying patients' risk category for foot ulceration helps to determine the frequency needed for provider foot examinations, the level of emphasis on self-care of the feet, and patient responsibilities.

## Sample Foot Screening Tool

### I. Medical History

Patients who have been diagnosed with any of the medical problems listed are likely to have had diabetes for several years and to be at risk for foot problems. If the patient is unable to feel the 10-gram monofilament on any site on either foot, he or she has peripheral neuropathy.

### II. Current History

#### Question 1: Any change in the foot since the last evaluation?

This question is to determine whether the patient has experienced any change in the strength or sensation in the feet. If this is the patient's first visit, enter N/A unless the patient has noticed a change in the past year.

#### Question 2: Does the patient have a foot ulcer now or a history of foot ulcer?

A positive history of a foot ulcer places the patient permanently in the high risk category. This person *always has an increased risk* for developing another foot ulcer, progressive deformity of the foot, and, ultimately, lower limb amputation.

#### Question 3: Is there pain in the calf muscles when walking--i.e., pain occurring in the calf or thigh when walking less than one block that is relieved by rest?

This question is to determine whether the patient experiences intermittent claudication when walking. This pain is an indication of peripheral vascular disease or impaired circulation.

### III. Foot Exam

#### Item 1: Are the nails thick, too long, ingrown, or infected with fungal disease?

Thick nails may indicate vascular or fungal disease. If severe nail problems are present, refer the patient to a podiatrist or a nurse foot care specialist.

#### Item 2: Foot Deformities

Indicate foot deformities listed or specify the type and date of amputation(s). The more serious deformities are illustrated below. Prominent metatarsal heads are evidence of major deformity such as midfoot collapse.



*Toe Deformities  
(Hammer/Claw Toes)*

*Bunions  
(Hallux Valgus)*

*Plantar View of  
Charcot Joint*

# DIABETES

## Item 3: Pedal Pulses

Check the pedal pulses in both feet and note whether they are present or absent.

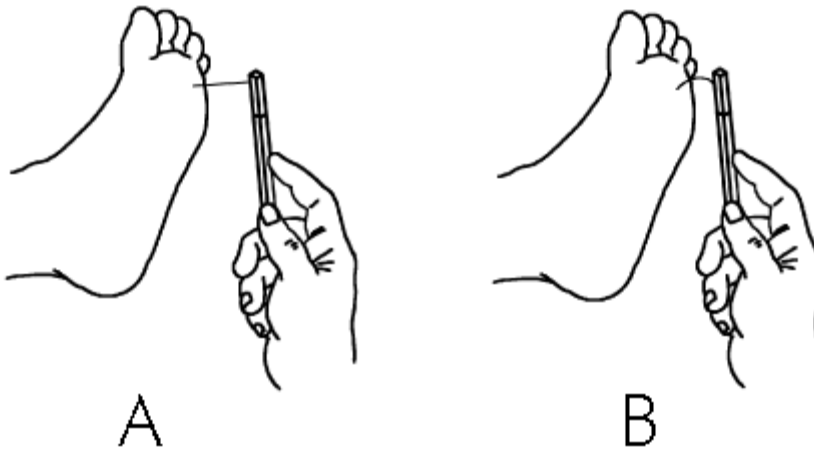
## Item 4: Skin Condition

Examine each foot and record the problems identified by drawing or labeling the condition on the foot diagram. If there are calluses, pre-ulcerative lesions (a closed lesion, such as a blister or hematoma), or open ulcers, measure and draw them in and use the appropriate symbol to indicate what type of lesion is present. Label areas that are significantly red, warm (warmer than the other parts of the foot or the opposite foot), dry, or macerated (friable, moist, soft tissue).

## IV. Sensory Foot Exam

The sensory testing device used to complete a foot exam is a 10-gram (5.07 Semmes-Weinstein) nylon filament mounted on a holder that has been standardized to deliver a 10-gram force when properly applied. Research has shown that a person who can feel the 10-gram filament in the selected sites is at reduced risk for developing ulcers.

- The sensory exam should be done in a quiet and relaxed setting. The patient must not watch while the examiner applies the filament.
- Test the monofilament on the patient's hand so he/she knows what to anticipate.
- Apply the monofilament perpendicular to the skin's surface (see diagram A below).
- Apply sufficient force to cause the filament to bend or buckle (see diagram B below).



- The total duration of the approach, skin contact, and departure of the filament should be approximately 1-1/2 seconds.
- Apply the filament along the perimeter and NOT ON an ulcer site, callus, scar or necrotic tissue. Do not allow the filament to slide across the skin or make repetitive contact at the test site.
- Press the filament to the skin such that it buckles at one of two times as you say "time one" or "time two." Have patients identify at which time they were touched. Randomize the sequence of applying the filament throughout the examination.

## V. Risk Categorization

Based on the foot exam, determine the patient's risk category. A definition of "low risk" or "high risk" for recurrent ulceration and ultimately, amputation, is provided in the chart below along with minimum suggested management guidelines. Individuals who are identified as "high risk" may require a more comprehensive evaluation.

# DIABETES

## Foot complications risk categories for patients with diabetes

Low Risk – None of 5 High Risk Factors listed below

- Loss of protective sensation
- Absent pedal pulses
- Severe foot deformity
- History of foot ulcer
- Prior amputation

High Risk – One or more of the 5 listed Risk Factors

Low Risk Management

- Conduct an annual foot screening exam.
- Assess/recommend appropriate footwear.
- Provide patient education for preventive self-care.

High Risk Management

- Conduct foot assessment every 3 months.
- Demonstrate preventive self-care of the feet.
- Refer to specialists and a diabetes educator as indicated.  
(Always refer to a specialist if Charcot joints are suspected.)
- Assess/prescribe appropriate footwear.

## VI. Footwear Assessment

Improper or poorly fitting shoes are major contributors to diabetes foot ulcerations. Counsel patients about appropriate footwear. All patients with diabetes need to pay special attention to the fit and style of their shoes and should avoid pointed-toe shoes or high heels. Properly fitted athletic or walking shoes are recommended for daily wear. If off-the-shelf shoes are used, make sure that there is room to accommodate any deformities.



High risk patients may require therapeutic shoes, depth-inlay shoes, custom-molded inserts (orthoses), or custom-molded shoes depending on the degree of foot deformity and history of ulceration.

## VII. Education

Patient education is an essential component of preventive care.

## VIII. Management Plan

Complete the management plan, indicating actions for patient education, any diagnostic studies, footwear recommendations, referrals, and follow-up care.

## Provider and Patient Education

In a randomized, controlled study, researchers provided intervention patients with foot care education, behavioral contracts, and telephone and postcard prompts.

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## DIABETES

The researchers placed foot care prompts on the medical record, and provided practice guidelines and flow sheets to clinicians assigned to those patients. Results showed that primary care physicians in the intervention group conducted more examinations of lower extremities, identified those at risk for amputation, and referred more patients for podiatric care. Patients in the intervention group received more patient education, made more changes in appropriate self-care behaviors, and had fewer short-term foot problems than patients in the control group.

### **The Components of Good Patient Education**

Findings from several studies help determine effective components of patient education that contribute to successful patient outcomes. These include giving detailed foot care recommendations, requesting patient commitment to self-care, demonstrating and practicing foot care procedures, and communicating a persistent message that foot complications can be avoided by self-care. In comparing the effectiveness of intensive versus conventional education, researchers found that patients in the intensive group showed greater improvement in foot care knowledge, better compliance with the recommended foot care routine, and greater reduction in the number of foot problems requiring treatment.

Foot care recommendations and demonstrations should include: washing, drying, and inspecting the feet; cutting toenails; treating minor foot problems; selecting suitable footwear; dealing with temperature extremes; and contacting the physician if problems do not resolve quickly. Patients with high-risk feet should inspect them twice a day. Those with peripheral neuropathy, vascular disease, or eye disease should not attempt to cut their own toe nails as this can lead to serious self-inflicted injury. It is important for the provider or diabetes educator to review with the patient all written take-home instructions for self-care of the feet.

Researchers found that the frequency of desired self-care behaviors improved when patients were given specific instructions such as "dry between toes" and "file calluses" rather than more general instructions such as "avoid injury to your feet." To be more effective, the investigators recommended that instructions should be stated as precisely as possible such as "don't go barefoot indoors."

Patients should never be allowed to walk on open plantar ulcers since continuous application of mechanical load will prevent healing. Walking aids, footwear modifications, or other interventions must be used to relieve weight.

A pilot program for African Americans consisted of a 15-minute orientation meeting between a diabetes nurse educator and the person with diabetes, a take-home foot self-care packet, and a follow-up telephone interview. During the telephone interviews, subjects reported that the most useful parts of the take-

## DIABETES

home packet were the patient instruction booklet, the large hand mirror included in the packet, and the foot care knowledge self-test with explanations of the answers. Subjects also valued the reminder cue that was repeated in bold face on each page of the booklet telling them to call the doctor immediately if any cut, bruise, or blister does not begin to heal after one day.

### **Provider Foot Care Practices**

In a study of provider practice, researchers found that clinicians were likely to prescribe preventive foot care behaviors when they were aware of a patient's high risk for LEA as evidenced by prior history of foot ulcer. Clinician awareness of two other risk factors (peripheral neuropathy or peripheral vascular disease), however, did not increase preventive care practices. The researchers concluded that physicians and patients need periodic reminders to identify patients in all high-risk categories for ulcer or amputation and to provide additional care such as podiatric visits and education in self-care.

A study of nurse practitioner practice patterns was conducted to determine their consistency with the American Diabetes Association (ADA) standards of care. An audit of 78 medical records representing a proportionate number for each of six masters-prepared, certified nurse practitioners revealed discrepancies between established standards and the degree to which they were documented. Comprehensive foot care examinations (required annually by ADA standards) were documented in 23 percent of the charts reviewed.

### **Self-care Limitations in the Elderly**

In one study, barriers to carrying out daily foot care noted by elderly subjects included lack of motivation, forgetfulness, vision problems, joint and knee problems, and family responsibilities. The ability of elderly people to identify foot lesions was investigated further in a matched comparison, controlled study. Findings showed that 43 percent of patients with a history of foot ulcers could not reach and remove simulated lesions on their toes; over 50 percent of the older subjects reported difficulty trimming their toe nails; and only 14 percent had sufficient joint flexibility to allow inspection of the plantar aspect of the foot. The investigators concluded that elderly people who are unable to perform daily self-care of the feet would benefit more from regular foot care given by others than from intensive education.

### **Repetitive Stress and Special Footwear**

People with intact sensation respond to repetitive stress that occurs during walking either by shifting the pressure to another part of the foot, by modifying the way the foot meets the ground, by resting, or by checking their shoes for problems. With the loss of peripheral sensation, however, many people with

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## DIABETES

diabetes have no indication of lower extremity pain, pressure, or trauma and do not take measures to modify repetitive pressures. Lack of feeling makes shoe-fitting assistance essential.

Properly constructed and well-fitting shoes and shoe inserts can minimize localized stresses by redistributing forces during walking. Besides helping patients keep feet healthy, shoes and orthoses also can help prevent diabetes complications. Investigators in a recent study found that after healing of the initial ulcer, re-ulceration occurred after one year in 58 percent of patients who resumed wearing their own footwear, compared to 28 percent of those who wore therapeutic footwear.

Another study compared the prevalence and severity of foot deformities and the development of ulceration in people with diabetes after a great toe amputation. The investigators found that because these patients were at high risk for subsequent ulceration, the use of special inserts and footwear to protect the feet was highly recommended.

### **Prescription Footwear**

Professionally fitted shoes and prescription footwear are an important part of the overall treatment of the insensate foot because they aid in preventing limb loss. Footwear should relieve areas of excessive pressure, reduce shock and shear, and accommodate, stabilize, and support deformities.

Shoes should be long enough, and have room in the toe area and over the instep. Shoes with laces allow adjustment for edema and deformities. Most people with early neuropathic changes can wear cushioned commercial footwear such as walking or athletic shoes. Some people also may need the pressure areas redistributed with custom orthotics that often require depth footwear. Depth-inlay shoes provide more room for toe deformities and for the insertion of customized insoles. Extra-wide shoes provide more room for bunions and other abnormalities. Rocker sole shoes reduce pressure under metatarsal heads and toes. They are particularly useful for reducing the risk of ulceration in patients with a stiff and rigid first metatarsal joint.

### **Diabetes and Foot Care Summary**

The staggering human and economic costs of diabetes foot disease may be reduced significantly with increased practice of several simple preventive care measures designed to prevent foot ulcers and lower extremity amputations. Routine annual foot screening facilitates early interventions to reduce the incidence of the most common precipitating events including injury and footwear-related trauma to the insensitive foot. The key elements of preventive care include: annual examination of the feet by health care providers to determine risk

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# DIABETES

factors for ulceration; subsequent exams of high risk feet at each patient visit; patient education about daily self-care of the feet; and careful glucose management. The national health objectives for the year 2000 to decrease the rate of amputation in the population overall, as well as in specific high risk minority groups, serve as a call to action for both health care providers and people with diabetes to make routine diabetes foot care a high priority.

## Steps to Prevent Diabetic Foot Problems

### 1. Screen Feet Annually.

- Conduct a physical exam and a sensory exam using a monofilament..
- Assess and document your patient's foot condition.

### 2. Categorize Your Findings.

- **Low Risk Patient** - *All of the following:*
  - Intact protective sensation
  - Pedal pulses present
  - No severe deformity
  - No prior foot ulcer
  - No amputation
- **High Risk Patient** - *One or more of the following:*
  - Loss of protective sensation
  - Absent pedal pulses
  - Severe foot deformity
  - History of foot ulcer
  - Prior amputation

### 3. Counsel Your Patients or Refer to a Diabetes Educator.

- Talk with your patients about their risk category.
- Demonstrate self-care techniques.
- Prescribe appropriate footwear.
- Give positive feedback for proper foot care.
- Give patients self-care booklet or tip sheet.
- Counsel about smoking cessation if needed.
- Reinforce the importance of blood glucose control to reduce the risk for foot problems and other complications.

### 4. Follow Up with High Risk Patients.

- Place "high risk feet" stickers on medical record.
- Examine feet at every visit.
- Special inserts and shoes as needed.
- Refer to specialists for a risk factor you cannot rectify.
- Provide education about self-care.
- Ensure that the elderly and blind have help for daily foot care.

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# DIABETES

## Diabetes and Children

In the United States each year, more than 13,000 children are diagnosed with type 1 diabetes. Increasingly, health care providers are finding more and more children and teens with type 2 diabetes, a disease usually seen in people over age 40. Although there are no national data, some clinics report that one-third to one-half of all new cases of childhood diabetes are now type 2. African American, Hispanic/Latino and American Indian children who are obese and have a family history of type 2 diabetes are at especially high risk for this type of diabetes.

Diabetes presents unique issues for children and teens with the disease. Simple things - like going to a birthday party, playing sports, or staying overnight with friends - need careful planning. Every day, children with diabetes may need to take insulin or oral medication. They also need to check their blood glucose several times during the day and remember to make correct food choices. For school-age children, these tasks can make them feel "different" from their classmates. These tasks can be particularly bothersome for teens.

Diabetes is stressful for both the children and their families. Parents should be alert for signs of depression or eating disorders and seek appropriate treatment. While all parents should talk to their children about avoiding tobacco, alcohol, and other drugs, this is particularly important for children with diabetes. Smoking and diabetes each increase the risk of cardiovascular disease and people with diabetes who smoke have a greatly increased risk of heart disease and circulatory problems. Binge drinking can increase the risk of hypoglycemia (low blood sugar) and symptoms of hypoglycemia can be mistaken for those of intoxication and not properly treated. Local peer groups for children and teens with diabetes can provide positive role models and group activities.

Several Federal and state laws provide protections to children with disabilities, including children or teens with diabetes. These children must have full access to public programs, including public schools, and to most private schools as well. Students with diabetes are entitled to accommodations and modifications necessary for them to stay healthy at school and have the same access to an education as other students do. A child's or teen's school should prepare a plan that outlines how the child's special health care needs will be met. The plan should identify school staff responsible for making sure the plan is followed. The parents should be present during development of the plan. Any changes to the plan should be made only with the parents' consent. Ideally, the plan should be updated every year.

# DIABETES

## **Diabetes and African Americans**

The following statistics illustrate the magnitude of this disease among African Americans.

- 2.8 million African Americans have diabetes.
- On average, African Americans are twice as likely to have diabetes as white Americans of similar age.
- Approximately 13 percent of all African Americans have diabetes.
- African Americans with diabetes are more likely to develop diabetes complications and experience greater disability from the complications than white Americans with diabetes.

Death rates for people with diabetes are 27 percent higher for African Americans compared with whites

The proportion of the African American population that has diabetes rises from less than 1 percent for those aged younger than 20 years to as high as 32 percent for women age 65-74 years. Overall, among those age 20 years or older, the rate is 11.8 percent for women and 8.5 percent for men.

About one-third of total diabetes cases are undiagnosed among African Americans. This is similar to the proportion for other racial/ethnic groups in the United States.

National health surveys during the past 35 years show that the percentage of the African American population that has been diagnosed with diabetes is increasing dramatically. The surveys measured fasting plasma glucose and thus allowed an assessment of the prevalence of undiagnosed diabetes as well as of previously diagnosed diabetes. When first studied, total diabetes prevalence in African Americans ages 40 to 74 years was 8.9 percent; in a follow up study, total prevalence had increased to 18.2 percent--a doubling of the rate in just 12 years. Prevalence in African Americans is much higher than in white Americans. Among those ages 40 to 74 years in the 1988-94 survey, the rate was 11.2 percent for whites, but was 18.2 percent for African Americans.

### **Diabetes in African American Children**

African American children seem to have lower rates of type 1 diabetes than white American children. Researchers tend to agree that genetics probably makes type 1 diabetes less common among children with African ancestry compared with children of European ancestry. However, recent reports indicate an increasing prevalence of type 2 diabetes in children, especially in those with African American, American Indian, or Hispanic family background.

### **Gestational Diabetes in African American Women**

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## DIABETES

Several studies have shown that the occurrence of gestational diabetes in African American women may be 50 percent to 80 percent more frequent than in white women.

### **Diabetes Complications in African Americans**

Compared with white Americans, African Americans experience higher rates of diabetes complications such as eye disease, kidney failure, and amputations.

They also experience greater disability from these complications.

The frequency of diabetic retinopathy is 40 percent to 50 percent higher in African Americans than in white Americans, according to NHANES III data. Retinopathy may also occur more frequently in African Americans than in whites because of their higher rate of hypertension. Although blindness caused by diabetic retinopathy is believed to be more frequent in African Americans than in whites, there are no valid studies that compare rates of blindness between the two groups.

African Americans with diabetes experience kidney failure, also called end-stage renal disease (ESRD), about four times more often than diabetic white Americans. There are approximately 28,000 new cases annually of ESRD attributed to diabetes in African Americans. Diabetes is the leading cause of kidney failure and account for 43 percent of the new cases of ESRD among African Americans. Hypertension, the second leading cause of ESRD, accounts for 42 percent of cases. In spite of their high rates of ESRD, African Americans have better survival rates after they develop kidney failure than white Americans.

Based on U.S. hospital discharge data, there are about 13,000 amputations among African American diabetic individuals annually, which involved 155,000 days in the hospital. African Americans with diabetes are much more likely to undergo a lower-extremity amputation than white or Hispanic Americans with diabetes. The hospitalization rate of amputations for African Americans is approximately 9.3 per 1,000 patients, compared with 5.8 per 1,000 white diabetic patients. However, the average length of hospital stay is lower for African Americans (12.1 days) than for white Americans (16.5 days).

### **Diabetes and Mortality in African Americans**

Diabetes was an uncommon cause of death among African Americans at the turn of the 20<sup>th</sup> century. By 1994, however, death certificates listed diabetes as the seventh leading cause of death for African Americans. For those age 45 years or older, it was the fifth leading cause of death.

Death rates (mortality) for people with diabetes are higher for African Americans than for whites. The overall mortality rate is 20 percent higher for African American men and 40 percent higher for African American women, compared with their white counterparts.

# DIABETES

## Diabetes and Native Americans

Diabetes mellitus is one of the most serious health challenges facing American Indians and Alaska Natives in the United States today. The disease is very common in many tribes, and morbidity and mortality from diabetes can be severe.

About 15 percent of American Indians and Alaska Natives who receive care from the Indian Health Service have been diagnosed with diabetes, a total of 105,000 people. On average, American Indians and Alaska Natives are 2.6 times as likely to have diagnosed diabetes as non-Hispanic whites of a similar age. The available data probably underestimate the true prevalence of diabetes in this population.

For example, 40 to 70 percent of American Indian adults age 45 to 74 were found to have diabetes in a screening study in three geographic areas. Data from the Navajo Health and Nutrition Survey showed that 22.9 percent of Navajo adults age 20 and older had diabetes. Fourteen percent had a history of diabetes, but another 7 percent were found to have undiagnosed diabetes during the survey. Type 2 diabetes is becoming increasingly common in youth.

In Pima Indians, the most widely studied American Indian group, the prevalence of type 2 diabetes is approximately 50 percent in individuals ages 30 to 64. During the period from 1986 to 1993, the prevalence of diabetes in Alaska Natives for all ages increased by 29 percent, from 15.2 to 19.6 cases per 1,000 people. Of these, most had type 2 diabetes.

The prevalence of type 2 diabetes in Alaska Natives varies by subgroup:

- Eskimo groups (Inupiaq Eskimos in the northern and northwestern coastal areas and Yup'ik Eskimos in the southwestern coastal regions and St. Lawrence Island) had a prevalence of 12.1 per 1,000.
- Indian groups (Athabascan in the interior region; Tlingit, Haida, and Tsimshian in the coastal areas) had a prevalence of 24.3 per 1,000
- Aleut groups (residents of the Aleutian Islands, the Pribilof Islands, the western tip of the Alaska Peninsula, the Kodiak area, and the southcentral coastal areas) had a prevalence of 32.6 per 1,000.

### Type 1 Diabetes

Type 1 diabetes is relatively rare in American Indians and Alaska Natives. Most cases of type 1 diabetes are seen in people who have both American Indian and Caucasian heritage.

### Genetic Risk Factors

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# DIABETES

Genetic background is a determining factor in the prevalence of type 2 diabetes. In both the Choctaw Indians and the Pima Indians, the more full-blooded individuals were found to have the highest prevalence of type 2 diabetes, as compared with those of more mixed heritage. In Pima Indians, diabetes rates were found to be highest in children whose parents developed diabetes at an early age.

Although the specific genes responsible for the inheritance of type 2 diabetes have not been located, NIDDK scientists studying the Pima Indians have identified a gene called FABP2 that may play a role in insulin resistance. More recent studies have shown that a variant in the PPPIR3 gene that is more common in Pimas than Caucasians is associated with type 2 diabetes and insulin resistance.

## **Obesity Risk Factors**

Obesity is a major risk factor for type 2 diabetes among all races and ethnic groups. Increasing rates of obesity have been measured in many American Indian and Alaska Native communities. In Pima Indians, 95 percent of those with diabetes are overweight.

Studies of obesity and energy metabolism in Pima Indians has not identified exact causes but has revealed that Pima Indian families share the trait of low metabolic rate. This trait is considered predictive of weight gain and development of type 2 diabetes. A "thrifty gene" is also thought to cause a genetic predisposition to obesity, although this gene has not been identified. The thrifty gene theory, first proposed in 1962, suggests that populations of indigenous people who experienced alternating periods of feast and famine gradually adapted by developing a way to store fat more efficiently during periods of plenty to better survive famines.

The degree to which obesity is a risk factor for diabetes depends greatly on the location of the excess weight. Central or upper-body obesity is a stronger risk factor for type 2 diabetes than excess weight carried below the waist. In young Pima Indians, waist-to-hip ratio, a measure of central obesity, was more strongly associated with diabetes than body mass index, a measure of overall obesity.

## **Diet and Physical Inactivity**

Both diet and physical activity have changed for many members of American Indian and Alaska Native groups over the past several decades. Diets are higher in fat and calories than traditional diets; physical activity has decreased. Changes in diet and physical activity are associated with the increased prevalence of type 2 diabetes. For example, Pima Indians living in Mexico who consumed a more traditional diet (less animal fat and more complex carbohydrates) had a lower

## DIABETES

prevalence of type 2 diabetes than Pima Indians living in Arizona. Pima Indians in Mexico also expended more calories through activity.

### **Prediabetes**

American Indians with impaired glucose tolerance have a higher incidence of diabetes than those whose glucose tolerance test results are in the normal range.

### **Hyperinsulinemia and Insulin Resistance**

Studies of Pima Indians have shown that both increased insulin secretion and insulin resistance occur in conjunction with impaired glucose tolerance.

### **Gestational Diabetes in American Indian and Alaska Native Women**

Both long- and short-term consequences of diabetes during pregnancy are evident in American Indians and Alaska Natives.

The prevalence of gestational diabetes in certain groups of American Indians and Alaska Natives is as follows:

- 14.5 percent of pregnancies in Zuni Indians
- 3.4 percent of deliveries in Navajo Indians
- 5.8 percent of deliveries in Yup'ik Eskimos

Follow-up studies of American Indian women with gestational diabetes found a high risk of developing subsequent diabetes: 27.5 percent of Pima Indian women developed diabetes within 4 to 8 years, and 30 percent of Zuni Indian women developed diabetes within 6 months to 9 years after pregnancy.

Longitudinal studies of diabetes in Pima Indians have shown that adult offspring of women with diabetes during pregnancy have significantly higher rates of diabetes than adult offspring of women without diabetes, showing the possible effect of the diabetic intrauterine environment. In fact, 45 percent of adult offspring of Pima Indian women who were diagnosed with type 2 diabetes predating pregnancy developed diabetes by age 20 to 24. In comparison, only 1.4 percent of adult offspring of women without diabetes during pregnancy went on to develop diabetes by age 24. The strongest single risk factor for diabetes in Pima children was exposure to diabetes in utero.

### **Diabetes Complications in American Indians and Alaska Natives**

**Diabetic Retinopathy** - One study showed a 49 percent prevalence of diabetic retinopathy in Oklahoma Indians. Pima Indians also have excessive rates of diabetic retinopathy.

**Cataracts** - The incidence of cataract extraction among Pima Indians with diabetes is more than twice the rate of people without diabetes.

## DIABETES

**Diabetic Nephropathy** - American Indians with diabetes experience end-stage renal disease (the final stage of kidney disease associated with kidney failure and dialysis) six times more frequently than non-Hispanic whites. Especially high rates of diabetic nephropathy (kidney disease) were seen in Alaska Native, Cherokee, Chippewa, Navajo, Oklahoma, Pima, Sioux, and Zuni tribes. End-stage renal disease is a leading cause of death among Pima Indians with diabetes.

Among Alaska Natives, women are more likely to develop end-stage renal disease and more likely to die of renal failure than men. The overall incidence of dialysis caused by diabetic renal disease in Alaska Natives is two per 1,000 person-years of diabetes.

**Lower Extremity Amputation** - Rates of lower extremity amputation are high in some American Indians but vary by tribe. Several studies indicate a higher amputation rate among men than among women. Loss of protective sensation as detected by a screening monofilament test identified diabetic individuals at high risk for amputation and foot ulceration

**Periodontal Disease** - Among Pima Indians, the periodontal disease rate is 2.6 times higher in people with diabetes than in those without it. Poor glycemic control among American Indians has been associated with an increased risk of periodontal disease.

**Infections** - Infections related to diabetes in American Indians are of particular concern. A study in Sioux Indians showed that those with diabetes were 4.4 times more likely to develop tuberculosis than were Sioux Indians without diabetes. Mortality in Pima Indians with infectious diseases is significant, according to a study that found that five out of six people who died from a serious infection (coccidioidomycosis) had diabetes. Tuberculosis mortality among American Indians was 5.8 times higher than the rate among all races in the United States.

### **Diabetes Related Morbidity and Mortality in American Indians and Alaska Natives.**

Diabetes is the sixth leading cause of death among American Indians and Alaska Natives in the United States.

Because mortality rates are based on the underlying cause of death on death certificates, the impact of diabetes on mortality among American Indians and Alaska Natives has been underestimated. Diabetes contributes to several of the leading causes of death in American Indians: heart disease, cerebrovascular disease, pneumonia, and influenza. In addition, one study found that American Indian heritage was underreported on death certificates by 65 percent. The adjusted mortality rate for diabetes in American Indians is 4.3 times the rate in

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## DIABETES

non-Hispanic whites. Age- and sex-adjusted death rate studies of Pima Indians found that the mortality rate for diabetes was nearly 12 times greater than the mortality rate for all races in the United States. Both the duration of the disease and the presence of proteinuria (indicating kidney disease) were factors associated with increased mortality.

According to the Alaska Area Native Health Service, the mortality rate for diabetes in Alaska Natives is 43.2 per 1,000 person-years of diabetes. Average age at death was 70.3 years. Mortality rates were similar for Aleuts, Eskimos, and Indians.

### **Diabetes and Hispanics**

Hispanic Americans are the second-largest and fastest growing minority group in the United States. Currently, there are approximately 40 million Hispanics in the United States, representing 11 percent of the population. By the year 2050, it is estimated that Hispanics will number 97 million and constitute 25 percent of the U.S. population.

About one-third of total diabetes among Hispanic Americans is undiagnosed. This is similar to the proportion for other racial/ethnic groups in the United States. Diabetes in Hispanic Americans is a serious health challenge because of the increased prevalence of diabetes in this population, the greater number of risk factors for diabetes in Hispanics, the greater incidence of several diabetes complications, and the growing number of people of Hispanic ethnicity in the United States.

The following statistics illustrate the magnitude of diabetes among Hispanic Americans:

- Of the 40 million Hispanic Americans, about 2 million had been diagnosed with diabetes.
- About 10.2 percent of all Hispanic Americans have diabetes.
- On average, Hispanic Americans are 1.9 times more likely to have diabetes than non-Hispanic whites of similar age.
- Diabetes is particularly common among middle-aged and older Hispanic Americans. For those age 50 or older, about 25 to 30 percent have either diagnosed or undiagnosed diabetes.
- Diabetes is twice as common in Mexican American and Puerto Rican adults as in non-Hispanic whites. The prevalence of diabetes in Cuban Americans is lower, but still higher than that of non-Hispanic whites.
- As in all populations, having risk factors for diabetes increases the chance that a Hispanic American will develop diabetes. Risk factors seem to be more common among Hispanics than non-Hispanic whites. These factors include a family history of diabetes, gestational diabetes, impaired glucose tolerance, hyperinsulinemia and insulin resistance, obesity, and physical inactivity.

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## DIABETES

- Higher rates of the diabetes complications nephropathy (kidney disease), retinopathy (eye disease), and peripheral vascular disease have been documented in studies of Mexican Americans, whereas lower rates of myocardial infarctions (heart attacks) have been found.

### **Pre-diabetes (Impaired Glucose Tolerance and Impaired Fasting Glucose)**

Rates of impaired glucose tolerance among adults ages 40 to 74 are higher for Mexican Americans (19 percent) than for non-Hispanic white Americans (15 percent).

### **Gestational Diabetes**

Mexican American women may be at particularly high risk for developing type 2 diabetes. One study of 666 women with gestational diabetes in southern California found that each year an average of 12 percent developed type 2 diabetes after pregnancy.

### **Hyperinsulinemia and Insulin Resistance**

Several studies have shown a higher rate of hyperinsulinemia in Hispanics than in non-Hispanics.

### **Obesity**

Hispanics are more likely than non-Hispanic whites to be overweight. Mexican American adults, particularly women, have substantially higher rates of obesity than non-Hispanic white Americans, but rates that are similar to those of African Americans.

### **Physical Activity**

Researchers suspect that a lack of exercise is one factor contributing to the high rates of diabetes in Hispanic Americans. 65 percent of Mexican American men and 74 percent of Mexican American women report that they participate in little or no leisure-time physical activity.

### **Hispanic Children**

Mexican American children in Colorado had lower rates of type 1 diabetes than non-Hispanic white children. However, the incidence of type 1 diabetes in Puerto Rican children in Philadelphia was similar to that of white children. Genetic, immunologic, and environmental factors are thought to be involved in the development of type 1 diabetes. Recent reports indicate an increase in the prevalence of type 2 diabetes among Mexican American youth, especially among those who are overweight.

### **Kidney Disease**

The prevalence of clinical evidence of kidney damage (proteinuria) is more frequent in Mexican Americans with diabetes than in non-Hispanic whites. A higher incidence of protein in the urine (microalbuminuria), an early indicator of diabetic nephropathy, was also seen in the San Antonio Heart Study comparing

## DIABETES

Mexican Americans with non-Hispanic whites. However, the San Luis Valley Diabetes Study showed no difference between Hispanics and non-Hispanic whites in the incidence of diabetic nephropathy.

Mexican Americans who develop kidney failure fare better than many others on dialysis. According to a report from Texas, Mexican Americans survived longer on renal dialysis than non-Hispanic white Americans.

### **Nerve Disease**

There is no significant difference in the prevalence of diabetic neuropathy between Hispanics and non-Hispanic whites. However, in the National Health Interview Survey, symptoms of sensory neuropathy were reported more frequently by Mexican Americans than by non-Hispanic whites or African Americans.

### **Peripheral Vascular Disease**

In the San Antonio Heart Study, Mexican Americans with type 2 diabetes had a higher rate of peripheral vascular disease than non-Hispanic whites; however, this increased incidence was not statistically significant.

### **Heart Disease**

Heart disease is the most common cause of death in people with both type 1 and type 2 diabetes. However, in the Texas and Colorado studies, Mexican Americans had lower rates of myocardial infarctions than non-Hispanic white Americans.

## **Diabetes Research**

NIDDK conducts research in its own laboratories and supports a great deal of basic and clinical research in medical centers and hospitals throughout the United States. It also gathers and analyzes statistics about diabetes. Other Institutes at the National Institutes of Health (NIH) conduct and support research on diabetes-related eye diseases, heart and vascular complications, pregnancy, and dental problems.

Other Government agencies that sponsor diabetes programs are the Centers for Disease Control and Prevention, the Indian Health Service, the Health Resources and Services Administration, the Department of Veterans Affairs, and the Department of Defense.

Many organizations outside of the Government support diabetes research and education activities. These organizations include the American Diabetes Association, the Juvenile Diabetes Research Foundation International, and the American Association of Diabetes Educators.

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## DIABETES

In recent years, advances in diabetes research have led to better ways to manage diabetes and treat its complications. Major advances include

- The development of a quick-acting insulin analog.
- Better ways to monitor blood glucose and for people with diabetes to check their own blood glucose levels.
- Development of external insulin pumps that deliver insulin, replacing daily injections.
- Laser treatment for diabetic eye disease, reducing the risk of blindness.
- Successful transplantation of kidneys and pancreas in people whose own kidneys fail because of diabetes.
- Better ways of managing diabetes in pregnant women, improving chances of successful outcomes.
- New drugs to treat type 2 diabetes and better ways to manage this form of diabetes through weight control.
- Evidence that intensive management of blood glucose reduces and may prevent development of diabetes complications.
- Demonstration that antihypertensive drugs called ACE (angiotensin-converting enzyme) inhibitors prevent or delay kidney failure in people with diabetes.
- Promising results with islet transplantation for type 1 diabetes reported by the University of Alberta in Canada. A nationwide clinical trial funded by the NIH and the Juvenile Diabetes Research Foundation International is currently trying to replicate the Canadian advance.

Researchers continue to search for the cause or causes of diabetes and ways to prevent and cure the disorder. Scientists are looking for genes that may be involved in type 1 or type 2 diabetes. Some genetic markers for type 1 diabetes have been identified, and it is now possible to screen relatives of people with type 1 diabetes to see if they are at risk.

The Diabetes Prevention Trial--Type 1 (DPT-1) identifies relatives at risk for developing type 1 diabetes and treats them with an oral form of insulin in the hope of preventing type 1 diabetes. In the same study, researchers recently completed a separate trial in which they found that low-dose insulin injections do not prevent type 1 diabetes in relatives of people with type 1 diabetes.

The DPT-1 is funded by the NIDDK, the National Institute of Allergy and Infectious Diseases, the National Institute of Child Health and Human Development, and the National Center for Research Resources within the National Institutes of Health as well as the American Diabetes Association and the Juvenile Diabetes Research Foundation International.

### **The Diabetes Prevention Program**

Several years ago, NIDDK launched its Diabetes Prevention Program (DPP). The goal of this research effort was to learn how to prevent or delay type 2

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## DIABETES

diabetes in people with impaired glucose tolerance (IGT), a strong risk factor for type 2 diabetes.

Of the 3,234 participants enrolled in the DPP, 45 percent were from minority groups that suffer disproportionately from type 2 diabetes: African Americans, Hispanic Americans, Asian Americans and Pacific Islanders, and American Indians. The trial also recruited other groups known to be at higher risk for type 2 diabetes, including individuals age 60 and older, women with a history of gestational diabetes, and people with a first-degree relative with type 2 diabetes.

The DPP found that over the 3 years of the study, diet and exercise sharply reduced the chances that a person with IGT would develop diabetes. Metformin also reduced risk, although less dramatically. The DPP resolved these questions so quickly that, on the advice of an external monitoring board, the program was halted a year early. The researchers published their findings in the *New England Journal of Medicine*.

Participants randomly assigned to intensive lifestyle intervention reduced their risk of getting type 2 diabetes by 58 percent. On average, this group maintained their physical activity at 30 minutes per day, usually with walking or other moderate intensity exercise, and lost 5 to 7 percent of their body weight. Participants randomized to treatment with metformin reduced their risk of getting type 2 diabetes by 31 percent.

### **DPP Study Design and Goals**

In the DPP, participants from 27 clinical centers around the country were randomly split into different treatment groups. The first group, called the lifestyle intervention group, received intensive training in diet, exercise, and behavior modification. By eating less fat and fewer calories and exercising for a total of 150 minutes a week, they aimed to lose 7 percent of their body weight and maintain that loss.

The second group took 850 mg of metformin twice a day. The third group received placebo pills instead of metformin. The metformin and placebo groups also received information on diet and exercise, but no intensive counseling efforts. A fourth group was treated with the drug troglitazone (Rezulin), but this part of the study was discontinued after researchers discovered that troglitazone can cause serious liver damage.

All 3,234 study participants were overweight and had IGT, which are well recognized risk factors for the development of type 2 diabetes. In addition, 45 percent of the participants were from minority groups--African American, Hispanic American/Latino, Asian American or Pacific Islander, or American Indian--that are at increased risk of developing diabetes.

### **DPP Results**

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## DIABETES

The DPP's striking results tell us that millions of high-risk people can use diet, exercise, and behavior modification to avoid developing type 2 diabetes. The DPP also suggests that metformin is effective in delaying the onset of diabetes.

Participants in the lifestyle intervention group--those receiving intensive counseling on effective diet, exercise, and behavior modification--reduced their risk of developing diabetes by 58 percent. This finding was true across all participating ethnic groups and for both men and women. Lifestyle changes worked particularly well for participants aged 60 and older, reducing their risk by 71 percent. About 5 percent of the lifestyle intervention group developed diabetes each year during the study period, compared with 11 percent in those who did not get the intervention. Researchers think that weight loss--achieved through better eating habits and exercise--reduces the risk of diabetes by improving the ability of the body to use insulin and process glucose.

Participants taking metformin reduced their risk of developing diabetes by 31 percent. Metformin was effective for both men and women, but it was least effective in people aged 45 and older. Metformin was most effective in people 25 to 44 years old and in those with a body mass index of 35 or higher (at least 60 pounds overweight). About 7.8 percent of the metformin group developed diabetes each year during the study, compared with 11 percent of the group receiving the placebo.

### **Transplantation**

Transplantation of the pancreas or insulin-producing beta cells offers the best hope of cure for people with type 1 diabetes. Some pancreas transplants have been successful. However, people who have transplants must take powerful drugs to prevent rejection of the transplanted organ. These drugs are costly and may eventually cause other health problems.

Scientists have made many advances in islet transplantation in recent years. Since reporting their findings in the *New England Journal of Medicine*, researchers at the University of Alberta in Edmonton, Canada, have continued to use a procedure called the Edmonton protocol to transplant pancreatic islets into people with type 1 diabetes. A multicenter clinical trial of the Edmonton protocol for islet transplantation is currently under way, and results will be announced in several years. According to the International Islet Transplant Registry, about 50 percent of the patients have remained insulin-free up to 1 year after receiving a transplant. A clinical trial of the Edmonton protocol is also being conducted by the Immune Tolerance Network, funded by the National Institutes of Health and the Juvenile Diabetes Research Foundation International.

Researchers use specialized enzymes to remove islets from the pancreas of a deceased donor. Because the islets are fragile, transplantation occurs soon after they are removed.

## DIABETES

During the transplant, the surgeon uses ultrasound to guide placement of a small plastic tube (catheter) through the upper abdomen and into the liver. The islets are then injected through the catheter into the liver. The patient will receive a local anesthetic. If a patient cannot tolerate local anesthesia, the surgeon may use general anesthesia and do the transplant through a small incision. Possible risks include bleeding or blood clots.

It takes time for the cells to attach to new blood vessels and begin releasing insulin. The doctor will order many tests to check blood glucose levels after the transplant, and insulin may be needed until control is achieved.

The goal of islet transplantation is to infuse enough islets to control the blood glucose level without insulin injections. For an average-size person (70 kg), a typical transplant requires about 1 million islets, extracted from two donor pancreases. Because good control of blood glucose can slow or prevent the progression of complications associated with diabetes, such as nerve or eye damage, a successful transplant may reduce the risk of these complications. But a transplant recipient will need to take immunosuppressive drugs that stop the immune system from rejecting the transplanted islets.

Researchers are trying to find new approaches that will allow successful transplantation without the use of immunosuppressive drugs, thus eliminating the side effects that may accompany their long-term use.

Rejection is the biggest problem with any transplant. The immune system is programmed to destroy bacteria, viruses, and tissue it recognizes as "foreign," including transplanted islets. Immunosuppressive drugs are needed to keep the transplanted islets functioning.

The Edmonton protocol uses a combination of immunosuppressive drugs, also called antirejection drugs, including dacliximab (Zenapax), sirolimus (Rapamune), and tacrolimus (Prograf). Dacliximab is given intravenously right after the transplant and then discontinued. Sirolimus and tacrolimus, the two main drugs that keep the immune system from destroying the transplanted islets, must be taken for life.

These drugs have significant side effects and their long-term effects are still not known. Immediate side effects of immunosuppressive drugs may include mouth sores and gastrointestinal problems, such as stomach upset or diarrhea. Patients may also have increased blood cholesterol levels, decreased white blood cell counts, decreased kidney function, and increased susceptibility to bacterial and viral infections. Taking immunosuppressive drugs increases the risk of tumors and cancer as well.

Researchers do not fully know what long-term effects this procedure may have. Also, although the early results of the Edmonton protocol are very encouraging,

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## DIABETES

more research is needed to answer questions about how long the islets will survive and how often the transplantation procedure will be successful.

A major obstacle to widespread use of islet transplantation will be the shortage of islet cells. The supply available from deceased donors will be enough for only a small percentage of those with type 1 diabetes. However, researchers are pursuing avenues for alternative sources, such as creating islet cells from other types of cells. New technologies could then be employed to grow islet cells in the laboratory.

A clinical trial funded by the NIH and the Juvenile Diabetes Research Foundation International will try to replicate the Edmonton advance. With the insights gained from this trial and other studies, scientists hope to further refine methods of islet harvesting and transplantation and learn more about the immune processes that affect rejection and acceptance of transplanted islets.

### **Future Research**

Researchers will perform other analyses to try to determine the relative contribution of diet and exercise to the reduction in diabetes. The DPP was not designed to examine diet versus exercise, however, so the analyses may not provide a definitive answer. Researchers will also analyze the information from the study to try to determine how lifestyle intervention and metformin affect the development of heart and blood vessel diseases, which are more common in people with pre-diabetes and type 2 diabetes.

DPP researchers plan to continue examining the roles of lifestyle and metformin in preventing type 2 diabetes. They will also continue to monitor participants to learn more about the study's long-term effects. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is encouraging new research to look at cost-effective methods of delivering lifestyle modifications in group settings and over the Internet, as well as methods to sustain behavior change and weight loss. The National Diabetes Education Program (NDEP)--a joint project of the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and more than 200 public and private organizations--will disseminate the findings and protocols stemming from the DPP.

# DIABETES

## Resources

### **National Diabetes Education Program**

1 Diabetes Way  
Bethesda, MD 20892-3600  
Phone: 1-800-438-5383  
Internet: <http://ndep.nih.gov>

### **American Diabetes Association**

National Service Center  
1701 North Beauregard Street  
Alexandria, VA 22311  
Phone: 1-800-342-2383 or (703) 549-1500  
Internet: [www.diabetes.org](http://www.diabetes.org)

### **Juvenile Diabetes Research Foundation International**

120 Wall Street, 19th Floor  
New York, NY 10005  
Phone: 1-800-533-2873 or (212) 785-9500  
Internet: [www.jdrf.org](http://www.jdrf.org)

### **National Diabetes Information Clearinghouse**

1 Information Way  
Bethesda, MD 20892-3560

# DIABETES

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## DIABETES

### DIABETES

#### POST-TEST

1. What is the most common form of Diabetes?
  - A. Type 1 Diabetes
  - B. Type 2 Diabetes
  - C. Gestational Diabetes
  - D. Diabetes Insipidus
2. Which of the following is a condition associated with Metabolic Syndrome?
  - A. Low blood pressure
  - B. Triglycerides 20 mg/dL or lower
  - C. Waist measurement greater than 35 inches in women
  - D. Fasting Blood glucose levels 110 mg/dL or lower
3. Which of the following is a positive test result for diabetes?
  - A. 130mg/dL Casual Plasma Glucose level
  - B. 130mg/dL Fasting Plasma Glucose value
  - C. 130mg/dL OGTT value
  - D. 130mg/dL Glucagon Titer level
4. Which medications restrict or delay the absorption of carbohydrates after eating?
  - A. Alpha-Glucosidase inhibitors
  - B. Biguanides and Thiazolidinediones
  - C. Sulfonylureas
  - D. Meglitinides
5. Bezoar formation is a potentially dangerous complication of \_\_\_\_\_.
  - A. Diabetic Retinopathy
  - B. Gastroparesis
  - C. Hypoglycemia
  - D. Diabetic kidney failure
6. Which stage of kidney failure is also known as “advanced clinical nephropathy”?
  - A. Stage II
  - B. Stage III
  - C. Stage IV
  - D. Stage V

## DIABETES

7. Which of the following is NOT a type of diabetic neuropathy?
  - A. Peripheral
  - B. Autonomic
  - C. Systemic
  - D. Focal
  
8. Which sensory testing device should be used as part of a thorough diabetic foot exam?
  - A. 10 gram nylon filament
  - B. 6 spoke sensory wheel
  - C. 15 gram braided wire
  - D. 3 point sensory compass
  
9. What percentage of African–Americans have diabetes?
  - A. 4%
  - B. 8%
  - C. 11%
  - D. 13%
  
10. The Diabetes Prevention Program (DPP) found that \_\_\_\_\_ sharply reduced the chances that a person with impaired glucose tolerance would develop Type 2 diabetes.
  - A. Prophylactic insulin injections
  - B. Improved diet and increased exercise
  - C. Rezulin
  - D. Daily glucose monitoring