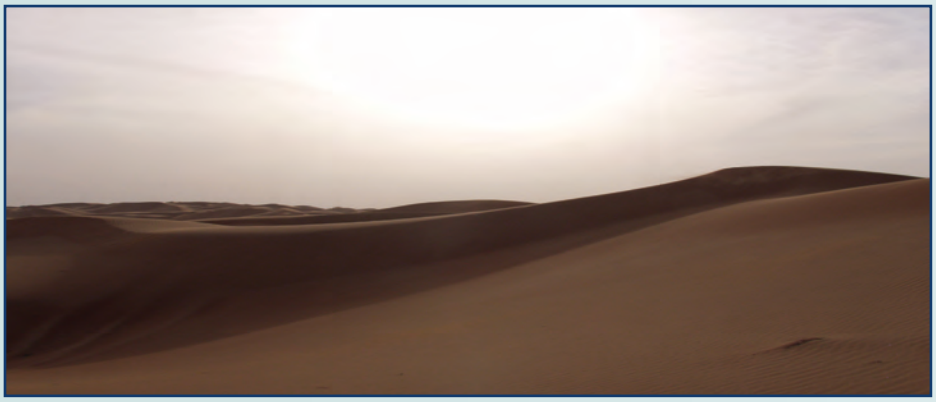
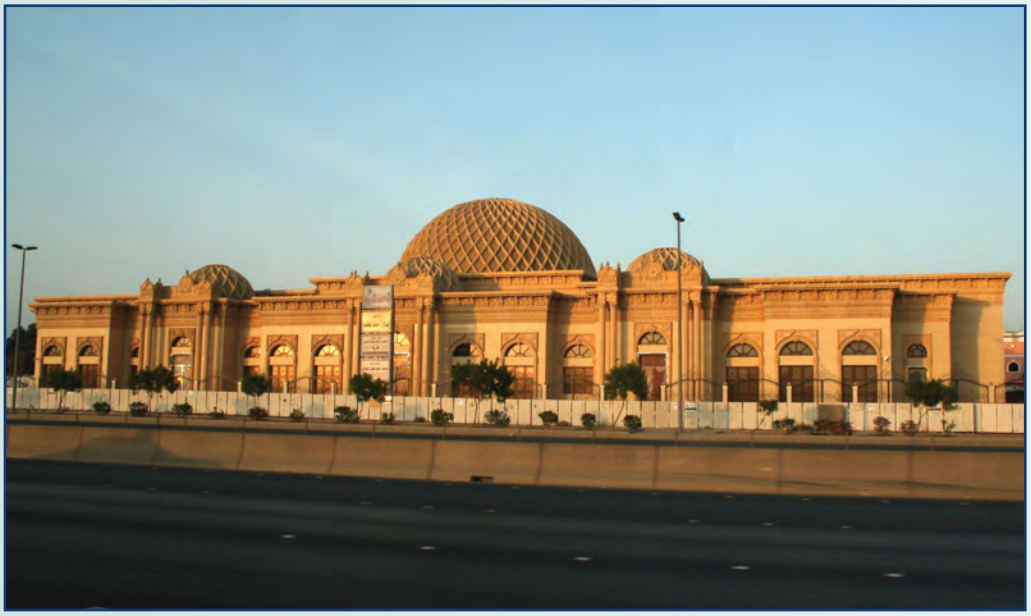




Diabetes in the Middle East - Update

EPINEX DIAGNOSTICS, INC.

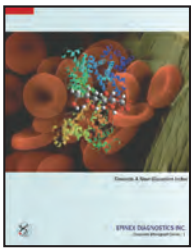
Corporate Information Series - 6

Foreword

This is the sixth in a series of corporate informational documents that we hope will provide critical data for our partners, collaborators, supporters, doctors, educations, and investors. This educational presentation, an update to our original report – Diabetes in the Middle East – published in 2009, was prepared by our Director of Corporate Communications, Dr. David Trasoff, assisted by Jacqueline Morales, Clinical Sciences Manager, Rachel Bohunis, Manager of Public Relations and Marketing, and Jaycee M Ambida, Manager of Research and Engineering. The report presents information on the state of diabetes management in the Middle East region, the challenges faced by the region's leaders and the general population, and the latest efforts made to control the diabetes epidemic. This report also outlines a proposal for a new MONTHLY diabetes healthcare paradigm, based on glycated albumin testing, that may greatly help in management, diagnosis, and screening and prevention of diabetes.

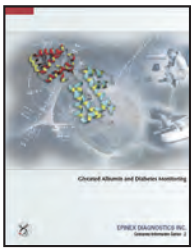
I sincerely hope that readers find this document helpful. We continue to strive to disseminate information that will contribute to stemming the tide of diabetes.

Asad R. Zaidi, President
Epinex Diagnostics, Inc.



Toward a New Glycation Index

Understanding Diabetes



Glycated Albumin and Diabetes Monitoring

Diabetes in the Middle East

Diabetes Prevention: Challenge and Opportunity

Diabetes in the Middle East - Update

Diabetes in the Middle East

Update

EPINEX DIAGNOSTICS, INC.

Scientific Advisory Board

CORPORATE OFFICES
Epinex Diagnostics, Inc.
14351 Myford Road,
Unit J
Tustin, CA 92780
Phone: (949) 660-7770
Fax: (949) 660-7772
email: info@epinex.com
www.epinex.com

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Introduction

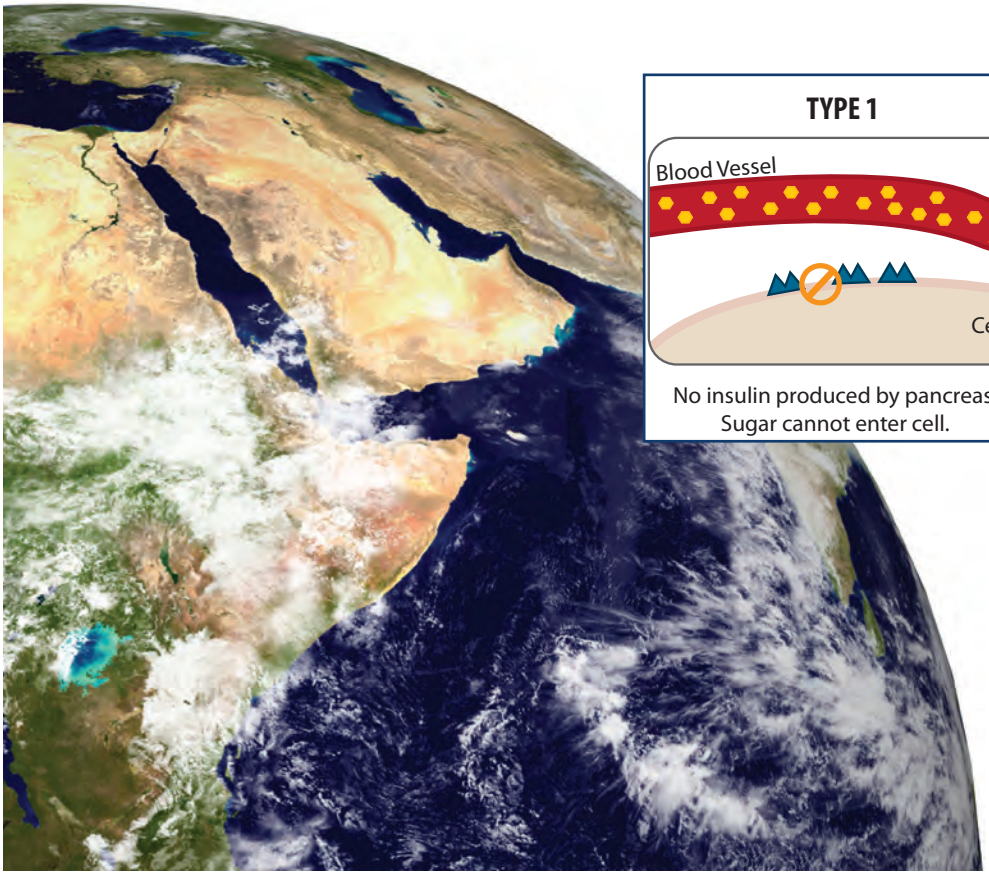
It has been three years since Epinex first published Diabetes in the Middle East, a report that detailed the trends and prevalence of the disease, along with the efforts made to treat those affected and to control its spread in the region. Since that time, great advancements have been made in healthcare, particularly in the six member countries of the Gulf Cooperation Council (GCC), namely Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and United Arab Emirates. However, a lot of work remains to be done as the diabetes epidemic continues to rise worldwide. In this report, we provide an update on the current status of the epidemic, the initiatives being undertaken in the GCC, the unique challenges faced by the region, and the latest advancements and understanding of diabetes healthcare.

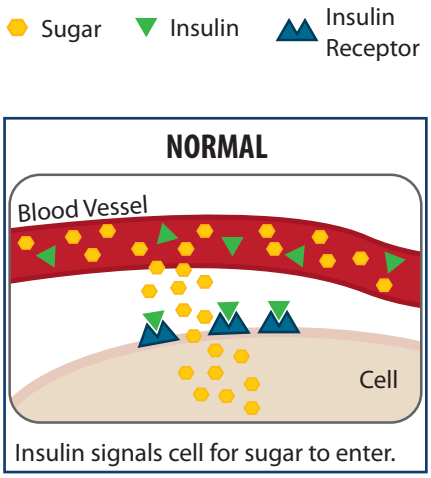
The Middle East, which has the world's highest comparative prevalence of diabetes, is facing a great challenge that has the potential to halt the economic and social progress the region has made in the last 30 years. In order to reverse the trend and ensure a healthy, productive population, its leaders must think beyond disease management and monitoring. Diabetes prevention and screening should play a larger role in the strategy that the Middle East needs to employ to stem the tide of diabetes. Glycated albumin monitoring may just be the tool to make this possible.

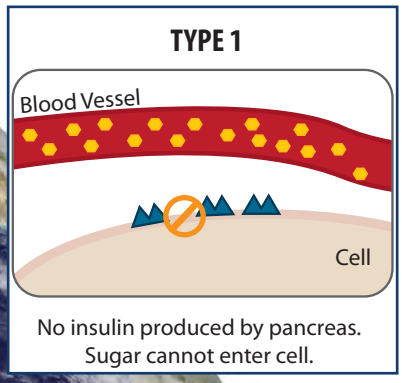
What is Diabetes?

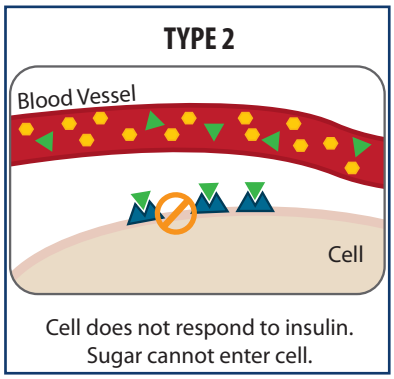
Diabetes is a chronic metabolic disorder, where in the body has trouble regulating its blood glucose (blood sugar) levels because:

1. The pancreas produces little or no insulin (type 1 diabetes), or
2. The body's cells do not respond properly to the insulin produced (type 2 diabetes).



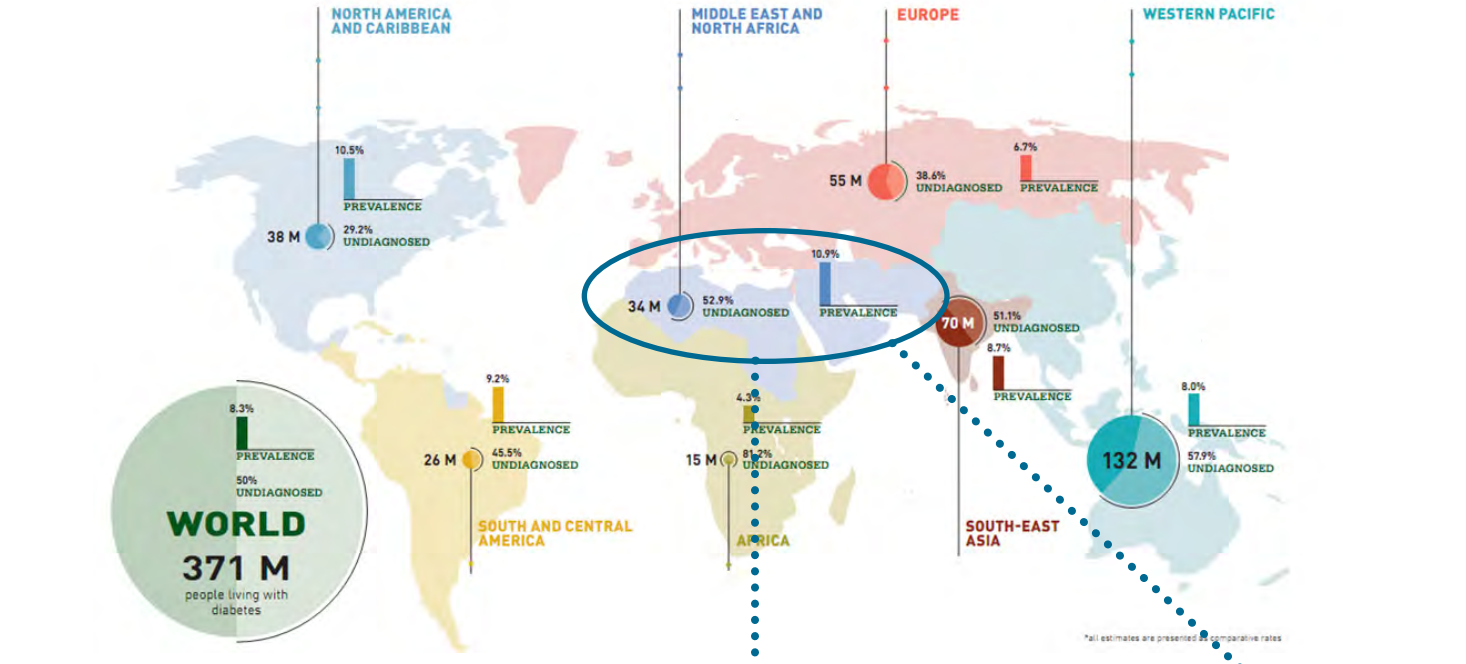






Diabetes by the Numbers

In 2007, the diabetes epidemic in the Middle East was at a record high. Five years later, those numbers are still growing exponentially. While this is consistent with the global trend, there are several factors that are unique to Middle Eastern countries that exacerbate the problem. Most notably, the uniquely rapid economic development of the region over the last 30 years has led to a rise in affluence that has enabled significant lifestyle changes. The region's increasing fondness for Western-style fast food, cultural practices and norms that discourage physical activity and encourage a sedentary lifestyle, and misconceptions about diabetes due to limited health education, makes efforts to bring the diabetes epidemic under control is an especially daunting task.



Key Facts

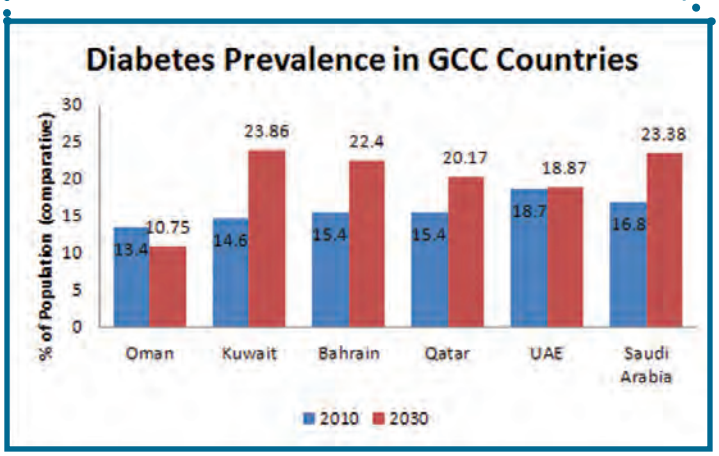
6 out of 10 countries with high diabetes prevalence are from the Middle East (Kuwait, Lebanon, Qatar, Saudi Arabia, Bahrain, and United Arab Emirates)

51.7 million people will have diabetes in the Middle East and North African region (MENA) by 2030, according to the IDF, double the current number.

10% of pregnant women in the Middle East will have gestational diabetes (GDM). These women will have 6 times greater risk of developing type 2 diabetes within 10 years than pregnant women without GDM.

Less than 10% of people diagnosed with diabetes have coronary heart disease, according to a study in the United Arab Emirates (UAE)

54% of people with diabetes show signs of early-stage kidney disease in Saudi Arabia



Keypoint

The economic growth and future development of the Middle East is being threatened by the Diabetes Epidemic. With one in five people in the region suffering from the disease, these countries are faced with the choice of devoting public resources to diabetes today or dealing with a very sick, disabled population in the future.

The total number of diabetics in the Middle East is projected to increase by more than 160% from 2000 to 2030. The member countries of the Gulf Cooperation Council already spend $5.5 billion per year on diabetes and the IDF projects healthcare costs in the GCC region to reach US $60 billion by 2025.

A major problem is the prevailing mindset that a person's health is the responsibility of the doctor, not the individual. This has led to a traditional healthcare structure focused on finding cures rather than promoting prevention and self-management. A 2010 study of 991 Saudi diabetic patients has shown that 40% had poor blood glucose control. A study in Jordan found that approximately 2/3 of type 2 diabetic patients did not adhere to effective lifestyle regimens such as meal plans, exercise, and glucose testing. However, 92% were highly adherent to their medications.

Metabolic Syndrome

Metabolic syndrome is a combination of medical disorders that increase the risk of developing cardiovascular disease and diabetes. It affects up to one in four people in the Middle East and prevalence increases with age. Risk factors of metabolic syndrome include large waist circumference, elevated triglycerides, low HDL cholesterol concentration, high blood pressure, and elevated fasting plasma glucose. The presence of 3 or more of these risk factors represents a five-fold increased risk for developing diabetes. In a study conducted by the Gulf Registry of Coronary Events, which enrolled 8716 patients with acute coronary syndrome from 65 centers in Middle East (Bahrain, Kuwait, Qatar, Oman, UAE, Yemen) it was found that 46% of patients had Metabolic Syndrome.

Other Looming Issues...

1. ***Gestational diabetes (GDM)*** – estimated to affect at least 10% of all pregnant women in the Middle East. GDM increases the woman's and the infant's risk of developing type 2 diabetes later in life.
2. ***Obesity*** – obese adults have a 50% greater chance of developing diabetes by the time they reach 40-50 years of age.

Additional Challenges Faced

Before the Middle East can effectively mitigate the problem of diabetes, it must first overcome the following barriers:

- Misplaced focus on high short-term costs of prevention and therapy rather than the long-term implications (and higher overall costs) of letting diabetes run unchecked and unmanaged
- Poor understanding of diabetes among patients, and even among some healthcare professionals
- Cultural resistance to healthier diet and lifestyle (e.g. some cultures view obesity as a sign of affluence and of health)

Like the rest of the world, cost is a major issue in public health for governments in the Middle East, particularly those in the more advanced and prosperous Gulf Cooperation Council (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates). More than 70% of total spending in the healthcare sector in GCC comes from public finances, according to Alpen Capital, a leading investment bank in GCC.

The challenge for Ministries of Health in the Middle East is how to stretch the limited resources and manpower in order to reach out to patients beyond the urban areas and to overcome the traditional health services mode, which is based on treating symptoms and complications, rather than disease prevention and management of disease progression. This curative rather than preventive model is becoming increasingly more expensive to maintain and has been proven to be limited in its ability to address the diabetes epidemic.

Evidence-based medicine has shown that self-management of diabetes, in the form of lifestyle changes, education, and self-testing, is the cornerstone of successful diabetes management. Diabetes patients in the region have repeatedly indicated that the time spent with their doctors on health education has been insufficient and misconceptions about diabetes abound in the region (e.g. some people believe that indulging in dates and honey is acceptable because these are "natural" foods).

Middle East Adopts Modern Management Practices

The GCC has responded to the diabetes epidemic with a series of initiatives designed to shore up their healthcare systems and bring state-of-the-art technology and practices to their people. Efforts made within the past 3 years include:

- Providing free glucose testing and placement of diabetes screening centers in major shopping malls for easier access
- Establishment of an online registry for diabetes patients and health care providers in the UAE
- MSD, a medical products and services supplier in the GCC has worked with authorities in Kuwait, Qatar, Saudi Arabia, and the UAE to introduce a training program for nurses on counseling diabetics, a diabetic cookbook, and Ramadan iPhone app
- In 2011, the Emirates Diabetes Society launched its "Win Over Diabetes" kit featuring the UAE's first ever real-time blood glucose monitor, which transmits instant blood glucose data to a special portal account set up for the patient, as well as directly to their mobile phones for easy tracking
- Collaboration with Western groups to improve healthcare services in the Middle East. These efforts include:

    1. *Excellence Across Borders* with Bayer Health – sharing of diabetes management strategies between the Middle East, Africa, and Europe
    2. Joslin Diabetes Center – sponsored training program for educating nutritionists and nurses on proper care for diabetes patients
    3. The 1st American Diabetes Association – Middle East Congress is being held in Dubai on December 2012.
    4. HealthPlus Diabetes & Endocrinology Center in Abu Dhabi, UAE – sponsored by United Eastern Medical Services and managed by Diabetes Zentrum Mergentheim (DZM) of Germany who will train UAE's diabetes health professionals and provide state-of-the-art health services to diabetics.

To improve efficiency and better serve its citizens, Saudi Arabia plans to increase the number of hospitals by almost 40% over the next four years. Many Middle Eastern states are moving towards a US-style approach to healthcare (i.e. from government-subsidized care to employer-provided insurance). In response, UnitedHealth is working with Optum to set-up the IT infrastructure to accommodate the requirements of third-party billing and reimbursement system. Other companies are looking at the Middle East as a prime site for healthcare investment, including Royal Philips Electronics, which established their Saudi health unit and is working with Al Faisaliah Medical Systems to provide healthcare products to Saudi Arabia. Latterrell Venture Partners is working with Bridge Partners FZE to start a healthcare fund and a factory to produce insulin delivery devices in the kingdom. Pfizer has committed to open a pharmaceutical plant in Jeddah, set to start its operations in 2015.

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Joslin Diabetes Center

Despite current efforts worldwide, a solution has yet to be developed to stop the rise of the diabetes epidemic. Western-style disease management has helped millions cope with the disease and somewhat stave off the development of diabetes-related complications. However, the number of diabetics, prediabetics, and people with impaired glucose tolerance is still on the rise.

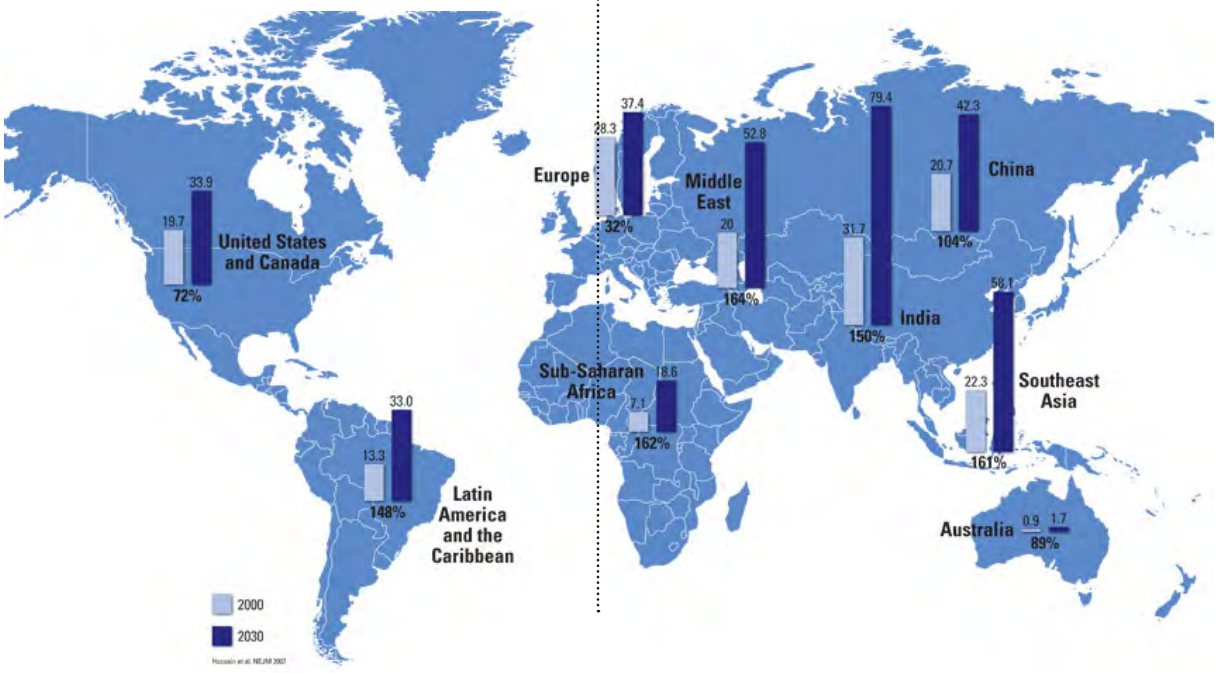
Large-scale studies of diabetes intervention and management have shown conflicting results:

- From UKPDS – extended "legacy effect" whereby the early glycemic environment is remembered by target organs and affects future vascular changes. This means that prior intensive diabetes therapy may reduce the risk of any cardiovascular disease event, risk of nonfatal myocardial infarction, stroke, or death from cardiovascular disease.
- From ACCORD – the use of intensive therapy to achieve a target A1c below 6% reduced 5-year nonfatal myocardial infarctions but increased 5-year mortality. Based on this, intensive glycemic control aiming toward an A1c level of less than 6% cannot be recommended in patients with advanced type 2 diabetes and a high risk of cardiovascular disease.
- From ADVANCE – the overall benefit of decreasing A1c from 8.4% to 6.9% over 5-6 years was modest and primarily limited to reduced progression of albuminuria.
- From VADT – in subjects with less than 15 years of diabetes at the time of enrollment, intensive glycemic control significantly reduced cardiovascular outcomes. In contrast, with more than 15 years of diabetes, intensive treatment was associated with increased cardiovascular events and was significantly worse than standard therapy after 20 years or more of diabetes

A meta-analysis of these studies indicated that there is limited benefit to intensive glucose lowering therapy on all-cause mortality and deaths from cardiovascular causes. Patients with newly diagnosed diabetes and without any obvious macrovascular complications may derive the greatest benefit from intensive glycemic control. However, in order to be able to apply the treatment early enough, there needs to be a means to cost-effectively and accurately screen for diabetes and prediabetes.

The recent endorsement of A1c testing for diabetes diagnosis offered a hope for affordable mass screening for diabetes and prediabetes. However, a recent study of Arab-Americans found that using A1c alone as a screening tool resulted in a high proportion of false-negative test results for both prediabetics and diabetics, which could well result in delayed diagnosis and progression of diabetes-related complications.

In the UKPDS study, treatment of diabetes-related complications accounted for 63% of overall costs of treatment. The Abu Dhabi Health Authority estimated that the overall social cost of diabetes in the UAE is about $1.9 billion. Daman, the leading health insurance company in the UAE claims the cost of managing diabetes in the UAE will reach $2.7 billion by 2020, up from the current $272 million the UAE already spends annually on diabetes treatment. Healthcare access is still limited, particularly for the rural poor. These numbers highlight the need for an evidence-based cost-effective system for the prevention and control of the diabetes epidemic, both for diagnosis and monitoring of complications, without overly straining the healthcare system.



Changing Diabetes Management in the Middle East

Preventive Care & Monthly Management

In addition to diagnosing and treating those already affected, a great deal of effort must be put towards predicting risk and preventing disease progression. This will be costly in the short term because more widespread screening programs will be necessary, but in the long run, fewer patients and fewer complications will lead to decreased costs.

Pharmaceutical giant Novo Nordisk recently published their diabetes awareness survey and determined that raising awareness of key lifestyle risks, early diagnosis, more information and health education, along with more community support and monthly consultations are the key to controlling diabetes in the Middle East.

Multiple studies in the US have shown the power of community support, health education programs, and monthly consultations in encouraging healthy lifestyles and improved compliance with therapy. Social support has a positive influence on the physical and psychological well-being of patients, empowering them to take control of their diabetes, thus reducing the severity of their illness, which is then reflected in a better quality of life, leading to a positive-feedback cycle.

However, a critical component to an effective solution to the diabetes epidemic is missing. The US and Europe have been advocating evidence-based healthcare to ensure that any therapeutic or preventive care program achieves the desired outcomes in a cost-effective manner. In Qatar, healthcare providers require validated healthcare quality assessment tools. What has been missing is a way to precisely track patient progress, to generate evidence of therapy effectiveness, and to provide a clearly understandable marker that will guide healthcare workers and empower patients to take responsibility for improving their health.

The Epinex Approach

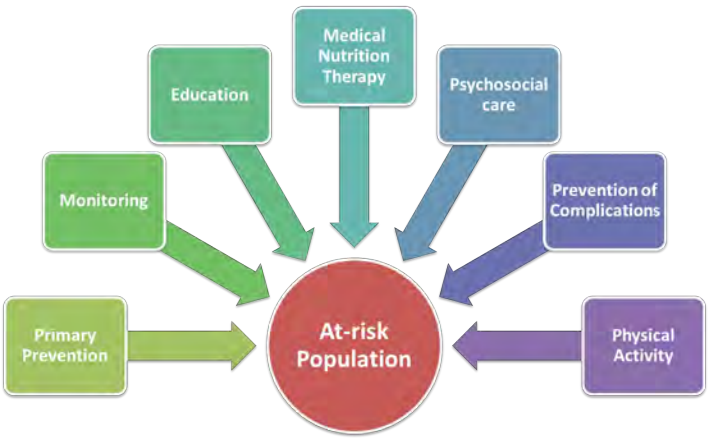
Epinex is dedicated to changing the way that healthcare is delivered and public education and dialogue with the medical community is essential to making this happen. Through the release of our 2008 report, Diabetes in the Middle East, Epinex has been acknowledged by the academic and scientific community in the Middle East, as well as received product inquiries from medical device distributors in the region. This report was sent to regional Ministries of Health, diabetes treatment centers and hospitals, prominent individuals in regional public health policy. We continue to reach out to groups worldwide in order to raise awareness and support for the new diabetes care paradigm, featuring the G1A™test.

Diabetes EPI-Center

Education, Prevention, Education

Epinex has developed a concept for a comprehensive diabetes care center that will incorporate the monthly diabetes management paradigm and provide a one-stop location for all diabetes education and management needs by:

- Educating diabetics and the general community
- Providing lifestyle intervention programs
- Helping patients monitor their disease and providing related medical and emotional care



Glycated Albumin and Monthly Monitoring

Evidence Based Medicine

The programs that have proven successful in improving the health of diabetics and controlling the cost of care have all had MONTHLY consultation as the key to their efficacy. This model can be particularly effective in the Middle East where people expect more personal interaction and guidance from their healthcare providers. Using monthly monitoring, consultation, and community support in addition to the current diabetes initiatives in the GCC, the healthcare systems will be better able tackle both aspects of the diabetes problem:

- Providing quality care for diabetics so that they avoid the progress of complications that lead to lost productivity and avoid the additional burden to society and the economy
- Finding out, in a cost-effective way, who are the undiagnosed diabetics and who are at risk of developing diabetes so that preventive care and monitoring can be initiated as soon as possible.

To aid the world in stemming the tide of the diabetes epidemic, Epinex is developing the G1A™ system – a rapid glycation test for use at the doctor's office, at nontraditional healthcare settings such as fairs and community outreaches, and by diabetics in their own home. The G1A™ tests for glycated albumin (GA) and is unaffected by the conditions that render the traditional glycation test, HbA1c, inaccurate. Glycated albumin is widely seen as a potentially superior marker for diabetes screening and diagnosis, as well as for monitoring its ongoing control. This marker has been directly linked to the pathogenesis of diabetes-related complications. Designed as a rapid test using a disposable test strip and a handheld meter, the G1A™ can make general population screening cost-effective and glycation monitoring timely and convenient.

Public Feedback

Epinex has received positive feedback from key opinion leaders in the diabetes industry. These decision makers have the power to influence treatment and diagnosis guidelines. Through the release of our 2008 report, Diabetes in the Middle East, Epinex was acknowledged by the academic and scientific community in the Middle East, and received product inquiries from medical device distributors in the region. The report was sent to regional Ministries of Health, diabetes treatment centers and hospitals. We continue to reach out to groups worldwide in order to raise awareness and support for the new diabetes care paradigm, featuring the G1A™test

David B. Sacks, Chief Clinical Chemistry and Senior Investigator
NIH, Department of Laboratory Medicine

"… I agree that GA is a very promising analyte that has a potentially important role in patients with diabetes."

Dr. Khalid Al-Rubeaan, Director
University Diabetes Center, King Saud University

"I found your work unique and interesting for us. We are in the same scope working to develop new markers and implementing them clinically. You should count on us supporting your work. I have forwarded your letter to my team which includes an endocrinologist and a molecular biologist for further action. I look forward to meet you here in Riyadh if it is feasible, otherwise you will hear from us."

David Klonoff, M.D., FACP
Editor-in-Chief, Journal of Diabetes Science and Technology
Medical Director, Mills-Peninsula Diabetes Research Institute
Clinical Professor of Medicine, UC San Francisco

Dr. Klonoff has supported Epinex's academic work since 2008. He is the editor-in-chief of JDST, where an Epinex review is published, and founder of the diabetes technology Society, who sponsored a Clinical Diabetes Technology Meeting where Epinex presented a scientific review poster.)

Closing Remarks

Conclusion

Diabetes and its complications can stifle a country's growth and progress. Medical communities all over the world have been trying to come up with the optimal disease management system but after decades, the threat still remains and the epidemic rages on. At last, an effective and reproducible paradigm for diabetes monitoring and control has been demonstrated through the use of monthly monitoring and community counseling. To aid this new paradigm of healthcare delivery, Epinex is developing the tool that can provide the evidence-based scientific result that will reinforce treatment. The G1A™ Rapid Diabetes Monitoring Index test, when used in conjunction with the new treatment paradigm, will transform diabetes care.

Call To Action

We understand that the scope and range of the problem cannot be tackled by any one group alone. We at Epinex are always looking for opportunities for collaboration and partnerships, be it in marketing and distribution, clinical trials, technology development and research, international regulations, or investments.

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Notes

CORPORATE OFFICES
Epinex Diagnostics, Inc.
14351 Myford Road, Unit J
Tustin, CA 92780
Phone: (949) 660-7770
Fax: (949) 660-7772
email: info@epinex.com
www.epinex.com

DCN-7401-1412-01