



Diabetes In The Middle East

EPINEX DIAGNOSTICS, INC.

Corporate Information Series - 4



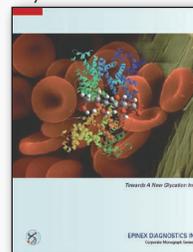
Foreword

This is the fourth 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 was prepared by our Director of Corporate Communications, Dr. David Trasoff, assisted by Jaycee Delizo, Bo Du, Christy Purnajo and Jacqueline Morales of the Epinex Department of Research and Development. The report presents detailed information on the state of the diabetes epidemic in the Middle East. It discusses current trends and prevalence of the disease, efforts to control its spread, and treatment methods implemented in the region. Problems involving the management of diabetes specific to the region are presented, concluding with a discussion of new possibilities to help stem the tide of the epidemic. I hope that this presentation will provide you with useful information that will encourage discussion to improve the available options for patient diagnosis and treatment, and help manage the potentially serious long-term consequences for the region's health and economy.

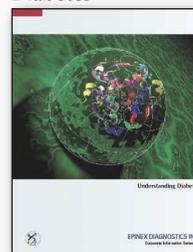
Asad R. Zaidi, President
Epinex Diagnostics, Inc.



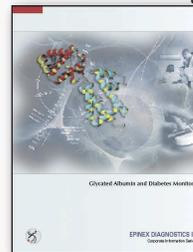
Toward a New Glycation Index



Understanding Diabetes



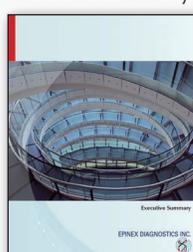
Glycated Albumin and Diabetes Monitoring



Diabetes in the Middle East



Executive Summary



Diabetes In The Middle East

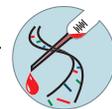
Scope and Solution

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Diabetes In The Middle East

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Managing Diabetes in the Middle East

According to the World Health Organization and the International Diabetes Federation, Diabetes has become the primary healthcare challenge of the twenty-first century. Nowhere will this challenge be greater than in the Middle East. This region is already afflicted by one of the highest per capita rates of diabetes in the world and will suffer dramatic social and economic consequences unless significant new initiatives are implemented to control the onset and progress of this disease.

The Middle East, especially the United Arab Emirates and neighboring Gulf States, has in recent years emerged as one of the principal financial and investment hubs in the world today. Ironically, this highly developed region now faces an estimated annual \$8 billion in lost productivity due to diabetes (Setrakian 2007). Stemming the tide of the human and financial cost of diabetes over the next several decades will test the resources and ingenuity of the region in the most unprecedented way. Currently, several diabetes initiatives are being undertaken by regional government ministries, private investment companies, and pharmaceutical multinationals. The success of these initiatives may well depend on finding cooperative strategies that enable governments and the private sector to work together towards the common goal of controlling the epidemic. As the problem is still rampant, none of these measures are adequate.

This report will present demographic information that details the present and projected extent of the diabetes epidemic in the Middle East region, with particular emphasis on the Gulf Region. The report then examines current methodologies and initiatives to manage diabetes, and the obstacles to success inherent in those methods. Diabetes monitoring is crucial to any scheme for controlling and managing diabetes. Current efforts in the Middle East are hampered by the lack of a workable diabetes monitoring methodology tailored to the region. What is needed now is an effective, inexpensive, convenient, program

for managing diabetes that best suits the region's unique economic, social, and cultural milieu.

We then offer a proposal for such a program, one with the potential to shift the current paradigm for diabetes monitoring and management. It consists of a monthly diabetes monitoring test, used in conjunction with a monthly consultation between the patient and a pharmacist, doctor, or diabetes educator. This promising new paradigm for diabetes care is based on a monthly testing and consultation program that has already shown success in the United States. It promotes increased patient responsibility for self-management of their condition by means of the monthly interaction and feedback, and allows for more timely therapeutic intervention to control the progress of the disease. Such an approach to diabetes management is designed to have an immediate fit into the existing healthcare management system of the Gulf States, and has the potential for expansion throughout the region.

Epinex Diagnostics, Inc. has developed a monthly test that can fit into this program, based on the innovative application of existing, proven technology. This report introduces the Epinex G1A™ Rapid Diabetes Monitoring Index Test and presents its main features and potential for immediate application to the diabetes epidemic in the Middle East.

The right test cannot succeed, either in its medical application or in the marketplace, without the coordinated support of partners in the region for test production, marketing, sales, service, and education. The technical, commercial and financial expertise that have propelled the area to its current heights have also exacerbated the conditions leading to the current epidemic. The same expertise, combined with strong local leadership, will be required to form a stable foundation to answer the challenge posed by diabetes and attempts to contain it.

What Is Diabetes?

Keypoint

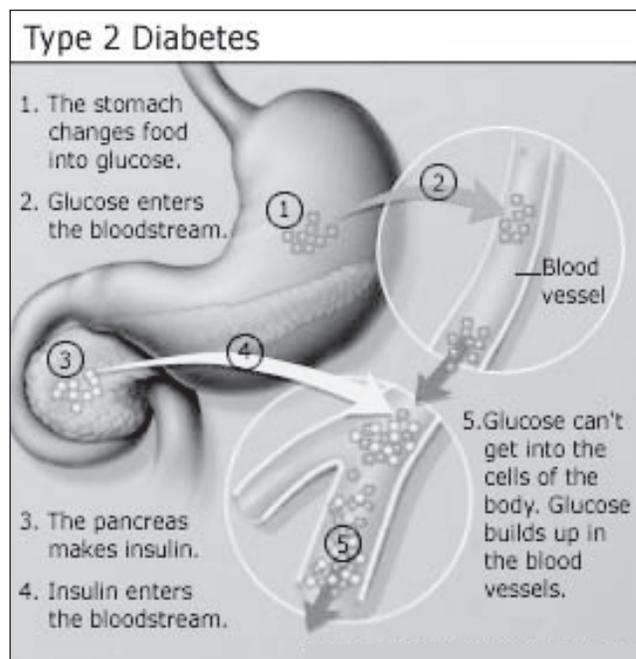
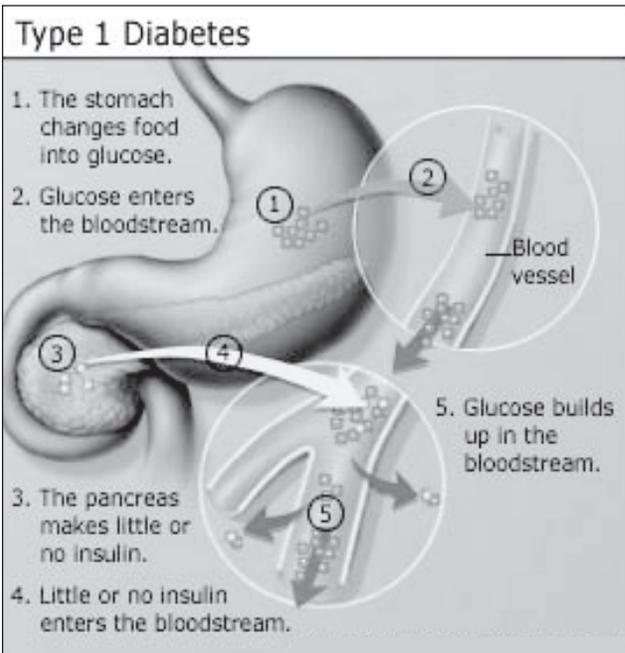
Diabetes is a chronic metabolic disorder in which the pancreas produces too little or no insulin, or the cells do not respond properly to the insulin that is produced. As a result, excess sugars build up in the bloodstream and cause damage to a variety of organs and bodily functions. The cause of diabetes 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. With diabetes, 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 and glucose intolerance). The cause of diabetes is unknown, although both genetics and environmental factors such as obesity and lack of exercise appear to play roles. Currently, there is no available rapid test for the diagnosis of diabetes.

There are 3 main types of diabetes.

- Type 1 diabetes is a genetic autoimmune deficiency in which the pancreas cells that produce insulin are destroyed, leaving the individual "insulin-dependent."
- Type 2 diabetes, often called "adult-onset" or "lifestyle" diabetes represents 90-95% of all cases of diabetes. The body loses the ability to produce and utilize insulin properly, most likely as a result of an individual's poor diet and exercise habits. Type 2 diabetics may eventually become "insulin-dependent" if proper treatment is not sought.
- Gestational diabetes is a form of glucose intolerance diagnosed in up to 10% of women during pregnancy, adding a 20-50% chance of developing type 2 diabetes within 5-10 years.

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.



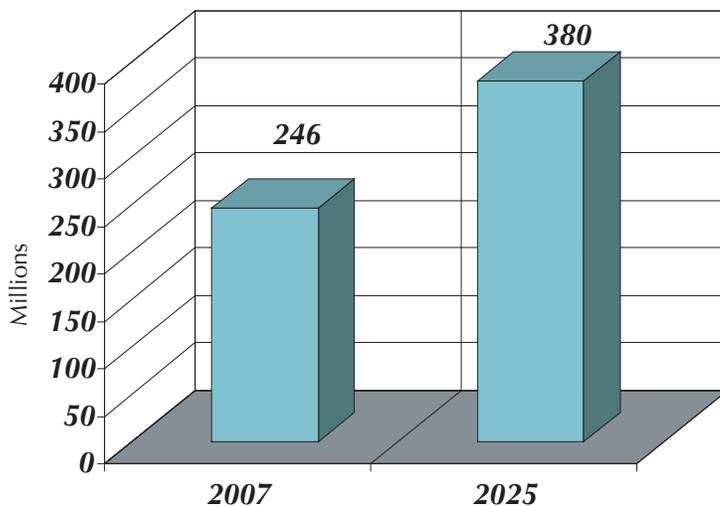
The Diabetes Epidemic Worldwide

Keypoint

There are estimated to be more than 246 million people with diabetes worldwide, expected to rise to 380 million by 2025. The average rate of diabetes is increasing much faster in developing countries, 170%, versus 42% for developed countries.



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.



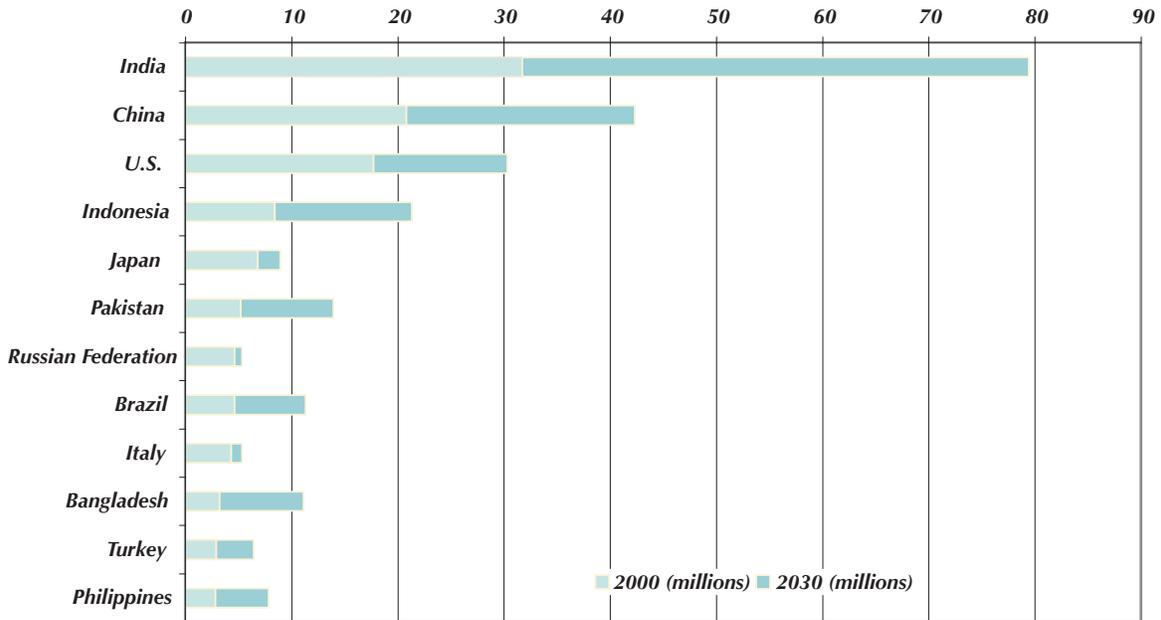
Projected Growth in Diabetes Cases Worldwide (IDF)

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%

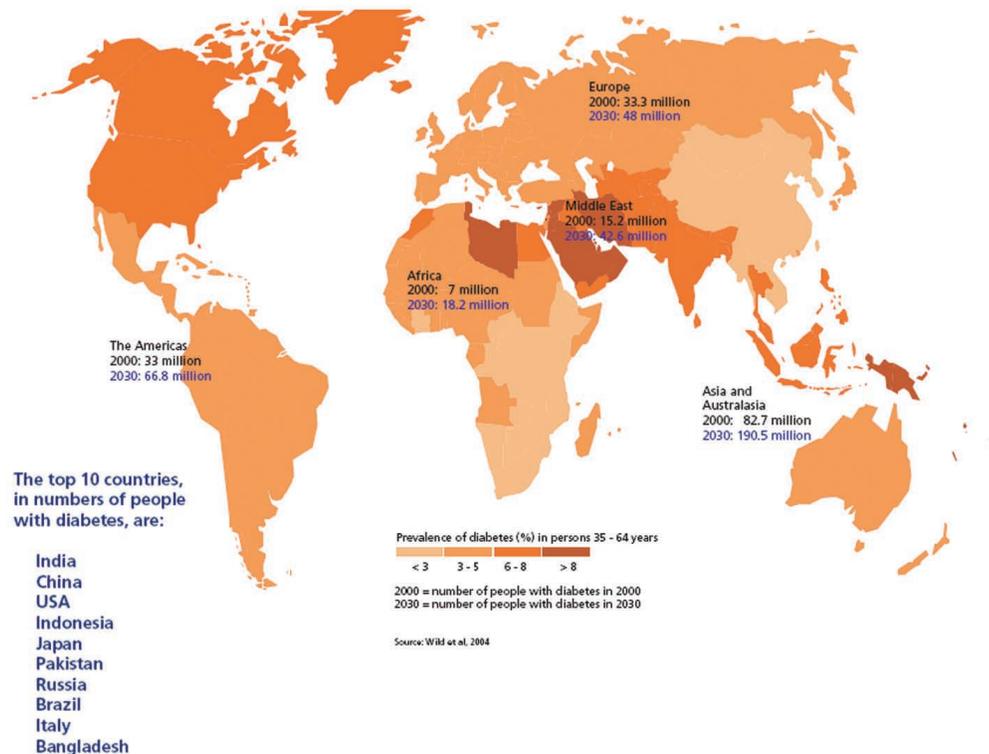
Diabetes Increase By Region (Wild 2004)

The Diabetes Epidemic Worldwide

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. From the current 7.9%, the prevalence of diabetes in developing countries is estimated to increase by 2025 to 98% (King 1998).



Prevalence of diabetes



The Diabetes Epidemic Worldwide

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%.

In developed countries, diabetes is the fourth main cause of death and the leading cause of blindness and visual impairment in adults. Diabetes is the most common cause of amputation that is not the result of an accident.

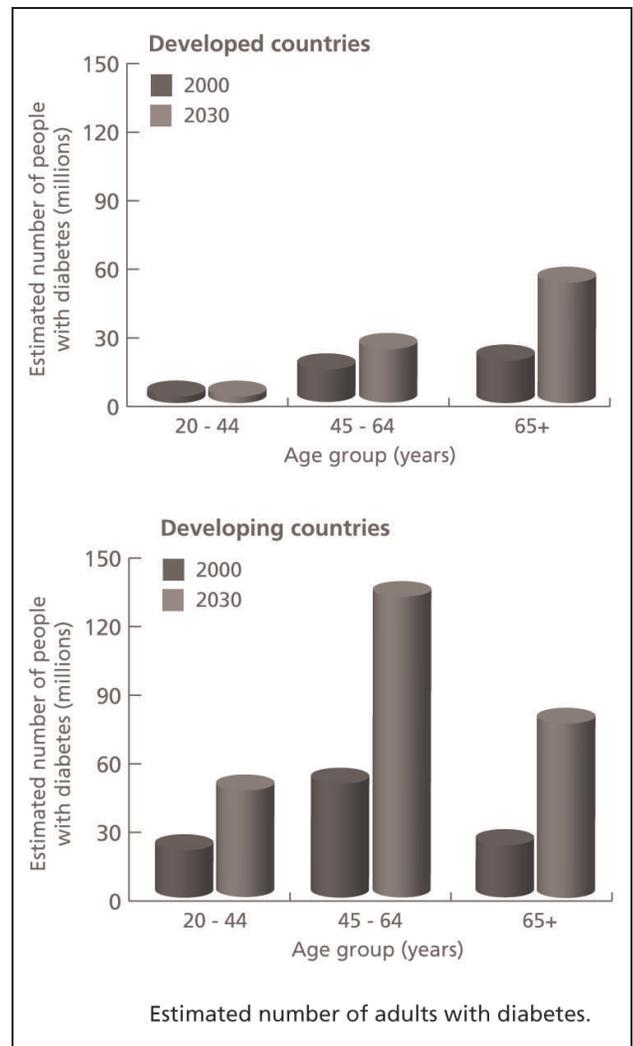
In developing countries, the diabetes epidemic is progressing faster than in other areas, with a projected increase in prevalence of 170%; for developed countries, there is a projected increase in prevalence of 42%.

Diabetes accounts for approximately 5%-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.

In developed countries, diabetes is increasing among the elderly. But in developing countries, diabetes is increasing much faster among middle-aged adults.

(IDF 2006)



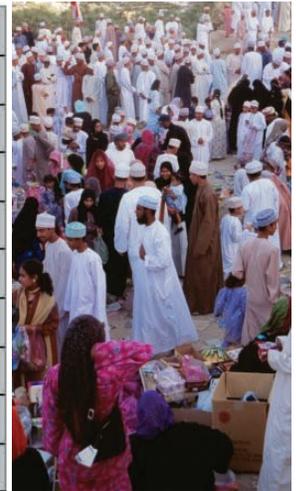
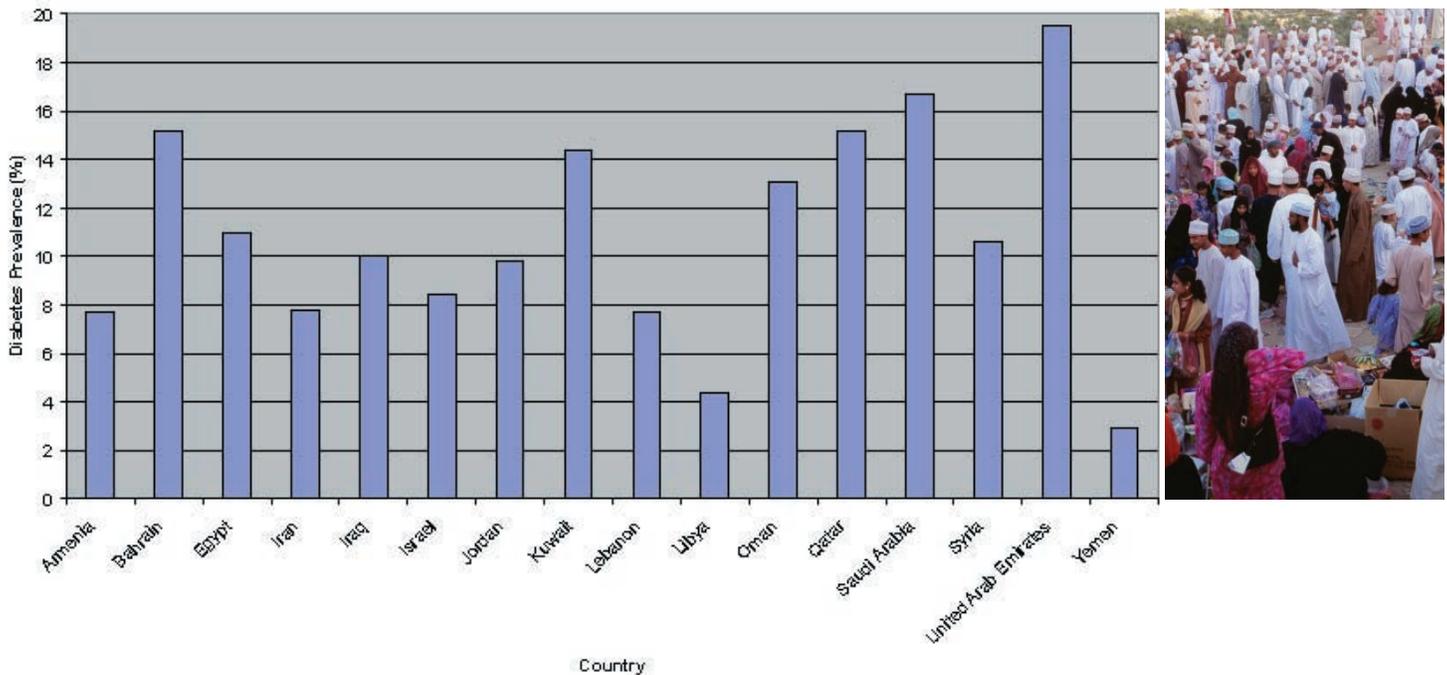
Source: WHO

The Diabetes Epidemic in the Middle East

Keypoint

The Eastern Mediterranean and Middle East Region has the highest comparative prevalence of diabetes in the entire world; a staggering 9.2%, affecting 22.5 million adults. It also has the highest mortality rates due to diabetes in both men and women.

Diabetes Prevalence in the Middle East



The Eastern Mediterranean and Middle East (EMME) Region, with a total population of 592 million includes Afghanistan, Algeria, Armenia, Bahrain, Egypt, Iran, Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco, Occupied Palestinian Territory, Oman, Pakistan, Qatar, Saudi Arabia, Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates, and Yemen. It has the highest comparative prevalence in the world, surpassing India (6.7% in 2007) and China (4.8% in 2007) which have the highest total number of diabetics.

The IDF conducted a study on six countries (Bahrain, Egypt, Kuwait, Oman, Saudi Arabia, UAE) and discovered that 7.7% of the adult population (24.5 million people) had diabetes in 2007. This is estimated to reach 9.0% of the adult population (44.5 million people) by the year 2025. The comparative prevalence of diabetes in the Middle East, which takes into account differences in age and sex per region in the world, is

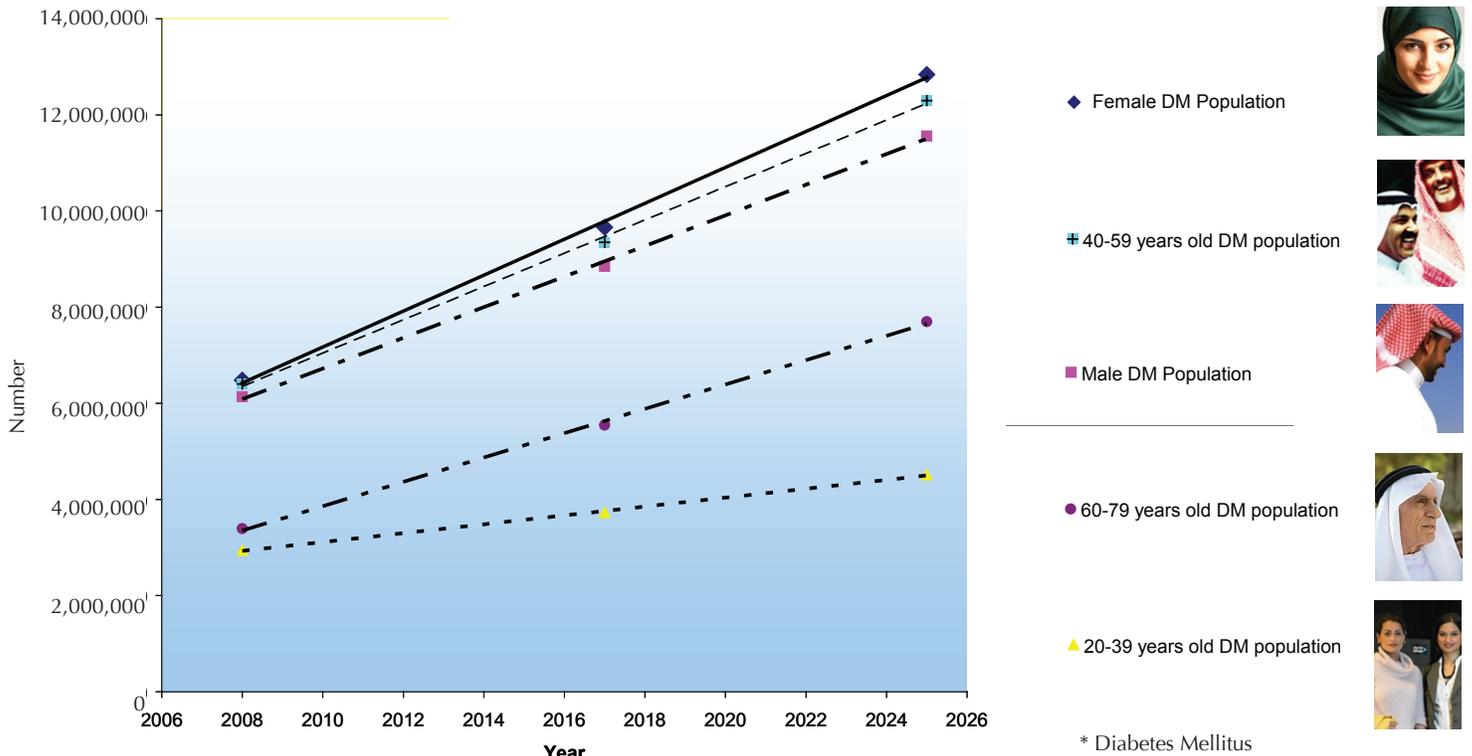
9.2% of the adult population in 2007 and is expected to increase to 10.4% in 2025 (IDF 2006).

While figures for gestational diabetes in the region reflect the increased overall rate of disease, research studies have established that women of Middle Eastern origin have an elevated risk for developing this condition (Berkowitz 1992). Dr. Bashir Salih, Chief of Service Obstetric Medicine at Corniche Hospital and Dr. Maha Taysir Barakat, Medical Research Director of the Imperial College London Diabetes Center (ICLDC) echoed this finding when they stated that mothers in the UAE are at high risk for gestational diabetes. This finding has additional significance because a link has been suggested between mothers developing gestational diabetes and the increased tendency for them and their offspring to develop type 2 diabetes at a later time (IDF 2006).

Epidemiology Projections

A comprehensive report forecasting the epidemiology of diabetes exclusively for the Middle East is not readily available. Epinex Diagnostics has therefore performed its own analysis using diabetes data from the International Diabetes Federation's (IDF) Diabetes Atlas (3rd Ed), general population data from the CIA World Factbook, and other pertinent information gathered from the most recent studies. The countries included in this analysis are: Armenia, Bahrain, Egypt, Iran, Iraq, Jordan, Kuwait, Lebanon, Libya, Occupied Palestinian Territory, Oman, Qatar, Saudi Arabia, Syrian Arab Republic, United Arab Emirates, and Yemen

Demographic Breakdown of Diabetic Cases in the Middle East



Type 2 Diabetes

As of 2008, the population of adults age 20-79 years old living in the Middle East is more than 155 million (IDF 2006). Using the IDF's published diabetes prevalence rates, we estimate that there are now 13 million adults with diabetes in the region. In the next five years, by 2013, the number of affected adults is expected to grow up to 16.5 million people. In ten years, the number will dramatically increase to 19.7 million affected persons (see graph above). This translates to a jump in diabetes prevalence from 8.2% in 2008 to 9.5% in just 10 years.

Middle-aged adults (age 40-59 years) are expected to experience the

highest increase in diabetes cases. In just the next five years, the number of affected people within that age group is expected to skyrocket from the current figure of almost 3 million to 8 million individuals, almost triple the current figure (IDF 2006).

Even more disturbing, young adults (age 20-39 years) are experiencing an increase in diabetes cases. Present projections state that approximately 2.9 million people within this age group in the Middle East have diabetes (IDF 2006). Within five years, this figure will increase by 400,000. In ten years, the total will have reached 3.8 million young adults in the region.

Gestational Diabetes

Keypoint

EMERGING THREAT

The high prevalence of gestational diabetes in the Middle East is an emerging threat to the future population

Women are at especially high risk for developing type 2 diabetes. Currently, there are 6.5 million women in the Middle East with diabetes (IDF 2006). The rate of increase among women is projected to outpace that of men with diabetes over the next 30 years (see graph in the previous page). In five years, the number of affected women is expected to increase by 20%, to 8.2 million.

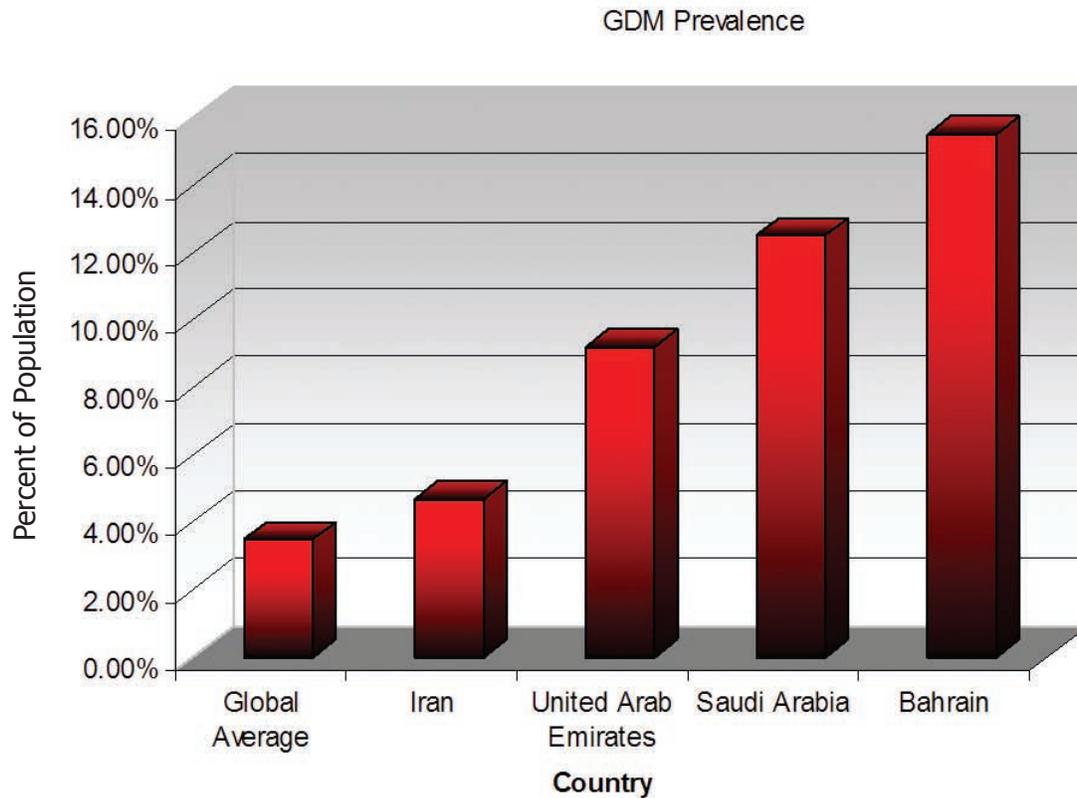
If nothing is done to stem the rise of diabetes cases in the Middle East, by 2018 the number of cases will soar past 10 million.

Gestational diabetes mellitus (GDM) is a major concern for pregnant women in the Middle East. Global figures from the IDF suggest that 2-5% of women worldwide develop diabetes during pregnancy. This figure is substantially higher throughout the Middle East. 10% of women who have had GDM develop type 2 diabetes within an average of 6 years (Hjelm, et al 2007). The table on page 13 shows the prevalence of GDM for several Middle Eastern countries.



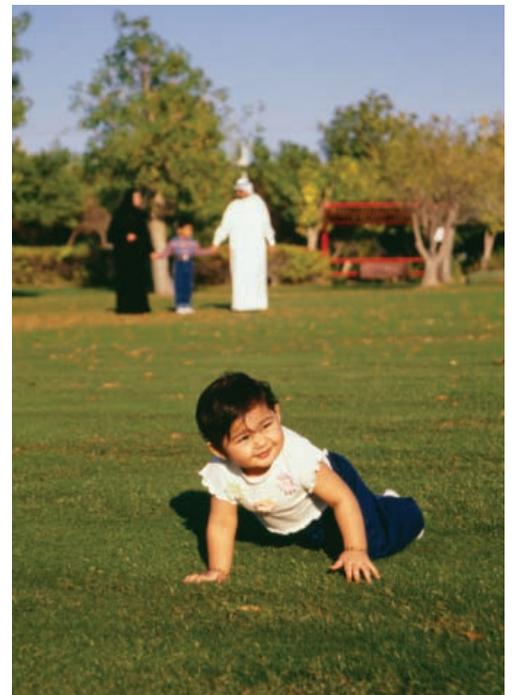
Gestational Diabetes

The table below shows the GDM prevalence data from several Middle Eastern countries.



Gestational Diabetes Mellitus Prevalence

Country	GDM Prevalence	Reference
Bahrain	15.5%	Mahroos, et al 2005
Saudi Arabia	12.5%	Ardawi, et al 2000
United Arab Emirates	9.2%	Ezimokhai, et al 2006
Iran	4.7%	Hosseini-Nezhad, et al 2007
Global Average	2-5%	Diabetes Atlas, 3rd Edition



Gestational Diabetes

Keypoint

EMERGING THREAT

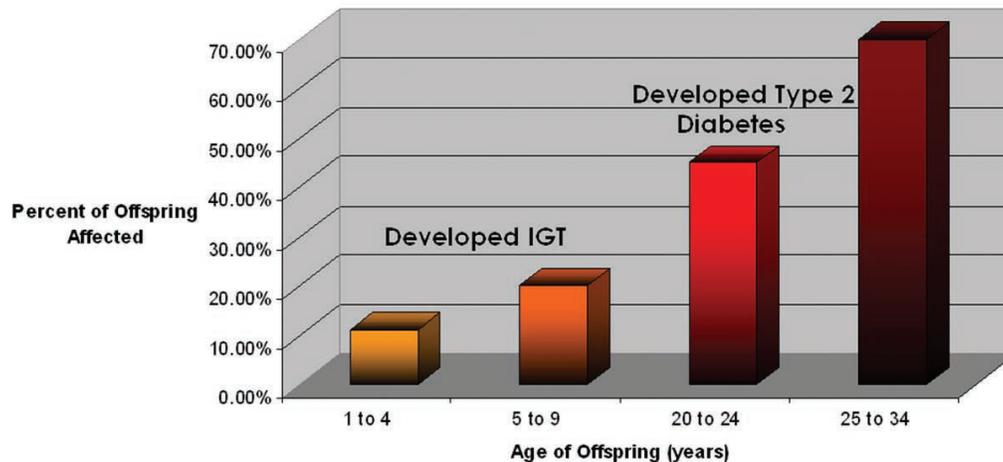
Gestational Diabetes and childhood obesity, both on the rise in the Middle East, are strong contributing factors to the early development of type 2 diabetes



Childhood Obesity and Type 2 Diabetes

Children, age 0-14 years, are becoming increasingly prone to type 2 diabetes. Studies show a dramatic increase in the number of overweight and obese children, linked to inactivity and poor food choices. While a study of childhood obesity in the United Arab Emirates in 2000 found that 9% of children were overweight and 8% were obese (Al-Haddad, et al 2000), by 2006 these numbers had significantly increased, to 20% overweight and 12% obese (Malik and Bakir, 2006). Another study in the UAE revealed that 12.5% of children diagnosed with diabetes mellitus (5 out of 40) had type 2 diabetes, rather than the type 1 more typically associated with childhood, and that 4 out of 5 of these children with type 2 diabetes were obese (Punnose et al, 2002). A study in Saudi Arabia found that 120 out of 100,000 children had type 2 diabetes (El-Hazmi and Warry 2000).

Effect of Gestational Diabetes on Offspring



A study on infants born to mothers with gestational diabetes found that at 1-4 years old, 11.1% had developed impaired glucose tolerance (IGT), a condition that precedes the onset of type 2 diabetes. At 5-9 years old, 20% had developed IGT (Plagemann, et al 1997). In another study, 45% of the offspring of mothers with gestational diabetes had themselves developed full-blown diabetes by age 20-24 years (Pettitt, et al 1988). By age 25-34 years, 70% of the offspring had type 2 diabetes (Babelea, et al 2000).



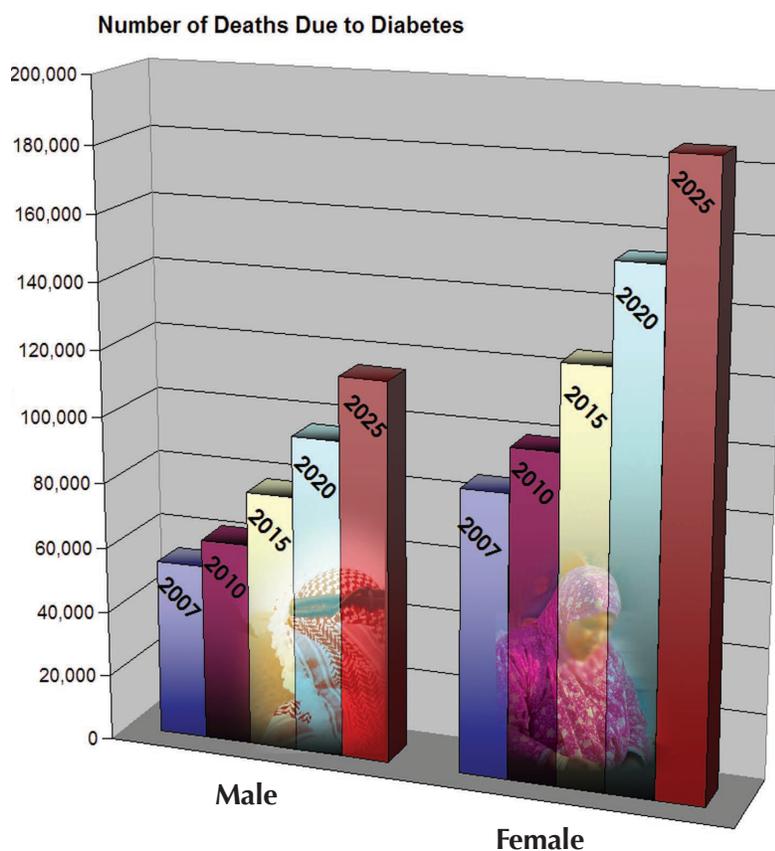
Keypoint

The diabetes-related death rate in the Middle East is one of the HIGHEST in the world and will continue to rise in the near future.

Projected Mortality Due To Diabetes

The strong correlation between the countries with the highest prevalence of diabetes and the highest rate of diabetes-related deaths is reflected in the table below, which shows the five countries with the highest percentage of deaths due to diabetes in men and women.

Country	Prevalence	Male Deaths	Female Deaths
United Arab Emirates	19.5%	17.3%	31.6%
Qatar	15.2%	14.7%	26.9%
Kuwait	14.4%	14.6%	25.8%
Bahrain	15.2%	13.3%	25.0%
Oman	13.1%	11.3%	21.7%



Most alarming is the female mortality rate due to diabetes, which is much higher than male mortality (see chart above). In 2007, diabetes took the lives of approximately 86,000 women and approximately 54,000 men in the Middle East. This represents 17.4% of all deaths for females and 8.4% of all deaths for males (IDF 2006). By 2015, a projected 125,000 women and 78,000 men will die yearly due to diabetes and diabetes-related complications (Mathers and Loncar, 2006; IDF 2006). By 2020, a total of about 252,000 people will die due to diabetes, an increase of 80% from the 2007 figures.

Cultural Issues and Risk Factors



According to the IDF, the increase in diabetes cases found in the Middle East is a result of socio-economic changes, westernization, and ageing of the population. Changes in nutrition, a decrease in physical activity, and the resulting tendency towards obesity are all factors contributing to the explosion of type 2 diabetes cases in the region (IDF 2006).

Specific regional studies support the role of changing lifestyle as a primary factor in the rise of diabetes prevalence. In Kuwait, rising income has led to a more sedentary lifestyle and unhealthy dietary changes. Prior to the discovery of oil, manual labor activities such as sailing, fishing, and pearl diving were common in the country (Serour 2007; Amuna and Zotor, 2008). A similar study in Oman confirmed that rapid socio-economic and social advances have led to cultural changes resulting in unhealthy eating habits, a decrease in physical activity, and manifestation of a wide range of non-communicable diseases, of which type 2 diabetes is the most prevalent. Education level has been cited as a factor in diabetes prevalence, with a negative correlation to literacy and level of education (Abdulhadi 2007).

Arab ethnicity has been designated as a risk factor for type 2 diabetes (WHO 2006). Studies done on diabetes in the U.S. on Arab-Americans show this group to have a diabetes prevalence approximately the same (41%) as the urban Arab population in the EMME region versus other ethnic groups. This rate is considerably higher than white, African-American, and Hispanic populations in the U.S. (Jaber 2003). Lifestyle changes leading to obesity combined with genetic predisposition for diabetes has been cited as among the causes of the increase in type 2 diabetes cases in the region (Elhadd 2007).

It is estimated that diabetes accounted for 11.5% of all deaths in 2007 in the EMME region, a figure well above the IDF's global estimate of 9.6% (IDF 2006). Mortality rates due to diabetes are elevated throughout the EMME region, but the data show that natives of the region are disproportionately affected. The disparity in diabetes prevalence between natives of the Gulf region and others has been noted by the UAE Ministry of Health, which reports that diabetes is responsible for 75% of deaths among UAE nationals but only 31% among non-national residents.

In 2006, the American Diabetes Association (ADA) released a new set of recommendations for the treatment and management of type 2 diabetes. These guidelines have been adopted as the standard for diabetes management throughout the Middle East and place emphasis on:

- Achieving and maintaining glycemia (blood sugar levels) within or as close to the non-diabetic range as is safely possible.
- Initiating lifestyle changes (exercise and diet) and treating with the drug metformin at the time of diagnosis. Metformin decreases the glucose output of the liver and lowers fasting blood glucose levels.
- Rapidly adding appropriate medications and transitioning to new treatment regimens when target glycemia is not achieved.
- Adding insulin therapy in patients who do not meet target levels at an early time.

(Nathan 2006)

Diabetes monitoring is an essential element of diabetes management and control. Uncontrolled excess glucose in the blood over a period of time leads to glycation, the process whereby the glucose adheres to and damages proteins in the body. Glycation has been established as an indicator of diabetes complications as well as a significant factor in the onset of those complications, which include blindness, kidney failure, neuropathy and heart disease (Cohen 2006, 1995; Okumura 2007; Shuvaev 2001). The goal of diabetes monitoring is to control glycation.



Diabetes monitoring allows 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 glycation control. Current methods for monitoring diabetes are the Self-Monitored Blood Glucose (SMBG) test and the glycated hemoglobin (HbA1c) test.

- SMBG tests for blood glucose levels using whole blood, obtained by daily multiple finger sticks, which is then 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. Current guidelines recommend that SMBG be done at least once a day but studies have found that more frequent testing may be optimal (Monnier and Colette 2005).
- The HbA1c test is a blood test that measures the average blood glucose level over the previous 3 to 6 months by measuring the level of glycated hemoglobin, the oxygen-transporting protein found in red blood cells. It is presently the "gold standard" test for protein glycation because it offers a standardized index of glycated hemoglobin to total hemoglobin. This test is usually performed in the doctor's office and processed in a clinical laboratory. The ADA recommends testing for HbA1c 2-4 times per year.

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 Methods

Keypoint

SMBG testing can only provide a snapshot of blood glucose levels and does not monitor protein glycation. The high cost and inconvenience of daily testing results in low test usage and poor patient compliance. 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. HbA1c testing may not be accurate in patients undergoing hemodialysis or suffering from blood disorders.



The efficacy of multiple daily blood glucose tests to monitor diabetes (SMBG) 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% (Monnier and Colette 2005). 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).

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. The average life span of red blood cells in the human body is 90-120 days. Because any change in the amount of glycation of the hemoglobin con-

tained in those cells cannot be detected until the body replaces those red blood cells, HbA1c cannot be tested more often than every three months. Diabetes complications can advance unchecked during this interval. In addition, the HbA1c test does not directly measure serum protein glycation, an immediate causal factor for serious diabetes complications such as heart disease, blindness and kidney failure. The HbA1c test has been found to be unreliable for patients with conditions that affect the metabolism of red blood cells. This includes patients undergoing hemodialysis and patients taking drugs such as erythropoietin (Peacock 2008). Of particular interest for the Middle East region, the HbA1c test can be unreliable for patients suffering from hemoglobinopathies (blood disorders due to abnormal hemoglobin), such as sickle cell anemia and thalassaemia. These blood disorders are found to be common on the Arabian Peninsula, especially in areas where the prevalence of diabetes is highest (Elhadd 2007).



Diabetes Management in the Middle East

Keypoint

Ministries of Health in the Middle East have adopted the management and treatment guidelines currently recommended by the American Diabetes Association (ADA). An essential part of these guidelines is the monitoring of blood glucose levels and other indicators of diabetes control such as protein glycation. These guidelines have proven to be ineffective in multiple regions of the world.

Despite current efforts, little progress has been reported in the fight against diabetes. Poor compliance with monitoring and treatment recommendations, poor patient participation, limited doctor-patient feedback, and lack of access to medical supplies and devices impede the improvement of diabetes management in the region.

The healthcare industry in the Middle East is composed of both public and private sectors. In countries with large expatriate worker populations, nationals generally receive free medical services while expatriates are required to pay for their treatment and drugs. The ministries of health of each country (MOH or MOPH) are the major government entities that provide primary health care to their nationals at little or no cost, offering an extensive network of public hospitals, health centers, physicians, and nurses. Private sector facilities funded by private insurance companies provide care for the expatriate communities. In the United Arab Emirates, the number of hospitals in the public and private sectors is now approximately equal, with a growing emphasis on private medical care. Several countries, such as the UAE, require employers to contribute to employee health costs (Holtz 2008). For low-income countries such as Yemen, a significant source of financing also comes from foreign assistance from non-governmental organizations (The World Bank, 1994).

While most countries in the EMME region have adopted national guidelines and plans for the prevention and management of diabetes (89% and 50% respectively, see table below), the majority of countries in the region have few centers for diabetes treatment, which are often not within reach of many people diagnosed with diabetes. The primary care infrastructure is not yet capable of implementation of routine screening procedures, monitoring diabetes control, and detecting common diabetes complications. The scarcity of trained and experienced diabetologists, nutritionists, diabetes nurse educators, and chiropodists in the overall region exacerbates the problem (WHO 2006).

WHO region	Diabetes		Hypertension		Bronchial asthma		Common cancers	
	P	M	P	M	P	M	P	M
Africa	44	53	35	53	28	41	29	43
Americas	70	50	65	45	52	40	83	48
Eastern Mediterranean	89	50	70	64	33	22	60	33
Europe	82	64	82	53	69	45	84	59
South East Asia	67	67	50	67	17	33	43	43
Western Pacific	58	76	53	76	35	63	65	47
Total	69	61	63	59	47	44	67	48

P: prevention guidelines

M: management guidelines

In Libya, for example, a study found that only 2.4% of type 1 diabetics use a blood glucose meter and only 8% of the diabetics surveyed use urine sticks to check their renal function. Of the 805 patients in the study, none have ever had an HbA1c test (Roaid and Kablan 2007). A study in Iran found that the greatest barriers to overall diabetes management included proper dietary and exercise behavior, and that non-compliance with recommended blood glucose testing guidelines was very high (Aghamolaei 2004). Effective management of diabetes has been hindered by lack of knowledge, local beliefs, and misconceptions due to social norms. In addition, many patients have been found to skip their medications due to financial reasons (Khatib 2007).

Dr. Huda Ezzeddin, Endocrinology and Diabetes Specialist from the Sheikh Khalifa City – Cleveland Clinic, and the principal investigator of the International Diabetes Management Practice Study stated that preliminary findings indicate that almost 75% of patients with type 2 diabetes in the Middle East and North Africa are not meeting standard international guidelines for HbA1c levels. (Kahn 2008).



Recent Control Initiatives

A 1995 study of diabetic patients in the Al Ain Medical District of the UAE showed that 20% of those surveyed did not know what diabetes was. 15% did not know what any of the symptoms of diabetes were, and 20% did not know about the complications of diabetes (Reed 2001). While awareness of and education about diabetes has greatly improved in the following years, there has been a substantial recent increase in diabetes education and awareness campaigns, as well as supplementary diabetes care structures, as the scope and impact of the epidemic has become clear. Programs are being initiated both by private investment and multinational pharmaceutical companies and by regional government health agencies. The following is a chronological sample of recently initiated programs now being conducted in the Middle East.



In July 2006, Mubadala Development, an Abu Dhabi investment company that owns stock in the investment firm Carlyle Group, and other U.S. companies, launched the Imperial College London Diabetes Center (ICLDC) in Abu Dhabi. Specifically targeted to diabetes care, the facility brings all needed specialties under one roof, to tackle the disease and its associated complications, from kidney disease, to eye disease, to heart problems. According to Dr. Maha Taysir Barakat, Medical and Research Director at the ICLDC, the center will focus on treatment, research, training, and public health to provide the most comprehensive treatment for diabetes available.

In 2006, Roche Diagnostics launched "Accu-Chek Diabetes Education Program", a program designed to improve the management of diabetes, to regions in the Middle East. Based on the world-renowned Berger programs, the Accu-Chek Diabetes Education Program is composed of four therapy modules: therapy without insulin, conventional insulin therapy, pre-prandial insulin therapy and intensified insulin therapy. Each module includes specific patient and educator components such as lifestyle guides, questionnaires, and pictures of various food plates, all of which are tailored to the Middle East. It also includes training of nurses, installation of a balanced train-the-trainer course, assistance with program implementation and formation of support groups.

In February 2007, Community Health Solutions, LLC launched www.diabetic-care.com, a website designed as a one-stop shop for diabetic supplies in the Middle East. From this website, one can purchase

testing supplies, diabetic accessories, food, and supplements, as well as educational literature from the Joslin Diabetes Center. Community Health Solutions is a subsidiary of Pharmatrade LLC, a distributor for leading multinationals in the healthcare field in the United Arab Emirates since 1977.

In April 2007, the ICLDC launched "Diabetes.Knowledge.Action", a campaign designed to educate people about the risks and complications associated with diabetes, how to maintain a healthy lifestyle and to provide access to the latest evidence-based treatments. Included within this campaign are five complementary initiatives: I Wonder (basic diabetes information), I Eat Right (diet tips), I Cook Healthily (recipe resource), I Walk (sponsored walkathon for diabetes awareness), and I Play Sports (emphasizes importance of physical activity). The campaign includes an Arabic-language website dedicated to diabetes education: www.diabetesuae.ae.

In September 2007, Qatar's National Health Authority announced plans to establish a specialized center for diabetes and obesity. This facility will provide treatment and patient guidance towards a healthy lifestyle, as well as conduct research on health conditions related to diabetes. It is expected to open in 2008.

In November 2007, Medcare Hospital in Dubai organized the "Diabetes Awareness Workshop." The campaign was aimed at mothers and young women to increase their awareness about the causes and effects of diabetes and its proliferation across the UAE, as well as methods to prevent its spread via healthy eating choices and daily exercise. This campaign was promoted in partnership with Shape Express, a fitness center designed exclusively for women. All the workshop participants were given a coupon for well-woman check-ups at discounted rates.

"Join the Movement," a campaign set up by the UAE Ministry of Health and the Emirates Diabetes Society was launched in February 2008, with aims to raise awareness of the causes of obesity. This campaign is composed of a series of outdoor exercise events, free body mass index (BMI) testing, blood sugar testing, and blood pressure testing, and lectures on obesity, diet and exercise.

In March 2008, specialists in the field of endocrinology and diabetes from the Middle East attended an educational program organized by the American Diabetes Association (ADA) entitled "Standing Together Against Diabetes". Designed to familiarize physicians with the ADA guidelines for treatment of diabetes, this meeting certified the attendees to present the ADA program in their home countries.

These recent public and private sector efforts reflect the realization among public and private sector health providers in the region of the gravity of the present situation. Whether these efforts will lead to a slowing or reversal of the rate of diabetes increase in the region remains to be seen. Similar efforts, following similar guidelines and methods, have been underway in other areas of the world for some time, and have not as of yet demonstrated substantial success.

The UAE and Gulf States

In contrast to the majority of countries included in the EMME region, the Gulf States, including the United Arab Emirates, Kuwait, Bahrain and Oman, have a well-developed healthcare infrastructure. In 1971 there were only 7 hospitals and 12 health centers in the UAE, for example, but by 2005 there were a total of 330 hospitals (Public & Private, including Primary Health Centers and Dental Clinics, Maternal & Child Health centers, School Health Care Centers), 973 pharmacies and 138 medical stores, mostly concentrated in the three key emirates of Abu Dhabi, Dubai and Sharjah. In the last few years there has been a steady annual growth of 10% in the healthcare industry in the region, and the momentum is expected to prevail due to the high rate of population growth. The government of the UAE has also been promoting investments in the private healthcare sector. While nationals receive free medical services, expatriates are required to pay for their treatment and drugs. UAE nationals make up only 10% of the population, whereas the Asian community, mainly people from South Asia (i.e. India & Pakistan) and the Far East (China, the Philippines) form 60% of the population. Western expatriates account for 15%, whereas non-local Arabs account for only 15% of the total population.



Delivery of medical care in the Emirates is shifting from public state-run facilities to privately operated clinics and hospitals. A recent survey by local media has revealed that only 15% of residents would prefer to be treated in a state-run hospital while more than 50% preferred the private sector. The public sector has traditionally been associated with long waiting lists and a shortage of medical specialists. For many years the government's programs were concentrated on improving the condition of medical services for the women, especially for those of childbearing age. As a result, Obstetrics and Gynecology are the only areas of the public health sector comparable to the private sector. In recent years many new private hospitals have entered the market and a steady increase in the number of hospitals is expected. This increase has brought about competition, which is expected to result in better

availability of high quality and affordable treatment in the country. The increase in the private sector has been mainly due to the government's decision to no longer offer free medical assistance to expatriates. In 2004, the private sector accounted for 56% of overall health expenditure, with a goal providing 70% of health services in the next ten years (Swiss Business Hub 2006).

Healthcare systems operating in the United Arab Emirates have focused on managing diabetes in accordance with guidelines adopted from those put forward by the American Diabetes Association for use in the United States. To date, these efforts have had mixed results. Dr. Ezzeddin's team found that only 30% of the patients they studied had taken an HbA1c test in the past six months, versus the recommended testing of every three months. SMBG testing was performed an average of three to five times per week, far below the ADA guidelines of at least one test per day. It was found that the inconvenience of SMBG testing generated treatment resistance among the patients (Kahn 2008).

Joanne Bladd, editor of Medical Times Middle East, stated that the educational campaigns being held all over the EMME region are having little to no impact on type 2 diabetic patients. The 150 endocrinologists in the UAE are reportedly overburdened with patients that would have been better handled in primary care. Clinical guidelines in the country forbid primary care physicians from managing type 2 diabetics (Bladd 2008). While regional studies have established that encouraging a patient's active participation is a key factor in improving diabetes control (Abdulhadi 2007), self-management of diabetes has not been sufficiently integrated into diabetes management programs in the EMME region. A study of attitudes among women of Middle Eastern origin found that many women did not believe it was necessary to take an active role in controlling their diabetes, making education and disease management an even higher priority for this group (Hjelm 2005).

A Control Initiative That Works

Keypoint

Patient empowerment is the key to success for diabetes control

A regimen of monthly consultations with a pharmacist or other diabetes care counselor has proven to be an effective method for diabetes control, resulting in improved health for diabetes patients, lowered healthcare costs and increased productivity by reducing absenteeism. This monthly paradigm can become the basis for revolutionizing diabetes management in the Middle East and worldwide.

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.

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 encourage self-management by providing 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).

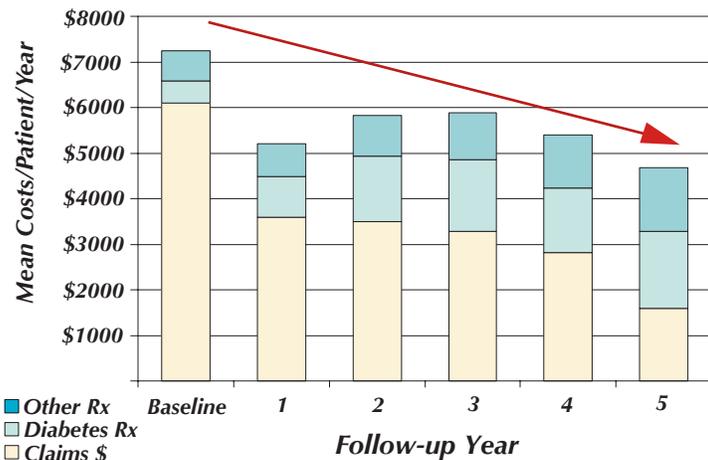
This new paradigm for diabetes monitoring based on community care, patient empowerment, and self-management is gaining widespread interest and acceptance, and is being reproduced in similar projects throughout the U.S.

The potential for self-management to be an effective tool for diabetes treatment in the Middle East is supported by a recent study in Al Ain, UAE, which demonstrated that diabetes care can be optimized via drug treatment, intensive education, and self-monitoring. Patients were encouraged to become actively involved in self-management and empowered to take control of their condition (Elnour 2008). In Oman, researchers have found that enhancing a patient’s active participation is a key factor in improving diabetes control (Abdulahdi 2007). Doctor-patient feedback on improvements in average glucose levels and protein glycation could provide the impetus needed by diabetes patients to continuing with their treatment regimen.



City of Asheville, North Carolina (Downtown)

Direct Medical Costs Over Time

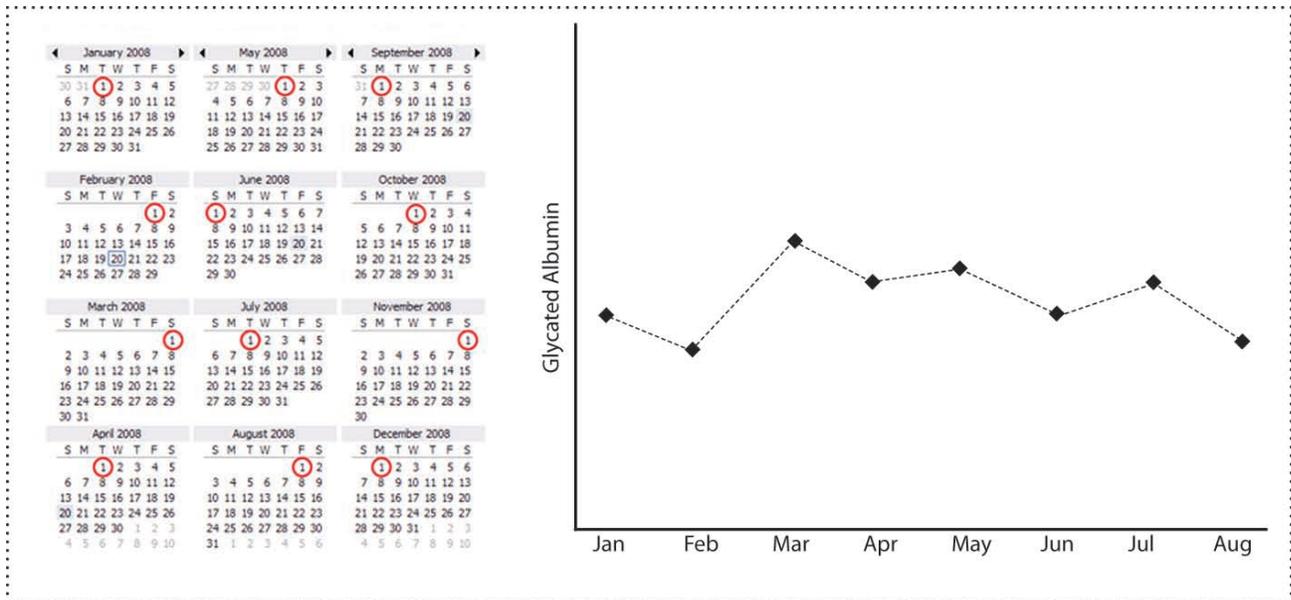


Results from the “Asheville Project” have shown that a regimen of monthly consultations with a pharmacist or other diabetes care counselor has proven to be an effective method for diabetes control. Use of the G1A™ test could encourage doctor-patient feedback, patient self-management, and timely therapeutic intervention to better control and prevent diabetes complications. Application of the Asheville model along with use of the Epinex G1A™ test could alleviate the load on specialty diabetes clinics in the Middle East, thus providing better and more accessible treatment to all diabetics in the region.

A Monthly Diabetes Care Paradigm

Keypoint

A monthly test is a perfect complement to the monthly diabetes care paradigm. Epinex Diagnostics has identified glycated albumin as the ideal marker for a monthly test to monitor diabetes. Glycated albumin monitoring enables earlier therapeutic intervention as compared with HbA1c testing. It has been recommended as a test for gestational diabetes and for diabetes patients undergoing hemodialysis. It is also a possible marker for other diabetes-related complications such as coronary artery disease. GA is a specific marker that can be measured with accuracy and stability. It is unaffected by the physiological conditions which encumber HbA1c testing.



The Problem: Current Diabetes Management Protocols are Ineffective

The current paradigm for monitoring diabetes, consisting of multiple daily blood glucose tests and an HbA1c test every 3-6 months, is too expensive and resource-intensive for rural and less affluent areas in the Middle East, as well as other parts of the world. It has also proven to be substantially ineffective for urban educated populations because of the expense and inconvenience of daily testing, and the information gap inherent in HbA1c testing.

Diabetes-related costs now consume an estimated 40% of the national healthcare budget in the UAE. Even as diabetes education and treatment options have begun to expand for the Middle East region, the scope of the problem demands further innovation in the methods available for diabetes monitoring, the critical link between patient awareness and medical response. In the less affluent areas of the region, health agencies need a method that is simple to use and understand, adaptable to a regional clinic model of care delivery, and that is cost effective in terms of time, expense and resources. In the highly developed urban centers, diabetes care centers need a method that encourages patient participation and compliance.

The Solution: A Monthly Paradigm for Diabetes Management using Glycated Albumin

A monthly test is a perfect complement to the monthly diabetes care paradigm. Epinex Diagnostics has identified glycated albumin as the ideal marker for a monthly test to monitor diabetes. Glycated albumin monitoring enables earlier therapeutic intervention as compared with HbA1c testing. It has been recommended as a test for gestational diabetes and for diabetes patients undergoing hemodialysis. It is also a possible marker for other diabetes-related complications such as coronary artery disease. GA is a specific marker that can be measured with accuracy and stability. It is unaffected by the physiological conditions which encumber HbA1c testing.

A glycated albumin index complements current methods for monitoring diabetes in two ways: the short turnover period for albumin allows it to be used as an intermediate glycation marker for diabetes complications by showing damage to proteins over the previous 2-3 weeks. In addition, glycated albumin plays a role in tissue damage. Recent research has pinpointed glycated albumin as one of the principal causes of diabetes complications. Byproducts of albumin glycation have been specifically implicated as causal factors in coronary artery disease and kidney failure, two of the most extensive and most serious complications of diabetes.

Benefits of Glycated Albumin Testing

Keypoint

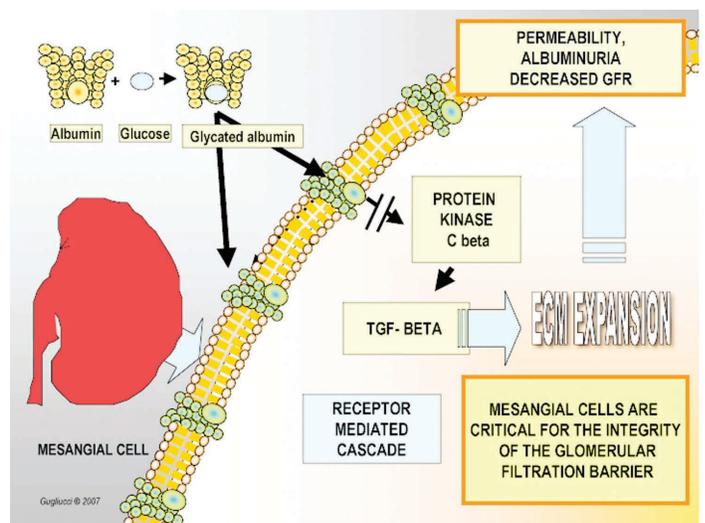
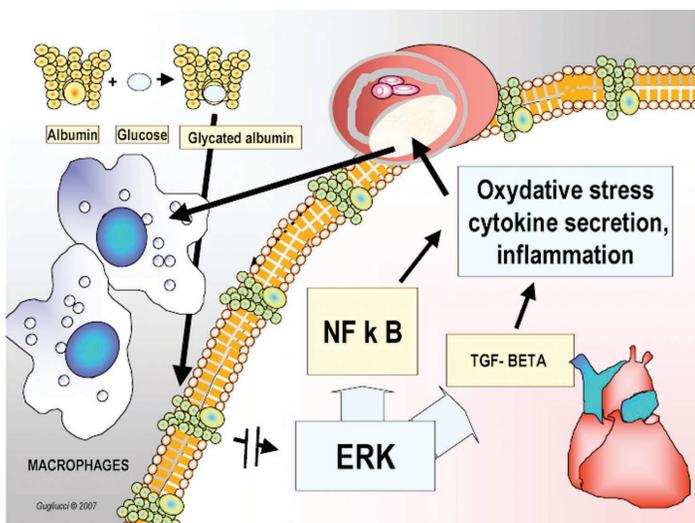
There is a demonstrated need for an intermediate glycation index to monitor diabetes. A test based on glycated albumin can provide a stable monthly index of glycemic control.

Recent studies have concluded that glycated albumin positively correlates with HbA1c in diabetic patients that have both good and poor control of their sugar levels. However, glycated albumin has proven to be a better indicator than HbA1c of short-term glycemic changes during treatments such as insulin administration (Paroni 2007). Because albumin is replaced in the body every 20-25 days, GA levels are a reflection of serum protein glycation over that period of time. This allows doctors to evaluate the effectiveness of therapies more promptly as compared to HbA1c. (Takahashi 2007).

Early intervention and better glycemic control are also essential in gestational diabetes, which has been indicated as a problem area in the Middle East. In a survey of endocrinologists conducted by Epinex, 95% of physicians indicated that intermediate-term glycemic testing is needed for control of gestational diabetes and 85% of this group believed that glycated albumin testing would be an excellent diagnostic tool. A symposium held in 1999 on point-of-care testing recommended the immediate adoption of glycated albumin testing for gestational diabetes. This recommendation has not yet been acted upon due to the lack of a convenient and inexpensive test for glycated albumin (Hicks 2001).

The results of a recently published clinical study of diabetic patients who are on hemodialysis have brought glycated albumin testing on to the front pages of the medical and business news worldwide (Peacock 2008). According to Dr. Barry I. Freedman, from Wake Forest University School of Medicine in Winston-Salem, North Carolina, the lead physician in the study, the outcome "supports the glycated albumin test as a more accurate measure of long-term blood sugar control among diabetic patients who are on hemodialysis." Diabetic patients on hemodialysis who believe their blood sugar levels are in the ideal range may actually have unacceptably high blood sugar levels, Dr. Freedman noted. "This was a surprise to the nephrology community. The test we've all come to accept as the gold standard has proven to be inaccurate in this patient population."

Glycated albumin could also provide a useful marker for early detection of the onset of coronary artery disease, one of the most pervasive complications among people with type 2 diabetes (Pu 2007). According to the International Diabetes Federation (IDF), the prevalence of coronary heart disease in diabetic patients in the Middle East ranged from 15.0% to 19.8%, a figure that is likely to increase significantly as the prevalence of diabetes in the Middle East increases, with predictions of up to a 164% increase by 2030 (Wild 2004).



The Mechanisms of Tissue Damage by Glycated Albumin

G1A™ - The Epinex Glycated Albumin Rapid Test System

Keypoint

The Epinex G1A™ Rapid Diabetes Monitoring Index Test is a monthly test that uses glycated albumin to measure protein glycation. It has the potential to close the information gap that exists now between daily blood glucose testing and the HbA1c test. It offers the means for a more effective program of diabetes monitoring and control.

The Epinex G1A™ Rapid Diabetes Monitoring Index Test is a rapid test that simultaneously measures glycated albumin and total albumin. It has the potential to close the information gap that exists now between the data provided by daily blood glucose testing and the information on the long-term health of the diabetic patient supplied by the HbA1c test. Diabetics, especially type 2, and their physicians need to have a convenient and cost-effective way to monitor whether their treatment is working to control glycation, and therefore manage or limit the onset of long-term complications. Until now, there has been no available alternative. A stable, easy-to-understand glycation index that provides monthly feedback will fulfill this need.

Significant Features of the Epinex G1A™ Rapid Diabetes Monitoring Index Test

• Monthly test	• Disposable Test Strip
• Physician office and home use	• Handheld Reader stores and analyzes results
• Accurate, convenient, inexpensive assessment of glycation	• Trend analysis
• More frequent monitoring = better control, lifestyle modification and better long-term patient outcome	

The following table compares glycated albumin to currently available diabetes monitoring techniques:

Type of Measurement	Period of Measurement	Testing Frequency	Function
Glucose	At a point in time	Once to several times daily	Tests fluctuations in blood glucose levels
HbA1c	4-6 month average	Twice a year	A measure of long-term glycation
Glycated albumin (Epinex G1A™ Test)	1 month average	Once monthly	A specific index for monitoring monthly glycation

G1A™ - The Epinex Glycated Albumin Rapid Test System

Commercial handheld reader:

- Expresses G1A™ Index as % Glycated Albumin
- Stores Readings
- Trend Analysis

Dual-Channel Test Strip:

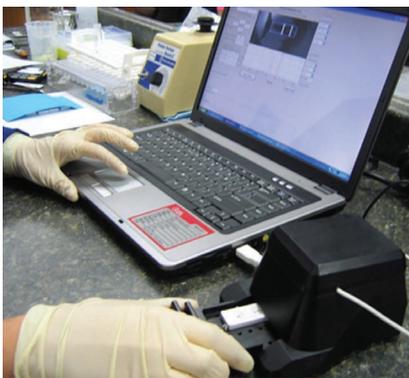
- Simultaneous Measurement of Glycated Albumin and Total Albumin .

The Company has a fully prepared protocol in place for product design, manufacture and testing. Subject to receiving the necessary funding, Epinex anticipates having the G1A™ test ready for marketing in the Middle East region by the second quarter of 2009.

Prototype

Epinex has successfully developed and tested a prototype for the G1A™ test strip, a handheld reader, and a desktop reader, and has completed plans for the miniaturization of the handheld device. Anticipated future funding will allow the Company to complete product development, commercialization and initial production and marketing.

Epinex G1A™ Desktop reader



Epinex G1A™ Prototype



Commercial handheld reader
(preliminary design rendering)



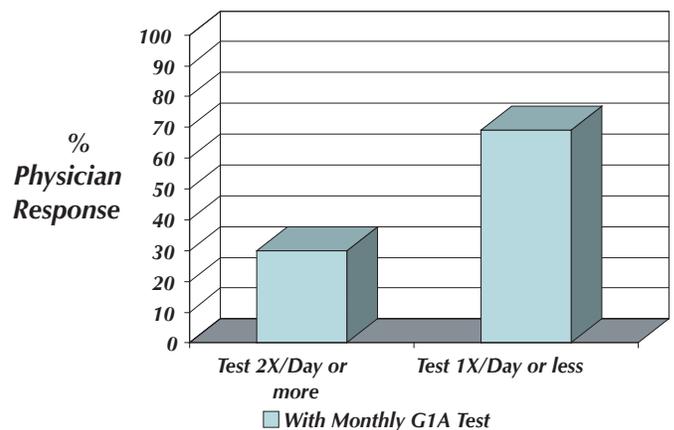
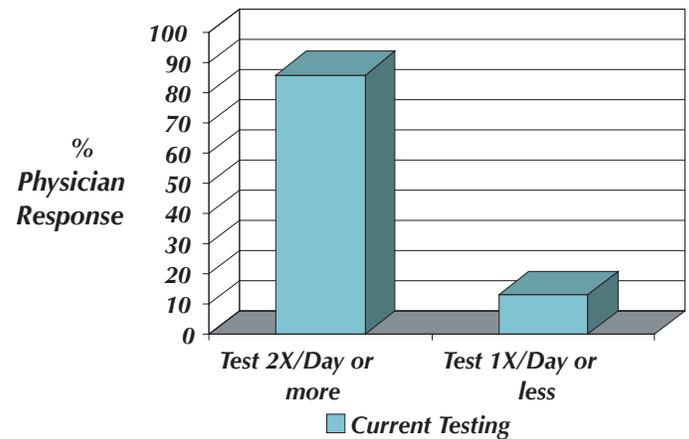
Physician Response to the Glycated Albumin Test

EpineX Diagnostics surveyed more than 3500 clinical and research endocrinologists and diabetes specialists worldwide about their current diagnostic practices for type 2 diabetes patients and their opinion of the utility of a monthly test for glycation based on glycated albumin.* The Company received a highly positive response to the product concept and technology from survey respondents.

Physician support for the G1A™ test	% positive physician response
Would recommend G1A™ test for gestational diabetes	89%
Would recommend G1A™ test for diabetic patients	67%
Interest in learning more about test	90%
Physician support for G1A™ concept to screen for diabetes	
Pre-diabetic indications	66%
Metabolic syndrome	66%
General screening test for diabetes	66%
*In September 2005, a six-page questionnaire was sent to more than 3500 endocrinologists and diabetes specialists. Margin of error: ±6.5% at a 95% confidence level.	

Impact on Daily Blood Glucose Testing

Diabetes specialists surveyed by EpineX indicated that they would recommend a reduction in daily blood glucose testing for stable type 2 patients in conjunction with a monthly glycated albumin test from a weighted average of 2.12 tests per day to 1 test per day.



Intellectual Property

Epinex has filed U.S and foreign patent applications to protect its proprietary position for a rapid test for glycated albumin. Epinex has engaged patent attorneys Kirkpatrick & Lockhart Preston Gates Ellis LLP to provide legal services for the Company's patent applications.

Country	Application information
United States	Application #: US20030505392P, Filed 23 September 2003 Acceptance of application 25 July 2006 Date of publication 05 October 2006, Serial # US10/538392 Official notification from the United States Patent and Trademark Office that the Company may use the terminology "Patent Pending."
WIPO (World Intellectual Property Organization)	# WO2005/031356 A1 International publication date: 7 April 05 Official opinion that no prior art exists for the patent 27 April 2006.
Canada	Patent Office of Canada # PCT/US2004/031202, filed 22 September 2004, file # 51432-15 Request for examination filed 1 August 2006
European Community	European National Phase Patent Application, # 04784881.7, filed 15 June 2005 Published 7 April 2005 Published by European Patent Office on 7 June 2006 (publication number EP-A-1,664,783).
Japan	Application pending, patent translated, request for examination filed 18 August 2006.
Hong Kong	Application filed 7 December 2006, based on European patent application. Title and abstract translated.

- **Monitoring for Type 2 Diabetes**

Articles demonstrating the utility of using glycosylated albumin as a test for diabetes monitoring and control have been published for 25 years. Numerous studies during that period have shown that GA levels respond faster and correlate more closely both to positive and negative changes in mean blood glucose levels than HbA1c.

- **Monthly Diabetes Care: A New Paradigm**

A regimen of monthly consultations with a pharmacist or other diabetes care counselor has proven to be an effective method for diabetes control. A convenient and inexpensive monthly test for glycation has the potential to be an ideal complement to this community-based system for diabetes control.

- **Gestational Diabetes**

Medical authorities have declared that ALL pregnant women should be tested. A symposium held in 1999 on point-of-care testing recommended the immediate adoption of glycosylated albumin testing for gestational diabetes.

- **Coronary Artery Disease**

In a clinical study published in 2007, serum glycosylated albumin levels correlated with the number of diseased arteries. The study concluded that there is "a strong and specific connection or association between elevated glycosylated albumin levels and coronary disease, with no correlation to HbA1c levels." The article suggested that testing for glycosylated albumin could provide a useful marker for predicting the onset of coronary artery disease in people with type 2 diabetes.

- **Hemodialysis Patients with Diabetes**

A study conducted in Japan published in 2007 found that testing for glycosylated albumin was a better indicator of glycemia than glycosylated hemoglobin (the HbA1c test) for diabetes patients on hemodialysis. The authors strongly recommended glycosylated albumin over HbA1c. A 2008 study from the Wake Forest University Baptist Medical Center confirmed the inaccuracy of the HbA1c test for dialysis patients.

- **GA as a Monthly Report Card for Type 1 Diabetics**

The clinical study comparing glycosylated albumin (GA) and glycosylated hemoglobin (HbA1c) in which GA decreased more rapidly than HbA1c for type 2 diabetic patients on intensive insulin treatment suggests that type 1 diabetics would also benefit from a GA test providing earlier glycemic control information enabling earlier therapeutic intervention upon discovery of increases in glycation levels (Takahashi 2007).

- **Pre-Diabetes and Metabolic Syndrome**

Epinex plans to explore application of the G1A™ test to screen for pre-diabetes and metabolic syndrome, which could open a market of as many as 54 million people in the U.S.A. and over 300 million people worldwide.

Market Potential for the Epinex G1A™ Rapid Test in the Middle East

The explosive rise in the prevalence of diabetes in the Middle East creates a strong potential for market growth. Immediate Applications of G1A™ targets more than 90% of the diabetic population. Using a very conservative adoption rate of 5%, the market size is predicted to yield revenues starting at \$132 million per year during the initial years of production.

Industry analysts predict strong growth in the diabetes product sector for at least the next decade. The growth is fueled by the ongoing diabetes epidemic, which healthcare providers are struggling to control. Also helping to drive this growth is the increasing awareness among business and government authorities that early detection and maintenance of diabetes translates into reduced treatment costs over the long term. Health care payers are beginning to understand the power of proactive medicine in reducing the overall healthcare costs, especially for those with diabetes.

According to the IDF, roughly 22 million type 2 diabetic patients live in the EMME region. The market for the G1A™ test in the Middle East can be calculated based on the unit price of the product and an anticipated adoption rate by the type 2 diabetic population. A conservative estimate of 5% adoption rate of the G1A™ rapid test, which will be sold at US \$10 per test strip, would translate into a market demand of US \$11 million per month, or US \$132 million per year. A 10% adoption rate translates to US \$264 million annually and 30% adoption rate translates to a US \$800 million annual market. This market size translates to G1A™ test profits of at least US \$53 million to US \$320 million in the initial years of production.

The IDF predicts that the type 2 diabetic population in the Middle East will rise to 40 million by 2025 (an 81% increase). Assuming constant adoption rates of 5%, 10% and 30%, the market size will increase by 2025 to US \$239 million annually for a 5% adoption rate, US \$478 million for a 10% adoption rate, and US \$1.45 billion for a 30% adoption rate.

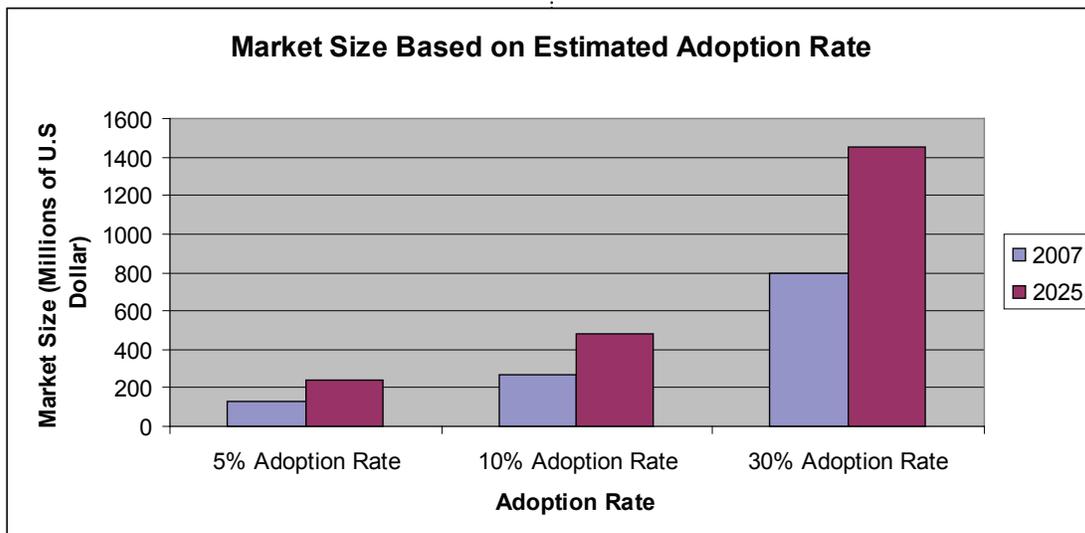
Adoption of a monthly care paradigm based on use of the Epinex G1A™ test would result in a significant reduction in outlay costs for daily glucose testing supplies. If, as recommended in the Epinex survey, physicians reduced their recommendation for SMBG testing by 50% for patients with optimal glucose control, potential savings in glucose testing supplies for the EMME region would be substantial. In addition, the G1A™ test could make diabetes management more accessible to those who cannot afford the expense of daily glucose testing.

Reimbursement

Epinex has determined that glycated albumin testing is covered by a Current Practice Terminology (CPT) code as administered by the Centers for Medicare and Medicaid Services (CMS) of the US Department of Health and Human Services, and is reimbursable under the Medicare system of the U.S. government.

CPT Code	Test Name
82985	Glycated Protein

The survey conducted by Epinex Diagnostics showed that use of the G1A™ test could reduce daily blood glucose testing by at least 25%, leading to a potential individual savings of \$75-100 every month (@ \$1 per glucose test strip). With the ever-increasing prevalence of diabetes, this translates into billions of dollars in savings. These dramatic savings will cause insurance companies in the Middle East to be highly motivated to support reimbursement for G1A™ testing.



Impact of the Epinex G1A™ Rapid Test in the Middle East

The G1A™ test offers a substantial potential savings of over \$1 billion in total monthly test costs. At present, 86% of physicians recommend blood glucose testing 2X or more per day for type 2 diabetic patients, while only 13% recommend 1X or less per day. Physicians surveyed responded that they would reduce daily testing in conjunction with a monthly test such as G1A™. Only 30% would then recommend testing 2X or more per day, and 69% would recommend 1X or less per day. This reduction in the number of daily tests will reduce patient inconvenience, save patients and healthcare providers money, and improve patient acceptance for G1A™ testing.



Impact of Epinex G1A™ Rapid Test

Potential Healthcare Cost Savings for Middle East:

- Reduction of daily SMBG for pre-diabetics and well-controlled type 2 diabetics
- Low initial and long-term costs for G1ATM rapid test and supplies

Improved Disease Management:

- Reduced patient anxiety and greater treatment compliance
- Better diabetes control
- Mitigate progress of complications

Clinical benefits include:

- Faster therapy feedback for doctor and patient to assess treatment effectiveness
- More reliable glycation index for patients under hemodialysis and for those with hemoglobinopathies
- Possible marker for gestational diabetes, cardiovascular disease and other diabetes-related complications

EpineX Strategy for Product Rollout

Keypoint

The G1A™ test will utilize the existing healthcare infrastructure for distribution and marketing of diabetes monitoring supplies. The monthly G1A™ test is expected to be readily integrated and accepted in the Middle East market by healthcare providers and patients.

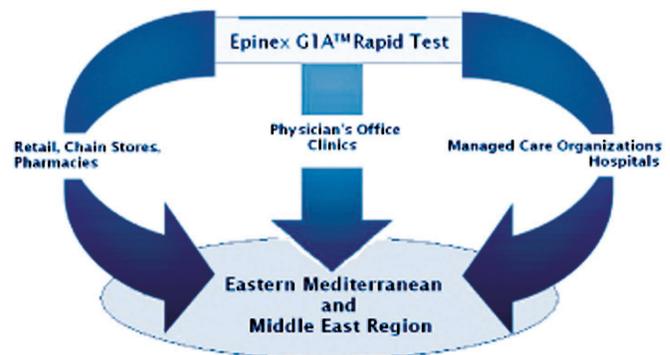
The commercialization plan for the EpineX G1A™ test utilizes three channels within the healthcare sector: Retail and Chain Store Pharmacies, Physician's Office Lab/Clinic and Managed Care Organizations.

There are a number of highly developed pharmacy retail chains in the different countries of the Middle East, with a major concentration in the Gulf region. Two examples are the Pharmatrade LLC network in the UAE, and Muscat Pharmacy LLC, which operates over 70 outlets in Oman. These wholesalers and retailers have recognized the growing trend in diabetes care and are moving the diabetes category from behind the counter to prominently displayed front-end counters. With a variety of high-margin items and a constant stream of product innovations, the diabetes section of a store currently represents a major growth opportunity for drug chains. Additionally, retail and chain store pharmacies are rededicating themselves to fostering health and wellness, with over-the-counter (OTC) diabetes medications and products becoming increasingly important.

Managed Care Organizations control the financing and delivery of health services to members who are enrolled in a specific type of healthcare plan. Managed-care organizations are largely focused on cost-containment and clinical outcomes. Daman, established by the UAE government to provide compulsory health plans to all expatriates, is the UAE's leading health insurance company. It offers its customers the largest network of private hospitals and pharmacies throughout 18 countries in the Middle East and abroad including Saudi Arabia, Oman, Qatar, Bahrain, Kuwait, Jordan, Syria, Egypt, and Lebanon (ICLDC, 2007). The goal of managed health care is to ensure that providers deliver high-quality care in an environment that manages or controls costs. Diabetes is a chronic health condition of great concern to managed care organizations: it is widespread and carries very serious complications; at the same time, it is treatable, and the onset of complications is preventable. The costs associated with diabetic patients in a managed care organization are typically 2.5 times higher per member than for similar members without diabetes. EpineX expects that the low initial and overall cost of the G1A™ test will make the device accessible to all diabetic patients, whether subsidized by the government or paying out-of-pocket.

In the Physician's Office Lab and Clinic the EpineX G1A™ test provides rapid results allowing doctor-patient discussion of the test results

during the visit. Access to immediate results facilitates doctor-patient feedback and interaction that promotes timely, successful therapeutic intervention. The test can also be administered in the physician's office lab to screen at-risk patients for early detection of type 2 diabetes. This will allow such patients to initiate aggressive treatment sooner, which will help them to reverse the damage caused by glycation and avoid or delay the onset of long-term complications. Patients with borderline results can be identified as pre-diabetic and monitored monthly. These patients can be educated to make lifestyle changes in order to avoid the onset of diabetes. Effective distribution of the G1A™ test will follow the model already in place within the Middle East. The infrastructure for distribution of diabetes management devices is already in place and in use in the Middle East by some of the largest multinational corporations. Bayer Diabetes Care, Abbott Diabetes Care, Bio-Rad, Lifescan, and Roche manufacture and export blood glucose monitors to the region via local distribution partners such as medical device suppliers and pharmacies.



Websites specifically tailored to the Middle East market provide easy access to product lists, product support and notifications, owner's manuals, package inserts, troubleshooting, FAQs, and warranty information. The distributors within each country then become the main local customer service contacts, providing efficient service customized to the region.

Prevailing market and distribution conditions for the Middle East region suggest that the most efficient means to produce and distribute the Epinex G1A™ test would be to establish a manufacturing facility in the region. The Company will therefore seek suitable financial, management and marketing partnerships that will best implement its production and marketing goals.

- The technical, service and financing infrastructure in the UAE is on par with any area in the world.
- It will be more efficient to localize the product for regulatory purposes, product labeling, etc.
- A localized service and support network will better support gaining market share.

The Company will also seek to partner with government and private sector healthcare providers in order to promote diabetes education, and in particular the advantages of a monthly paradigm for diabetes management.

Company financial projections place the cost-of-goods-sold for the G1A™ test at approximately 48%. Direct expenditure to manufacture the test will range from US \$50 million to \$300 million, depending on the degree of market penetration achieved for the test, in addition to expenditures for sales, marketing and education.



Barriers to Market Entry

EpineX has identified 4 potential barriers to market entry for the G1A™ test:

1) Patient compliance. The preliminary findings of the International Diabetes Management Practice Study in 2008 found that 75% of type 2 diabetics do not follow their doctor's recommendations and the ADA guidelines for HbA1c and SMBG. Patient compliance is very important in managing diabetes because it will minimize the risks of developing complications in the future and reduce the cost of medical care.

- A monthly test such as G1A™ is expected to have a higher degree of compliance than the daily SMBG test because of lower patient discomfort and inconvenience.

2) Patient-physician relationship. A qualitative analysis study conducted in Oman revealed that diabetic patients are largely dissatisfied with the service they receive from doctors and nurses due to poor communication and infrequent meetings.

- Patient self-empowerment via monthly G1A™ testing can supplement diabetes care and may result in greater patient satisfaction.

3) Education. Many patients are unaware of the symptoms of diabetes and its risks. Health education is usually provided by doctors or through written materials, which may not be effective, especially in rural areas where literacy levels are low (Reed 2001).

- Monthly consultations and discussion of patient results from G1A™ testing can enhance patient understanding of diabetes symptoms and risks.

4) Cultural barriers. Certain cultural and religious values can interfere with adherence to a recommended diet among diabetic patients in the Middle East. Patients may feel obligated to follow specific eating habits related to societal norms instead of adhering to their diabetes diet plan. This is especially likely during family gatherings where there is a large variety and quantity of foods, and it is customary that guests are coerced to indulge themselves. The concept of fatalism, which states that the events in life have been predetermined by God, can make patients feel helpless in self-managing their health. Many patients also consider doctors as responsible for their wellbeing, which can impede the development of a patient-centered care model, in which patients take a more active role in managing their health.

- Patient self-empowerment via monthly G1A™ testing can encourage a shift in mindset, thereby allowing for more active personal health management.



While Diabetes Mellitus is increasingly prevalent in the Middle East, the population remains largely unaware of the devastating effect of the disease. It is important both to educate health professionals and the people in the region and to effectively manage the disease in order to ultimately help control the epidemic. Preventative guidelines are already in place in the majority of the countries within the region. However, despite the implementation of the latest evidence-based therapies and extensive education efforts, there exists a deficiency in diabetes management techniques. Patient behaviors, attitudes, and beliefs, alongside issues such as finances and education, hinder effective diabetes control.

A new, more convenient and affordable testing method coupled with patient empowerment and cooperation with diabetes care professionals may hold the key to effectively addressing these deficiencies. The Epinex G1A™ Test, complemented by a monthly care paradigm for diabetes management, is poised to enter the diabetes market and lead the shift towards patient self-management.

The synergistic combination of effective monthly testing in conjunction with monthly counseling offers an opportunity both for patients as well as for governmental authorities and investors who chose to help implement this program. Programs based on the monthly counseling model have already demonstrated that they can be beneficial to patients and cost-effective for the business and healthcare sectors. In combination with the Epinex G1A™ Test, such programs have the potential to provide diabetes control that improves patient outcome, reduces the burden of diabetes complications, and supports itself financially through lowered healthcare costs and improved productivity.

With the limitations of self-monitoring blood glucose and HbA1c testing becoming increasingly evident, especially for type 2 patients, the diabetes market is ripe for the introduction of innovative products that would bridge the gap between the two older tests. A portable, easy to use monthly diabetes test that provides immediate results for both doctor and patient would substantially augment the diabetes market, especially a test that could be purchased over the counter and used at home as well as in the doctor's office or clinic. The Epinex G1A™ Test has the potential to be revolutionary in redefining the "gold standard" for diabetes testing as a monthly index and to be instrumental in the rapidly growing diabetes marketplace, both as a diagnostic tool and in the management of diabetes.

The deficiencies in current diabetes management techniques are evident in the Middle Eastern diabetic population. A monthly diabetes care paradigm, accompanied by the Epinex G1A™ Test, presents itself as the best solution, by easing overburdened healthcare systems and at the same time empowering diabetes patients to take responsibility for their own health and well-being.



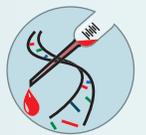
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