Understanding Diabetes

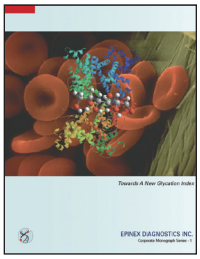
EPINEX DIAGNOSTICS INC.

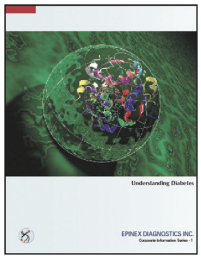
Corporate Information Series - 1

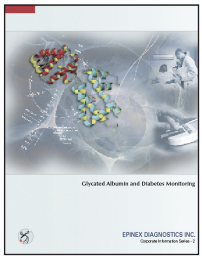
Foreword

This is the first in a series of corporate informational documents that we hope will provide critical data for our partners, collaborators, supporters, doctors, educators and investors concerned about the growing worldwide epidemic of diabetes, and the problems and opportunities it presents to the healthcare industry. This educational presentation, prepared by our Director of Corporate Communications, Dr. David Trasoff, assisted by Serop Gharibian, Executive Assistant, presents a detailed introduction to diabetes. It reviews basic information about diabetes types, causes and current treatment, examines the prevalence of diabetes worldwide and the economic burden it imposes on healthcare systems, and examines some of the long-term issues that affect diabetes diagnosis and care in the coming decades. It concludes with a look at the current state of diabetes monitoring, one of the most critical issues in the control of diabetes, and looks to new possibilities for helping to stem the tide of the epidemic. I hope that this presentation will provide you with useful information and will encourage discussion that may help to improve the available options for patient diagnosis and treatment.

Asad R. Zaidi, President
Epinex Diagnostics Inc.







Understanding Diabetes

The Global Diabetes Epidemic And Its Consequences

EPINEX DIAGNOSTICS INC.

Corporate Information Series - 1

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Understanding Diabetes

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Abstract

Diabetes is a chronic metabolic disorder in which the body does not produce or properly use insulin. The cause of diabetes is unknown, although both genetics and environmental factors such as obesity and lack of exercise appear to play roles. The progressive complications of unmanaged diabetes include heart disease, blindness, kidney failure, amputation of extremities due to circulation problems, and nerve disorders; as well as other chronic conditions. There are three types of diabetes: type 1, an autoimmune disease; type 2, associated with lack of exercise, poor diet, obesity and ageing; and gestational diabetes. Type 2 represents 90-95% of diabetes cases.

There are currently more than 246 million people with diabetes worldwide. The IDF estimates that if nothing is done to slow the epidemic, the number will exceed 380 million by 2025. The five countries with the largest numbers of persons with diabetes are India, China, the United States, Russia and Japan. The Centers for Disease Control estimated that as of 2004 there were 18.2 million cases of diabetes in the United States, of which only 13 million were diagnosed. The total cost of diabetes In the United States in 2002, including medical costs and lost productivity, was estimated at $132 billion. Long-term factors that will impact the course of the diabetes epidemic include obesity, prediabetes and metabolic syndrome. All three conditions affect many times the number of people currently diagnosed with diabetes, and all are recognized as possible indicators of future diabetes cases.

The goal of diabetes monitoring is to avoid the complications of diabetes by allowing patients and their health care providers to monitor the effectiveness of the patient's treatment regimen in controlling glycation, and to alter it as needed for better overall glucose control. Diabetes monitoring is presently done by two methods: 1) self-testing for blood glucose levels, usually done by the patient at home, measures the amount of glucose in the patient's blood at a particular point in time; and 2) testing for long-term glycation by measuring the level of glycated hemoglobin (HbA1c). This test is usually performed in the doctor's office and processed in a clinical laboratory.

The current paradigm for monitoring diabetes, consisting of multiple daily blood glucose tests and an HbA1c test every 3-6 months, may not work for many type 2 diabetics. Several recent studies have challenged the effectiveness of self-testing for blood glucose; other studies suggest that 3-6 months is too long an interval for glycation testing. In recent years a new paradigm for diabetes monitoring and care based on monthly counseling with a pharmacist or other diabetes care provider has shown significant success in improving patient health and lowering medical costs. Several studies have suggested that a monthly test for protein glycation would be a valuable addition to this more effective model for diabetes care.

What Is Diabetes?

Keypoint

Diabetes is a chronic metabolic disorder in which the pancreas produces too little or no insulin, or the cells do not respond properly to the insulin that is produced. As a result, excess sugars build up in the bloodstream and cause damage to a variety of organs and bodily functions. The cause of diabetes is unknown. The most prevalent form of diabetes is type 2, representing 90-95% of cases.

Diabetes is a chronic metabolic disorder in which the body does not produce or properly use insulin. Insulin is a hormone produced by the beta cells of the pancreas that is needed to convert sugars, starches and other food into energy by allowing sugars in the bloodstream to be absorbed into the cells. The body has trouble regulating its blood glucose (blood sugar) levels because the pancreas produces either little or no insulin, or the cells do not respond appropriately to the insulin that is produced. As a result, excess sugar builds up in the bloodstream (hyperglycemia). The cause of diabetes is unknown, although both genetics and environmental factors such as obesity and lack of exercise appear to play roles.

Some of the symptoms associated with diabetes include:

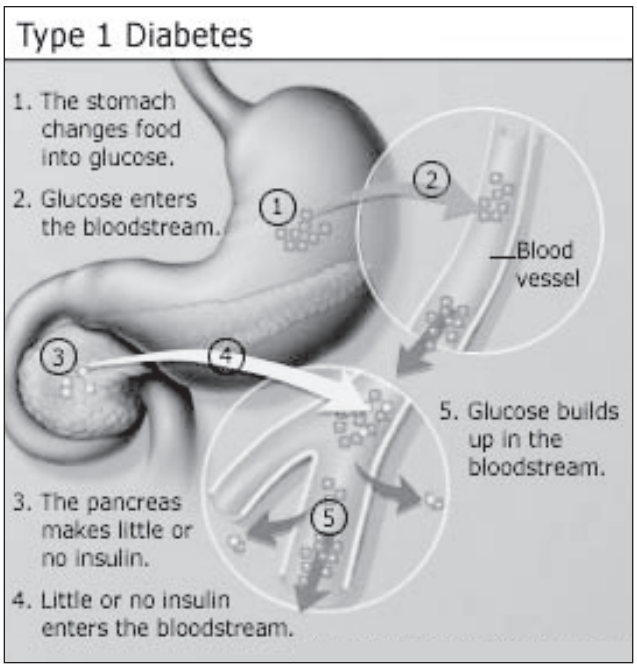
- Excessive thirst
- Excessive hunger
- Excessive urination
- Fatigue
- Sudden weight loss or gain
- Blurred vision
- Loss of feeling in the extremities

The progressive complications of unmanaged diabetes include heart disease, blindness, kidney failure, amputation of extremities due to circulation problems, and nerve disorders; as well as other chronic conditions. These complications are the cause of the immense personal, financial and societal costs of diabetes. Decades of research have established that prolonged exposure to excess glucose is the cause of diabetes complications, and that long-term control of blood glucose levels is required to avoid or lessen the damage caused by excess glucose. To achieve this control, diabetics must monitor the way that sugars are being processed in their bodies. Because diabetes itself may have no obvious symptoms, this long term monitoring is critical to the patient's health.

Types of Diabetes

Typ e 1 Diabetes

Type 1 diabetes is an autoimmune disease in which the cells that produce insulin in the pancreas are destroyed, leaving the individual completely dependent on an external source of insulin, typically injected several times a day. Previously known as juvenile onset diabetes, this condition is usually evident during childhood, and represents 5-10% of diabetics. Type 1 diabetics must very closely monitor their levels of blood sugar throughout the day in order to determine how much insulin they need.



Source: WebMD

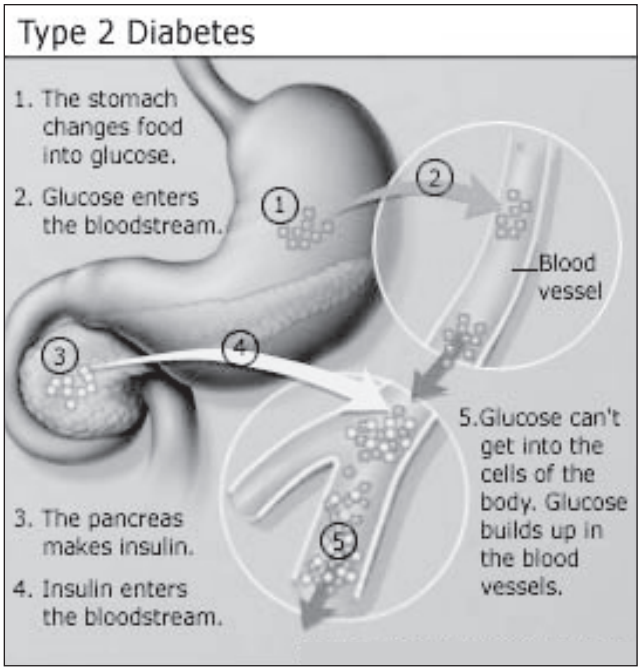
Gestational Diabetes

Gestational diabetes is defined as any degree of glucose intolerance that occurs during pregnancy. There are approximately 4 million pregnancies to term every year in the U.S.A. Up to 10% will develop gestational diabetes and the numbers are increasing. After pregnancy, 5-10% of women with gestational diabetes are diagnosed with type 2 diabetes, and 20-50% develop type 2 diabetes within 5-10 years (CDC). Gestational diabetes occurs when a woman who does not have diabetes develops a resistance to insulin because of the hormones of pregnancy. Women with gestational diabetes may be non-insulin dependent or insulin dependent. Gestational diabetes can cause complications to the baby, including macrosomia, birth injury, hypoglycemia, and respiratory distress (difficulty breathing). Therefore, it is extremely important for doctors to monitor pregnant women for any signs of glucose intolerance. Medical authorities have declared that ALL pregnant women should be tested.

Type 2 Diabetes

Type 2 diabetes (90-95% of all diabetes cases), often called 'adult-onset' or 'lifestyle' diabetes, develops as the body gradually loses the ability to process insulin properly. As the ability to process insulin declines, insulin production itself is eventually impaired as well. Type 2 diabetes is associated with lack of exercise, poor diet, obesity, ageing, certain ethnicities, and a family history of diabetes (80% of type 2 diabetics are overweight).

Over 70% of type 2 diabetics are non-insulin dependent and control their diabetes condition primarily through diet and exercise, and/or with an oral medication to help lower glucose levels. They need to monitor their level of sugar in the blood on a consistent basis over the long term, in order to prevent the onset of diabetes complications.



Source: WebMD

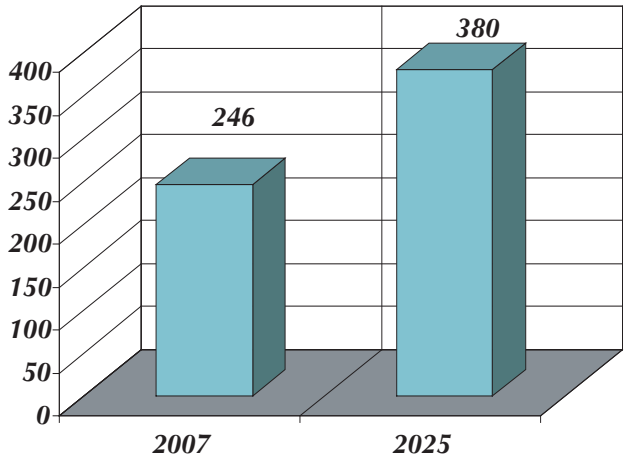
Keypoint

There are estimated to be more than 246 million people with diabetes worldwide, expected to rise to 380 million by 2025. Diabetes is rising fastest in developing countries, an average of 170%, versus 42% for developed countries. There are now more than 18 million cases of diabetes in the United States.

Diabetes Prevalence Worldwide

According to the International Diabetes Federation (IDF), there are currently more than 246 million people with diabetes worldwide. The IDF estimates that if nothing is done to slow the epidemic, the number will exceed 380 million by 2025.

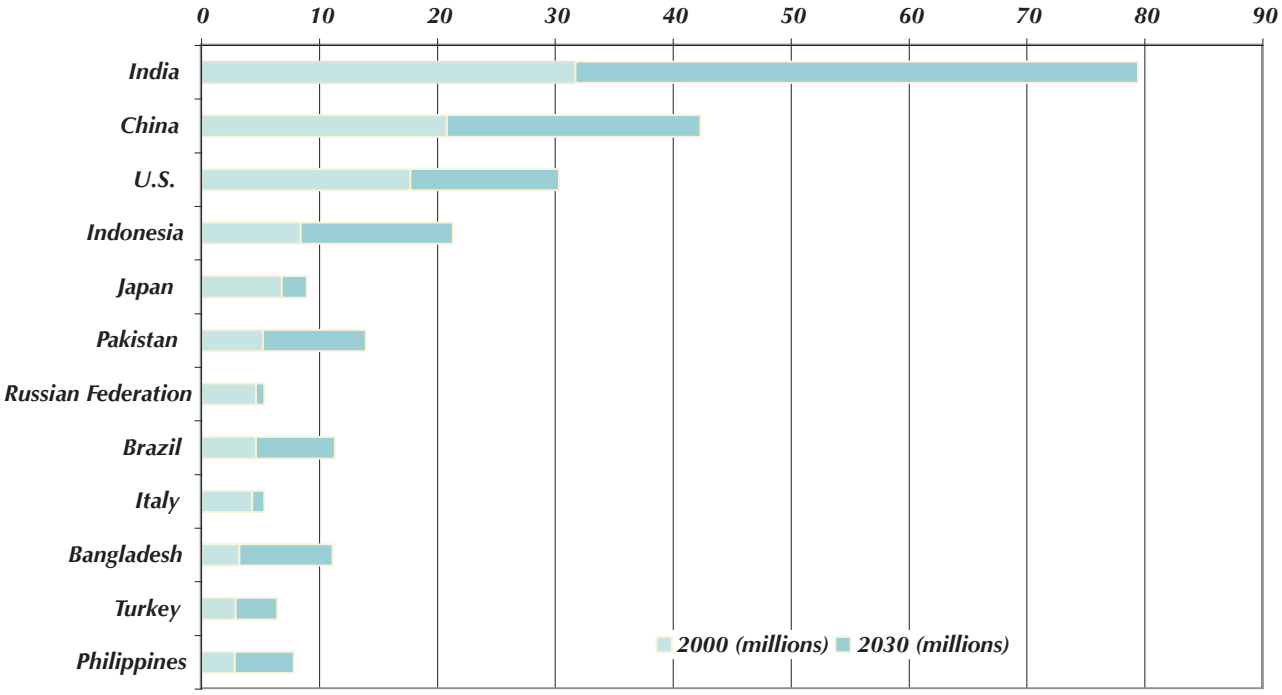
According to 2007 IDF figures, the five countries with the largest numbers of persons with diabetes are India (41 million), China (40 million), the United States (20 million), Russia (9.7 million) and Japan (6.7 million). The diabetes epidemic is largely attributed to the rise of type 2 diabetes cases, particularly affecting developing countries and migrants moving from these countries to industrialized societies. The prevalence of diabetes in developing countries is estimated to increase by 98% from the current 7.9% by 2025 (King 1998).



Projected Growth in Diabetes Cases Worldwide (IDF)

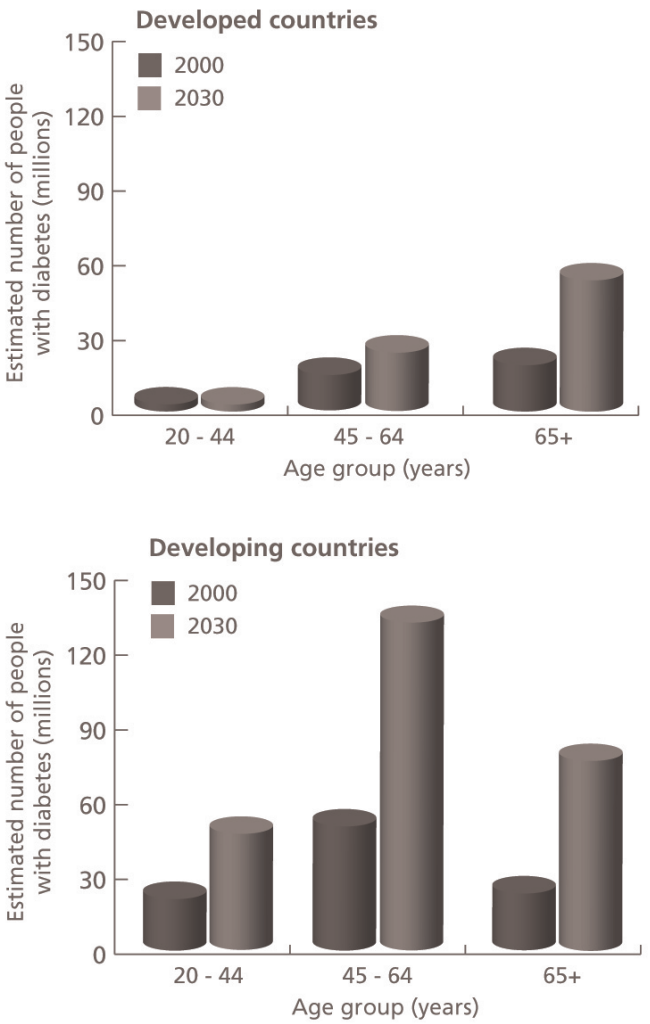
Millions	2000	2030	% Increase
US/Canada	19.7	33.9	72%
Europe	28.3	37.4	32%
China	20.7	42.3	104%
India	31.7	79.4	150%
Middle East	20.0	52.8	164%
Latin America	13.3	33.0	148%
South-East Asia	22.3	58.1	163%

Diabetes Increase By Region (Wild 2004)



Projected Growth of Diabetes Cases By Country - Top 12 (WHO)

Diabetes Statistics



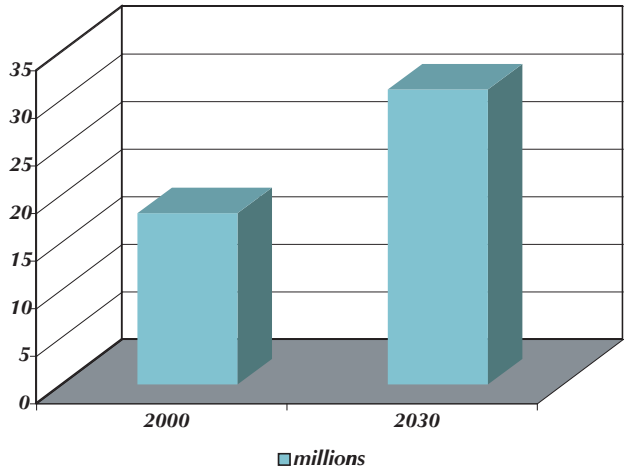
Estimated number of adults with diabetes.

Source: WHO

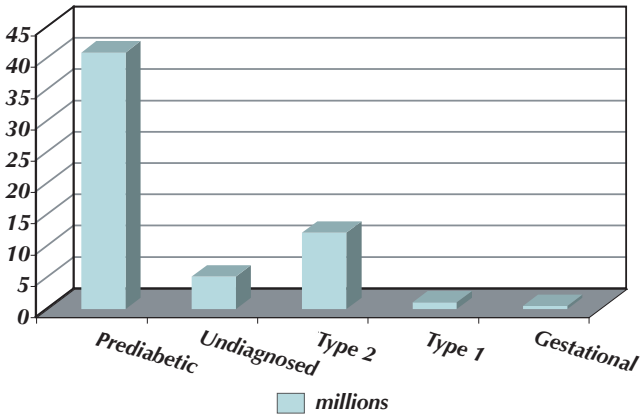
- It is estimated that at least 50% of all people with diabetes are unaware of their condition. In some countries this figure may rise to 80% (Diabetes Atlas 2007).
- Diabetes is the fourth main cause of death in most developed countries. It is the leading cause of blindness and visual impairment in adults in developed countries. Diabetes is the most common cause of amputation that is not the result of an accident.
- For developing countries, there will be a projected increase in the number of diabetes cases by 170%; for developed countries, there will be a projected increase by 42%. It is estimated that diabetes accounts for between 5% and 10% of a nation's health budget. An estimated 25% of the world's nations have not made any specific provision for diabetes care in national health plans.
- Diabetes increased by one-third during the 1990s, due to the prevalence of obesity and an ageing population.
- Diabetes is increasing among the elderly in developed countries, but is rising much faster among middle-aged adults in developing countries.

Diabetes Prevalence in the United States

The Centers for Disease Control estimated that as of 2004 there were 18.2 million cases of diabetes in the United States, of which only 13 million were diagnosed. This figure represents 6.3% of the population as a whole. The percentage rises to 8.7% for over age 20, and 18.3% for over age 60. Diabetes is the fifth leading cause of death by disease in the U.S.

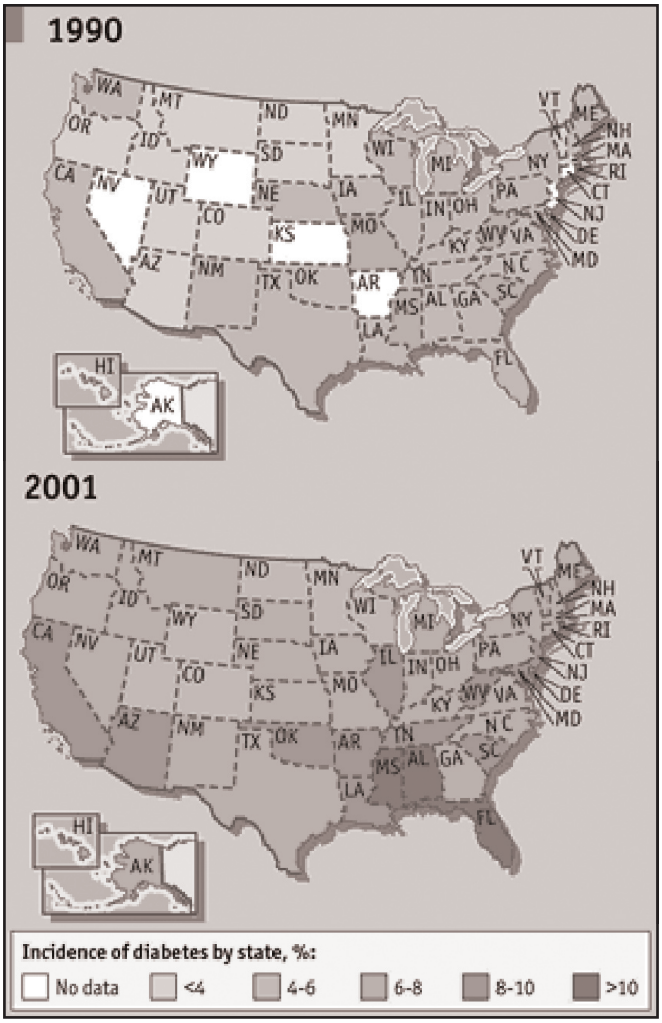


Projected Growth in Diabetes Cases: USA (WHO)



Diabetes Populations in the United States (CDC)

Diabetes has become more than twice as common since 1980, and the rate is rising precipitously. At least 54 million Americans have elevated blood sugar levels and are at risk of developing the full-blown disease. Rates are considerably higher among American Indians, African-Americans and Latinos. Obesity is a major contributor to the epidemic in the US. Between 1976-1980 and 1999, the prevalence of obesity increased from 13% to 27% among US adults (CDC 2005).



Source: CDC

Economic Burden of Diabetes

The devastating complications of diabetes, such as blindness, kidney failure and heart disease, are imposing a huge burden on healthcare services. It is estimated that diabetes accounts for between 5% and 10% of a nation's health budget. An estimated 25% of the world's nations have not made any specific provision for diabetes care in national health plans.

Keypoint

Diabetes is projected to account for between 5-10% of a nation's health care budget. In 2002, the cost of diabetes in the United States was $132 billion: over $90 billion in direct medical costs and $40 billion in lost productivity.

Costs of Diabetes in the Developing World

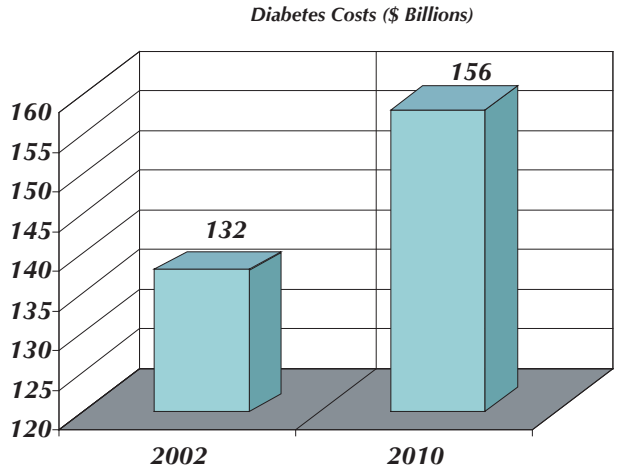
Although the epidemic is in the early stages of its upward trajectory in developing countries, the economic burden is already significant. It is estimated that 1 out of 3 hospital beds are occupied for diabetes-related causes. The average costs for a year of diabetic care, roughly $550 per person, exceeds the per capita gross domestic product (GDP) in many areas (Barcelo 2003). For diabetic individuals in India, 15-25% of household income is required to cover treatment costs (Shobhana 2000). In Tanzania, treatment amounts to 25% of the minimum wage or 20 times more than per capita health expenses (Neuhann 2002). This burden is often the greatest to the people who can't afford care.

Burden on Healthcare Systems in the United States

- In the United States, the total cost of diabetes in 2007, including medical costs and lost productivity, was estimated at $174 billion.
- Direct medical expenditures totaled $116 billion, including $27 billion for diabetes care, $58 billion for chronic diabetes-related complications and $31 billion for general medical conditions that are associated with diabetes (ADA 2008).
- The per capita annual costs of healthcare for people with diabetes rose more than 30 percent per person from 1997 to 2002 ($10,071 to $13,243). In contrast, healthcare costs for people without diabetes in 2002 amounted to only $2,560 per person.
- While those diagnosed with diabetes account for 6.3 percent of the total population, the disease represents 19 percent of total personal healthcare expenditures in the United States (Testa 1998).

Cost to Employers

- In 2007, indirect costs resulting from lost workdays, restricted activity, mortality, and permanent disability due to diabetes was estimated to be $58 billion (ADA).
- Diabetes accounted for nearly 88 million disability days.
- An estimated 176,000 cases of permanent disability were attributed to diabetes at a cost of $7.5 billion.
- Current data show that people with diabetes who are able to control their glucose levels cost employers only $24 a month, compared to $115 a month for people with diabetes who do not control their blood glucose.



Present and Projected Costs of Diabetes in the United States

According to the American Diabetes Association, classic symptoms of diabetes include abnormally high levels of hunger and thirst, and increased urination. However, the majority of people with early stages of type 2 diabetes do not show any symptoms. Physicians may therefore recommend testing for diabetes if a patient has a body mass index ≥27, an HDL cholesterol level < 35 mg/dl or triglycerides > 250 mg/dl, and or has a blood pressure at or above 140/90 millimeters of mercury (mmHg).

In clinical practice, the fasting plasma glucose test is the preferred test for diagnosing diabetes, although a diagnosis can be made based on any of the following test results, confirmed by retesting on a different day.

- Fasting Plasma Glucose Test (FPG): A test that measures the amount of sugar in the blood after fasting for eight hours. A blood glucose level ≥126 mg/dl- (milligrams per deciliter) equivalent to 7.0 mmol/l (millimoles/liter) is considered positive. Most non-diabetics have a blood glucose level between 70 and 110 mmHg.

- Oral Glucose Tolerance Test (OGTT): A blood sample is taken, following which the patient drinks a high glucose beverage. At different time intervals blood samples are taken to determine how the body uses glucose over time. A blood glucose level ≥ 200 mg/dl (11.1 mmol/l) 2 hours after drinking a beverage containing 75 grams of anhydrous glucose dissolved in water is considered positive for diabetes.

- Random Blood Glucose Test (Random Plasma Glucose): A test that measure the amount of sugar in the blood shortly after eating or drinking at any time during the day. A blood glucose level ≥ 200 mg/dl (11.1 mmol/l), in conjunction with the presence of diabetes symptoms, is considered a positive diagnosis.

Keypoint

The majority of people in the early stages of type 2 diabetes do not show symptoms. Currently, the preferred test for diagnosing diabetes is the Fasting Plasma Glucose test. All current tests for diagnosing diabetes must be performed in the laboratory.

Treatment Goals

Overall, among adults with diagnosed diabetes, 12% take both insulin and oral medications, 19% take insulin only, 53% take oral medications only, and 15% do not take either insulin or oral medications. The goals of diabetes treatment are to:

(1) eliminate symptoms related to hyperglycemia,

(2) reduce or eliminate the long-term microvascular and macrovascular complications of diabetes, and

(3) allow the patient to achieve as normal a life-style as possible.

Type 1

Replacement of beta cells through islet transplant therapy can, in some cases, temporarily render patients insulin-independent. However, life-long daily insulin therapy is eventually necessary to sustain life for people with type 1 diabetes.

Type 2

Currently available oral diabetic drugs work by increasing insulin secretion, reducing insulin resistance or reducing glucose production in the liver. These include metformin, the sulfonylureas, and thiazolidinediones (TZDs), as single agent therapy or in combination.

However, no single therapy is currently effective in controlling the disease over time and typically one or more oral medications are necessary to regulate blood glucose concentrations. Eventually, insulin is added to the treatment regimen for many people with type 2 diabetes when oral therapies become ineffective.

Classes of oral type 2 diabetes drugs:

There are currently five different classes of oral hypoglycemic drugs, including:

- Metformin (Biguanides): reduce glucose production in liver;
- Sulphonylureas: stimulate secretion by pancreas and hepatic insulin clearance;
- Meglitinide: stimulate insulin secretion by pancreas;
- Thiazolidinediones (TZDs): reduce insulin resistance; and
- a-glucosidase inhibitors: reduce glucose absorption from the intestine.

Keypoint

The goal of diabetes treatment is the long-term reduction of levels of serum glucose. 12% of diabetes patients take both insulin and oral medications, 19% take insulin only, 53% take oral medications only, and 15% do not take either insulin or oral medications.

Management of Type 2 Diabetes

Glucose Control:	Treat Associated Conditions:	Manage Complications:
Diet	Dislipidemias	Retinopathy
Exercise	Hypertension	Cardiovascular Disease
Oral Medications	Obesity	Nephropathy
Insulin	Heart Disease	Neuropathy

Keypoint

The goal of diabetes monitoring is to control glycation. Diabetes monitoring is presently done by using daily self-monitored blood glucose testing (SMBG), and by testing for glycated hemoglobin every 3-6 months (HbA1c).

The goal of diabetes monitoring is to control glycation and avoid the complications of diabetes by allowing patients and their health care providers to determine a treatment regimen, to monitor the effectiveness of the regimen and to alter it as needed for better overall glucose control.

Diabetes monitoring is presently done by two methods:

1) Self-testing for blood glucose levels using whole blood, obtained by daily multiple finger sticks, which is read by a blood glucose meter. This test, usually done by the patient at home, measures the amount of glucose in the patient's blood at a particular point in time; and
2) Testing for long-term glycation by measuring the level of glycated hemoglobin (HbA1c). This test is usually performed in the doctor's office and processed in a clinical laboratory.

Current Diabetes Monitoring Methods

Self-Monitoring Blood Glucose (SMBG)	Glycated Hemoglobin Test (HbA1c)
Point-in-time blood glucose reading, blood sugar level	Index of glycated hemoglobin level to total hemoglobin level; Damage to red blood cells
Multiple times per day at home	Every 3-6 months; at doctor's office.

Challenges to Current Diabetes Monitoring Practices

Keypoint

SMBG can only provide a snapshot of blood glucose levels and does not monitor glycation. Recent studies have shown no benefit to SMBG testing in improving glycemic control for type 2 diabetics. The HbA1c test cannot measure glycation within a three-month period, during which diabetes complications can advance unchecked.

The current paradigm for monitoring diabetes, consisting of multiple daily blood glucose tests and an HbA1c test every 3-6 months, may not work for many type 2 diabetics.

The efficacy of multiple daily blood glucose tests to monitor diabetes (SMBG or self-monitoring blood glucose) has come under challenge on multiple fronts in recent years. Daily testing for blood glucose does not provide any information on protein glycation, the underlying cause of potential long-term complications. Daily testing is inconvenient and stressful, which reduces compliance. Although diabetics claim a high compliance rate for blood glucose testing (60%), research indicates the actual rate of use for type 2 diabetics may be as low as 17%. Studies indicate that early intensive diabetes treatment can negatively affect stress levels and outcome of treatment. Articles published in the scientific journal of the American Diabetes Association stated "early and intensive treatment can affect patients' psychological outcomes, resulting in higher anxiety and less self-efficacy" (Thoolen 2006) and "[f]or patients who do not receive insulin, self-monitoring [of blood glucose] is associated with poorer metabolic control and greater psychological distress" (Franciosi 2001).

Several recent research studies dispute the conventional wisdom that daily blood glucose testing leads to improved glycemic control for type 2 diabetics. The Fremantle Study of 1,286 type 2 diabetes patients over 5 years, (Davis 2007) as well as a study of nearly 3,000 type 2 diabetes patients on OAD (oral medication) or diet alone in Germany and Austria, found "no benefit" from daily blood glucose testing "regardless of treatment" (Schutt 2006). A 2007 study published in the journal of the British Medical Association found no improvement in glycemic control even when enrolled patients were given training and encouragement (Farmer 2007).

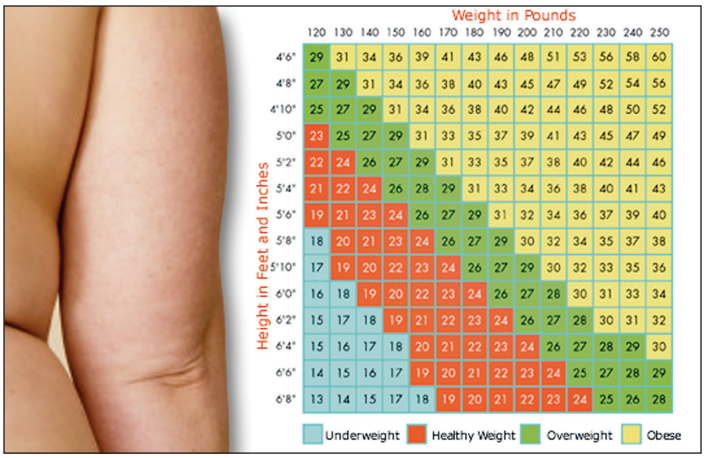
While the HbA1c test does provide information on glycation, that information is of limited use in helping diabetics and their healthcare providers in monitoring and modifying treatment, because the interval of the test, which may be as much as four to six months, is too long. Diabetes complications can advance unchecked during this interval. Because the A1c test is commonly sent out to a clinical laboratory, and the results are reported to the doctor at a later time, there is little or no opportunity for doctor-patient feedback and immediate treatment modification. In addition, the A1c test does not directly measure serum protein glycation, an immediate causal factor for serious diabetes complications such as heart disease, blindness and kidney failure.

Obesity

Obesity is an enormous clinical and economic problem in the United States and other developed countries. Obesity is a principal risk factor for type 2 diabetes, as roughly 60% of all diabetes cases can be directly attributed to weight gain (James 2003). An excess of body fat, especially when concentrated within the abdomen, has a range of potentially harmful consequences. Weight gain leads to insulin resistance through several mechanisms. Fat accumulation induces insulin resistance through changes in hormonal and other secretions. Insulin resistance in turn places a greater demand on the pancreas to produce insulin, which also declines with age, leading to the development of clinical diabetes. Physical inactivity, both a cause and consequence of weight gain, also contributes to insulin resistance.

Over recent years, rates of overweight and obesity have escalated rapidly in many parts of the world to epidemic proportions. This directly reflects the increased consumption of energy-dense diets high in fats and sugars, compounded by declining levels of physical activity. More than 1.1 billion people are estimated to be overweight, of whom around 320 million are now considered obese (Mingrone 2006).

Obesity is also increasingly seen in adolescents and children. Type 2 diabetes was diagnosed in only 1-2% of diabetic cases in children two decades ago. With the rising incidence of obesity, type 2 diabetes has begun to appear in children at alarming rates, in some countries representing up to 80% of all diabetic cases in the pediatric population (ADA 2000). Infants born to overweight or diabetic mothers are more likely to be diagnosed with diabetes.



Weight in Pounds

Height in Feet and Inches	120	130	140	150	160	170	180	190	200	210	220	230	240	250
4'6"	29	31	34	36	39	41	43	46	48	51	53	56	58	60
4'8"	27	29	31	34	36	38	40	43	45	47	49	52	54	56
4'10"	25	27	29	31	34	36	38	40	42	44	46	48	50	52
5'0"	23	25	27	29	31	33	35	37	39	41	43	45	47	49
5'2"	22	24	26	27	29	31	33	35	37	38	40	42	44	46
5'4"	21	22	24	26	28	29	31	33	34	36	38	40	41	43
5'6"	19	21	23	24	26	27	29	31	32	34	36	37	39	40
5'8"	18	20	21	23	24	26	27	29	30	32	34	35	37	38
5'10"	17	19	20	22	23	24	26	27	29	30	32	33	35	36
6'0"	16	18	19	20	22	23	24	26	27	28	30	31	33	34
6'2"	15	17	18	19	21	22	23	24	26	27	28	30	31	32
6'4"	15	16	17	18	20	21	22	23	24	26	27	28	29	30
6'6"	14	15	16	17	19	20	21	22	23	24	25	27	28	29
6'8"	13	14	15	17	18	19	20	21	22	23	24	25	26	28

Underweight Healthy Weight Overweight Obese

Within the past several decades, five important developments have led to an unfavorable equilibrium between caloric intake and expense:

1. Expanding labor opportunities for women;
2. Increased consumption of food away from home;
3. Rising costs of healthy foods relative to unhealthy foods;
4. Growing quantity of caloric intake with declining overall food prices;
5. Decreased requirement of occupational and environmental physical activity.

Pre-Diabetes

The term pre-diabetes is given to people whose blood glucose levels are high, but not high enough to be diagnosed as having diabetes. Pre-diabetes is also known as impaired glucose tolerance (IGT) or impaired fasting glucose (IFG), and is considered to be a stage in the development of type 2 diabetes. It is typically characterized by hyperglycemia and insulin resistance. In 2005, the International Diabetes Federation estimated that there were 97 million known cases of type 2 diabetes worldwide, an equivalent number of unknown cases, and around 314 million people with IGT. By 2025, it is estimated this number will rise to approximately 500 million people, raising concerns about a potential epidemic of cardiovascular disease (Zimmet 2005). Up to half of all people with impaired glucose tolerance will progress to type 2 diabetes within 10 years of diagnosis. People with pre-diabetes also are at a greater risk for micro- and macro vascular disease. In the United States, as many as 54 million people may have pre-diabetes. Pre-diabetics often include people who are overweight, older, of certain ethnicities (African American, Alaska Native, Pacific Islander American, Hispanic, Native or Asian American), and people with a family history of diabetes, all of whom are more prone to developing diabetes.

Keypoint

Obesity is a principal risk factor for diabetes and the increasing prevalence of obesity worldwide is a major contributor to the diabetes epidemic. Impaired glucose tolerance, an indicator of possible, incipient diabetes, affects three times the number of people known to have diabetes. High blood pressure, high cholesterol and insulin resistance, grouped as metabolic syndrome, are also indicators of a potential to develop diabetes.

Metabolic Syndrome

Metabolic Syndrome is a combination of medical disorders including high blood pressure, high cholesterol, obesity, and insulin resistance that can increase the risk of developing diabetes and cardiovascular disease.

Metabolic syndrome is characterized by a group of metabolic risk factors in one person (AHA 2008). These factors include:

- Abdominal obesity (excessive fat tissue in and around the abdomen)
- Atherogenic dyslipidemia (blood fat disorders — high triglycerides, low HDL cholesterol and high LDL cholesterol — that foster plaque buildups in artery walls)
- Elevated blood pressure
- Insulin resistance or glucose intolerance (the body can't properly use insulin or blood sugar)
- Prothrombotic state (e.g., high fibrinogen or plasminogen activator inhibitor–1 in the blood)
- Proinflammatory state (e.g., elevated C-reactive protein in the blood)

Although several formal definitions of the metabolic syndrome have been proposed, the definition adopted by the National Cholesterol Education Program Adult Treatment Panel (NCEP ATP) requires at least three of the following five criteria (Butler 2006):

1) Waist circumference greater than 102 cm in men and 88 cm in women;

2) Serum triglyceride levels of at least 150 mg/dl;

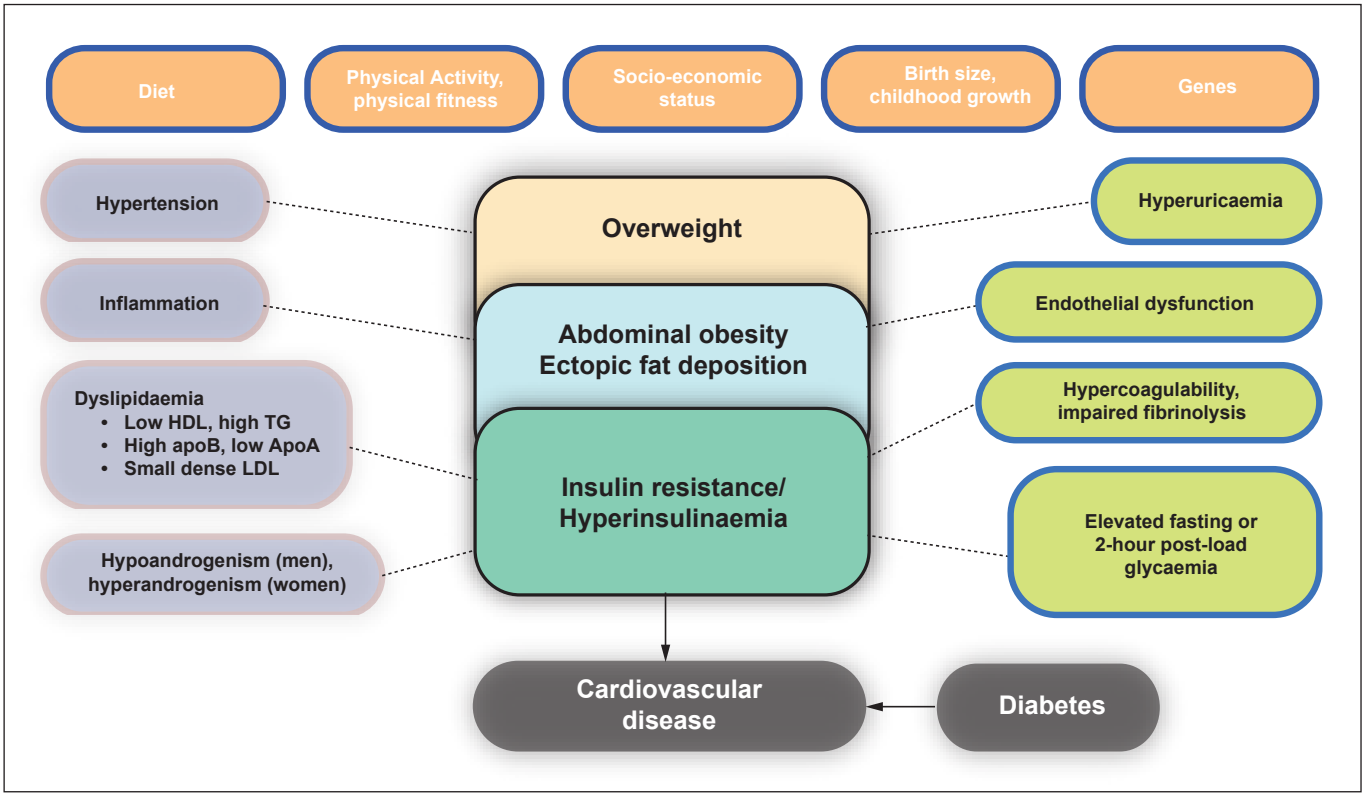
3) HDL cholesterol below 40 mg/dl in men and 50mg/dl in women;

4) Blood pressure of at least 130 mm/ 85 mm Hg;

5) Serum glucose concentration of at least 110 mg/dl.

Using these criteria, the prevalence of metabolic syndrome in the United States is almost 25%, or nearly 50 million people.

Metabolic syndrome comprises a cluster of risk factors for type 2 diabetes and cardiovascular disease



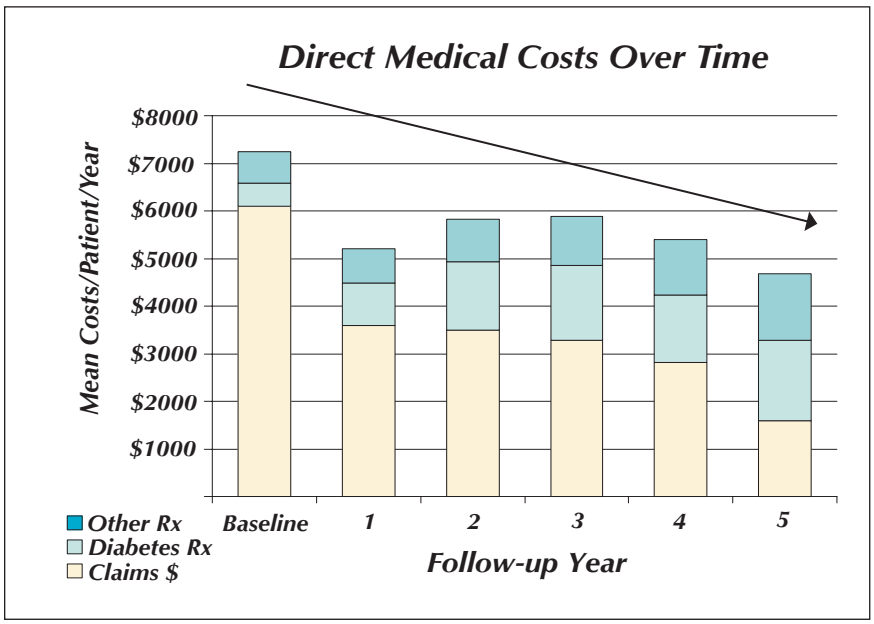
Keypoint

A regimen of monthly consultations with a pharmacist or other diabetes care counselor has proven to be an effective method for diabetes control. Several municipalities and corporations that have implemented this new paradigm have documented improved health for diabetes patients, lowered healthcare costs and increased productivity by reducing absenteeism.

As diabetes consumes an ever-greater share of healthcare resources, the sheer magnitude and urgency of the diabetes epidemic make it evident that the present diabetes care paradigm, in which the patient sees a physician at most twice a year, does not work now and will not work as a means to address the situation in the future. Spiraling, out-of-control healthcare costs also indicate that the present system may not be sustainable. There is general agreement among diabetes care professionals that self-management of diabetes is the single most significant component of the solution to the diabetes epidemic, and that patient empowerment is the key to successful diabetes control. In the past several years, a new paradigm for diabetes monitoring has been pioneered, based on monthly consultation with a pharmacist or other non-physician diabetes caregiver. Community-based diabetes care programs based on monthly consultation with a diabetes educator or pharmacist, supported by municipal and corporate employers, are showing success, as the program pays for itself through lower healthcare costs and higher productivity.

The "Asheville Project" For Diabetes Control

The city of Asheville, North Carolina, teamed with local industries and arranged for city and local company employees who require diabetes monitoring to see a pharmacist for a brief meeting once a month. The purpose of the meetings is to provide feedback for the patients' efforts to control their diabetes through diet, exercise, and, if required, medication. The experiment has generated strongly positive results. Significant improvement in diabetes metrics for enrolled patients has been recorded. Absenteeism related to illness is significantly down in the workplace, and productivity is increased, to the extent that the decrease in healthcare-related expenditure more than pays for the cost of the monitoring (Cranor 2003). This new paradigm for diabetes monitoring based on community care and patient empowerment, is gaining widespread interest and acceptance, and is being reproduced in similar projects throughout the U.S., as illustrated in a recent video feature produced for the Diabetes TV network.



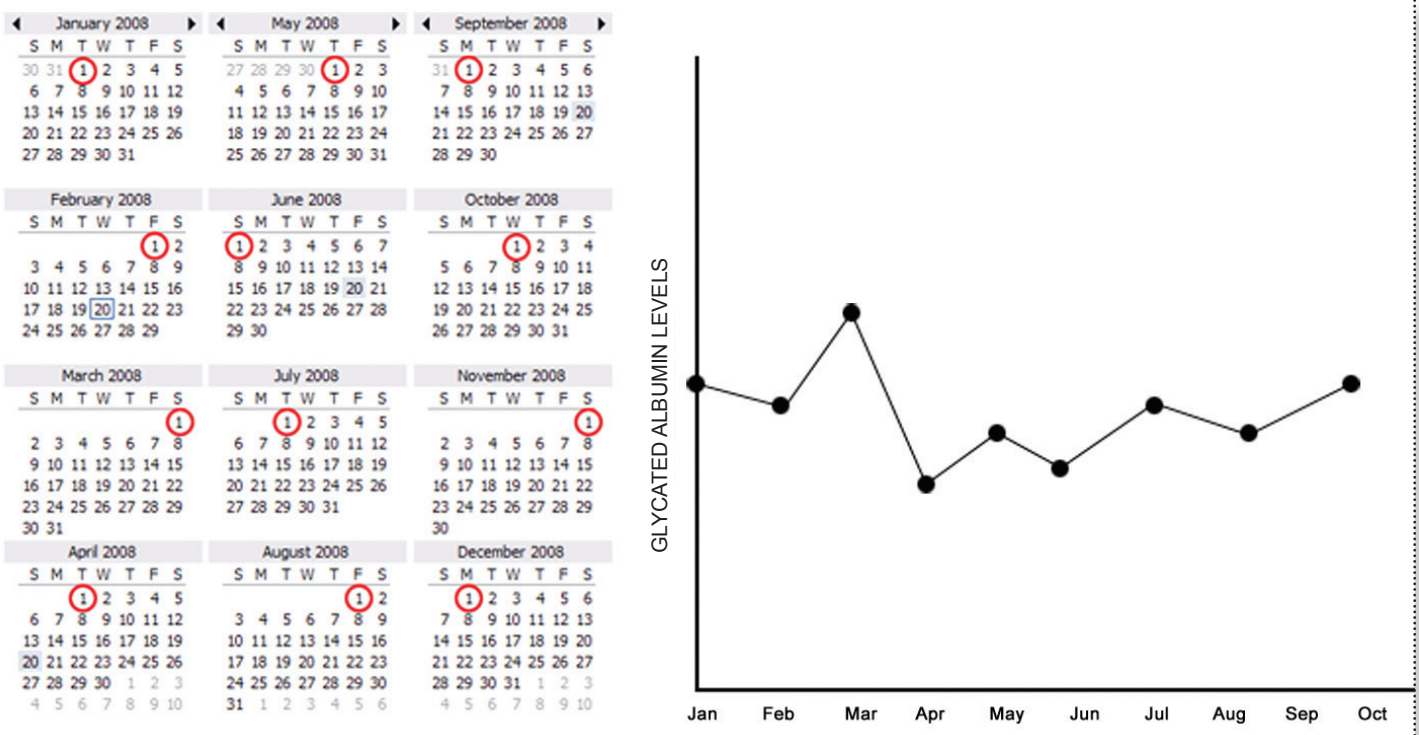
Asheville Project – Health Care Costs

Projected Role For A Monthly Glycation Index

Keypoint

There is a demonstrated need for an intermediate glycation index to monitor diabetes. A test based on glycated albumin can provide a stable monthly index of glycemic control.

Several recent studies have demonstrated the utility of a monthly index for glycation based on glycated albumin (Takahashi 2006; Kawamori 1996; Pu 2007; Inaba 2007). These studies have shown that diabetes monitoring based on glycated albumin can reflect changes in treatment more quickly than other methods, and that glycated albumin may be useful as a marker for cardiac disease and kidney problems in diabetics. A monthly test for protein glycation based on glycated albumin could be a valuable addition to this new model for diabetes care.



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