



Diabetes Prevention - Challenge and Opportunity



EPINEX DIAGNOSTICS, INC.

Corporate Information Series - 5

Foreword

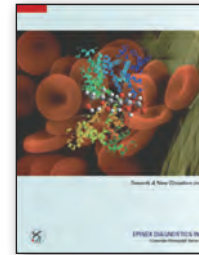
This is the fifth in a series of corporate informational documents that we hope will provide critical data for our partners, collaborators, supporters, doctors, educators, and investors concerned about the growing worldwide epidemic of diabetes, and the problems and opportunities it presents to the healthcare industry. This educational presentation was prepared by our Director of Corporate Communications, Dr. David Trasoff, assisted by Jaycee Ambida, Manager of the Epinex Department of Research and Engineering, and Rachel Bohunis, Manager of the Epinex Department of Public Relations and Marketing. The report presents information on the current state of the diabetes prevention and control initiatives. It defines the problem in terms of numbers, trends, and costs; and discusses the changes that will be brought about by the implementation of the Patient Protection and Affordable Care Act in the United States. The report also outlines recent advances in diabetes monitoring brought about by the adoption of glycated albumin (GA) as a new standard of measurement, and the ways that GA can work synergistically with the most effective methods of diabetes control currently advocated.

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.

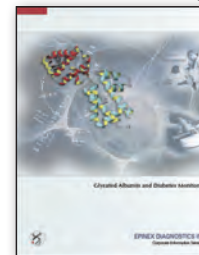
Toward a New Glycation Index



Understanding Diabetes



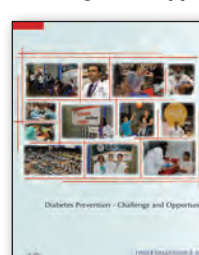
Glycated Albumin and Diabetes Monitoring



Diabetes in the Middle East



Diabetes Prevention: Challenge and Opportunity



Diabetes Prevention

Challenge and Opportunity

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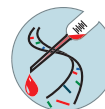
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Diabetes Prevention - Challenge and Opportunity

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Diabetes Prevention: Challenge and Opportunity

The enormous scope of the diabetes epidemic is apparent worldwide and in the United States. The potential human and economic costs are staggering, but the opportunity to reverse the health and financial toll by bringing the epidemic under control also offers great rewards in improved health and lower healthcare costs.

Even though the use of insulin and other medications offers a temporary solution to millions of diabetics, it does not provide a permanent cure for diabetes and its complications. poorly controlled diabetics run the risk of multiple complications such as kidney failure, retinopathy, cardiovascular disease, and amputations as well as incurring substantially greater healthcare costs. The only viable solution to this problem is to prevent these complications by early assessment, control, and management of diabetes.

Implementation of the Patient Protection and Affordable Care Act (PPACA) in 2010 is changing the template of diabetes care from individual management to community-based models of prevention and control largely based on monthly monitoring and counseling. With the support of the National Prevention Council and major healthcare insurers, pilot projects that have proven effective are being scaled up, with the goal of national implementation.

Glycated albumin (GA), a monthly measurement for glycation, is widely seen as a potentially superior marker for assessing the onset of diabetes as well as for monitoring its ongoing control. It has been directly linked to the pathogenesis of diabetes related complications such as nephropathy, coronary artery disease, retinopathy, and atherosclerosis. What is needed to make GA testing available on the scale required to work synergistically with an effective monthly care paradigm is a rapid test for GA that can be easily and cost-effectively used within the professional healthcare setting and by diabetics at home. Epinex Diagnostics is developing the G1A™ Rapid Diabetes Monitoring Index Test to fulfill that need.

About the Cover

The images on the cover of this report were taken at the second annual Care Harbor/LA Clinic, which was held at the Los Angeles Sports Arena on September 27th –30th, 2012 and served over 5,000 patients. Epinex Diagnostics was proud to be a sponsor at this year's clinic, which provided free medical, dental, and vision services to thousands of uninsured and underserved individuals in the Los Angeles community, as well as extensive education and counseling. Epinex Diagnostics Laboratories (EDL), a wholly owned subsidiary of Epinex Diagnostics, provided nearly 1,000 free A1c, glycoprotein, and other metabolic disease indicator tests at this year's event.

With the support of the Care Harbor/LA Clinic, Epinex is proud to serve the local LA community by providing free diabetes testing as part of its mission to promote diabetes awareness and prevention. Epinex CEO, Asad Zaidi, comments that, "this is only one of many steps the Company plans to take in our effort to help patients achieve healthy and productive lives."

About Care Harbor

Care Harbor brings help and hope to the uninsured and underserved in America's urban centers. The organization works with local community resources and volunteers to produce free clinics providing comprehensive medical, dental, and vision care to individuals and families who are without access to the healthcare they need. Their goal is to provide sustainable, quality care and promoting prevention and self-care among the most vulnerable populations. There is no cost to the patient for the services provided. Clinics are staffed by professional and general volunteers, and supported by donations – both financial and in-kind – from local and national supporters. To learn more about Care Harbor, please visit CareHarbor.org.

Introduction: The Challenge of Diabetes

The world is facing a great challenge – one with the potential to undo previous gains in social and economic progress over the next few decades. It is a stealth war that will drain resources, strain the abilities of nations to achieve their goals, and stifle progress and innovation. The challenge is diabetes, the incidence of which has increased nearly ten-fold in the past twenty years and will affect hundreds of millions within another twenty.

Diabetes and its complications are the cause of tremendous suffering and consume vast amounts of human, social, and economic resources. It is not a disease that can be cured or for which a vaccine can be developed; although if detected early enough it can be substantially mitigated or even reversed. It is a condition brought about by the shifting patterns of basic

human activities: where we live, what we eat, and how we work. If unchecked, diabetes is predicted to become the most predominant health problem in human history.

Resources are being mobilized all over the world in an ongoing effort to understand the factors at work in the spread of diabetes, and to create effective strategies to stem and, hopefully, reverse the tide. This report focuses on prevention efforts that are just now beginning to be put into place in the United States and examines forces that are driving these current efforts. If the cumulative efforts of the most powerful and successful nation on earth can demonstrate an effective strategy to contain diabetes, then perhaps these principles and methods can show a path for the wider world.



The Diabetes Prevention Landscape

A major shift is taking place within the United States health care system.

Adoption and implementation of the Patient Protection and Affordable Care Act (PPACA) of 2010 is already having an impact on the direction of health care. This impact will be increasingly evident over the next decade as the effects of its initial programs begin to be felt and as successive new programs are brought on line. One of the most powerful new programs that is already making a difference is the National Prevention Strategy, created through the efforts of the National Prevention Council in 2011. The recommendations and policies that have been included in the prevention strategy program will have an even more profound effect after 2014, when the Individual

Mandate and the associated Health Insurance Exchanges come into effect, broadening prevention-based coverage to millions of additional recipients.

Health insurance companies are also increasingly seeing the need to shift to prevention-based strategies and evidence based medicine, which is also mandated by the PPACA. UnitedHealth is among the leaders in proposing widespread adoption of effective programs that are helping individuals and communities control diabetes. Their 2010 report and its detailed financial analysis shows a stark picture of both the staggering costs of allowing the status quo to continue and the enormous benefits that can be realized by implementing effective prevention programs.



Defining the Problem: 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 blood stream and cause damage to a variety of organs and bodily functions. The most prevalent form of diabetes is type 2, representing 90-95% of cases.

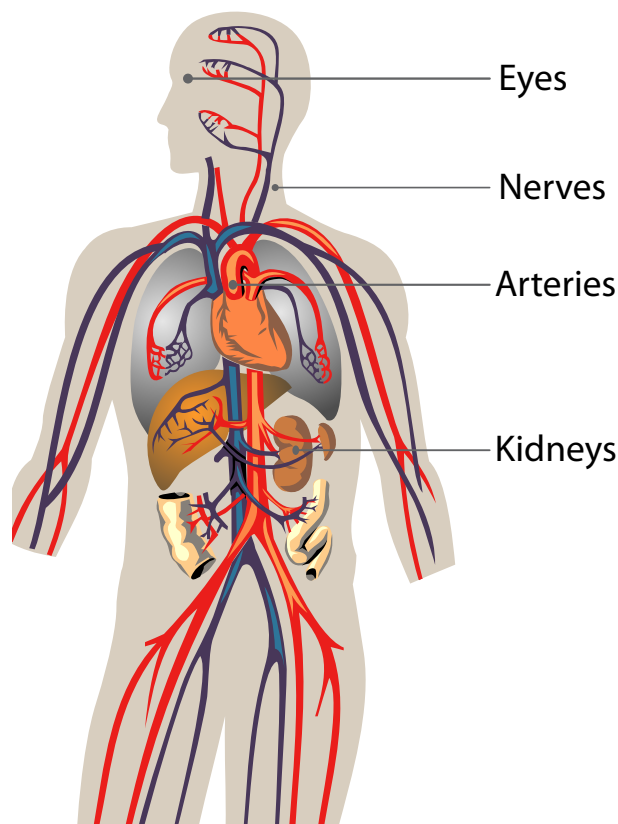
Diabetes is a chronic metabolic disorder in which the body does not produce or properly use insulin, a hormone that is needed to convert sugars, starches, and other food into energy. With diabetes, the body has trouble regulating its blood glucose (blood sugar) levels, resulting in abnormal sugar build-up in the blood stream (hyperglycemia and glucose intolerance). The exact cause of diabetes is unknown, although genetics and environmental factors such as obesity and lack of exercise appear to play roles.

Progressive complications of unmanaged diabetes include heart disease, blindness, kidney failure, amputation of extremities due to circulation problems, and nerve disorders, among others. These complications are the cause of 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 monitor the way sugars are being processed in their bodies. Because diabetes itself may have no obvious symptoms, this long-term monitoring is critical.

There are 3 main types of diabetes:

- Type 1 diabetes is a genetic autoimmune deficiency in which the pancreas cells that produce insulin are systematically destroyed, leaving the individual insulin-dependent, requiring insulin shots or an insulin pump to control blood glucose levels.
- Type 2 diabetes, often called “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. Most often diagnosed in older people, this disease is becoming more common in overweight and obese children and adolescents. Type 2 diabetes 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. Gestational diabetics have an increased chance of having overweight or obese children who may develop type 2 diabetes later on, resulting in a cycle of diabetes affecting multiple generations in a family.

It is estimated that at least 50% of all people with diabetes are unaware of their condition. In some countries, this figure can be as high as 80%. In developed countries, diabetes is the fourth main cause of death and the leading cause of blindness and visual impairment in adults. In addition, it is the most common cause of amputation that is not the result of an accident.



Defining the Problem: The Worldwide Epidemic

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.

With each passing year, the scope of the worldwide diabetes epidemic becomes more evident. According to the International Diabetes Federation (IDF) the total number of people with diabetes worldwide has risen from 30 million to over 240 million in just the last 20 years. In 2011, the United Nations General Assembly convened to discuss the growing diabetes crisis. The only other time the UN General Assembly discussed health issues was back in 2001, when it addressed HIV/AIDS. The IDF estimates that there are currently more than 246 million people with diabetes worldwide and that this population will grow to 380 million by 2025.

According to the 2011 IDF figures, the five countries with the largest numbers of persons with diabetes are China (90 million), India (61 million), the United States (23.7 million), Russia (12.6 million), and Brazil (12.4 million). Just four years earlier, the 2007 IDF diabetes figure for India was 41 million, for China was 40 million, for the United States was 20 million, for Russia was 9.7 million, and for Brazil was 7 million.

The factors that are driving this increase have become increasingly evident:

1. Longer lifespan – the overall prevalence of diabetes increases with age.
2. Obesity – Epidemiologists and diabetes researchers agree that perhaps the most significant factor driving increase in diabetes is the growing rate of obesity in adults and children. In a document specifically targeting the United States, The UnitedHealth Center for Health Reform and Modernization reports that:
 - Over the past two decades, the percentage of adults who are obese has more than doubled.
 - The share of adults who are obese may grow by four to five percentage points over the next decade.
 - 17 percent of children and adolescents are reported to be obese – a prevalence rate that is expected to increase over time.

Although obesity rates increase generally with age, demographic factors explain only a small percent of the rise in the share of obese adults over the two decades. There are numerous contributors to this trend including a rise in consumption of high-calorie foods, an increase in sedentary lifestyles, and changes in family dynamics, work activity, and environment.

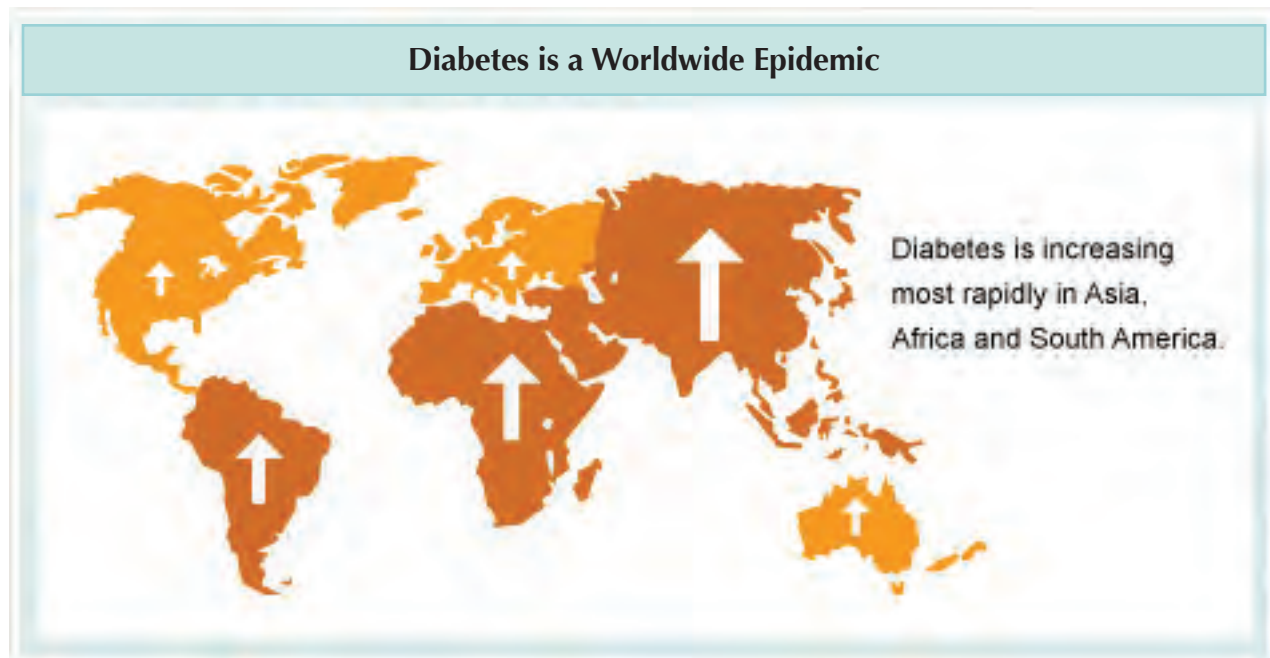
3. Access to intervention and treatment - as worldwide population continues to increase, the “rule of halves” makes diagnosis and treatment an escalating challenge. A simple and cost-effective means of diabetes diagnosis and monitoring will be able to improve the statistics.

Large-scale screening for diabetes and prediabetes would make it possible to begin to reduce the onslaught of full-blown diabetes and its complications. Present barriers to effective implementation of widespread screening include:

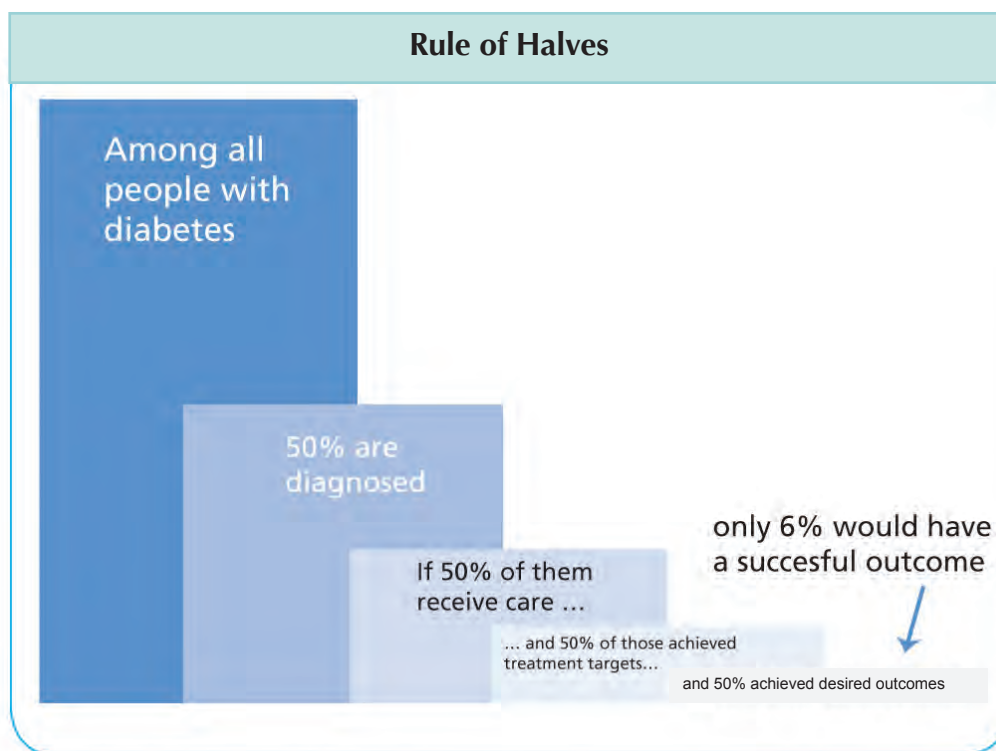
- Testing for diabetes or prediabetes requires fasting, which most patients find inconvenient.
- Several different tests are used, each of which can give different results.
- Tests must be performed twice to confirm the diagnosis.
- Most tests must be processed in a clinical laboratory, so results are not immediately available and follow-up is more difficult.
- The sheer number of tests to be performed is very large.



Defining the Problem: The Worldwide Epidemic



Source: University of California, San Francisco



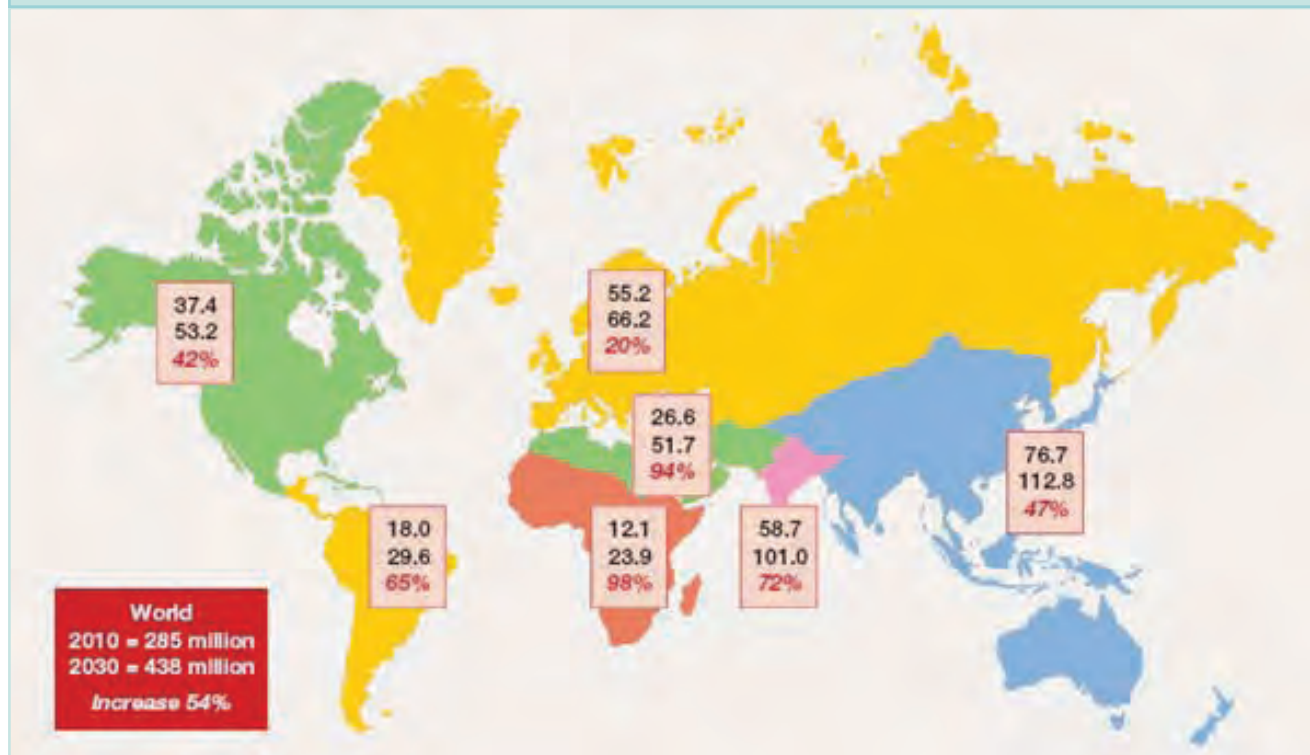
Source: Changing Diabetes Barometer, Novo Nordisk

Defining the Problem: The Worldwide Epidemic

Top 10: Countries/territories of number of people with diabetes (20-79 years), 2011 and 2030		
Country/Territory	2011 (millions)	2030 (millions)
China	90	129.7
India	61.3	101.2
USA	23.7	29.6
Russian Federation	12.6	19.6
Brazil	12.4	16.8
Japan	10.7	16.4
Mexico	10.3	14.1
Bangladesh	8.4	12.4
Egypt	7.3	11.8
Indonesia	7.3	11.4

Source: IDF

Global projections for the diabetes epidemic: 2010-2030 (millions)



Source: IDF

Defining the Problem: The Worldwide Epidemic (Summary)

Keypoint

Annual healthcare costs in 2010 per diabetic individual were estimated to range from over \$7,000 to nearly \$10,000, almost three times higher than for non-diabetics. Diabetes accounts for 5%-10% of a nation's health budget. Healthcare costs directly attributable to prediabetes and diabetes for US adults are expected to grow from approximately \$194 billion in 2010 to almost \$500 billion in 2020.

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%.

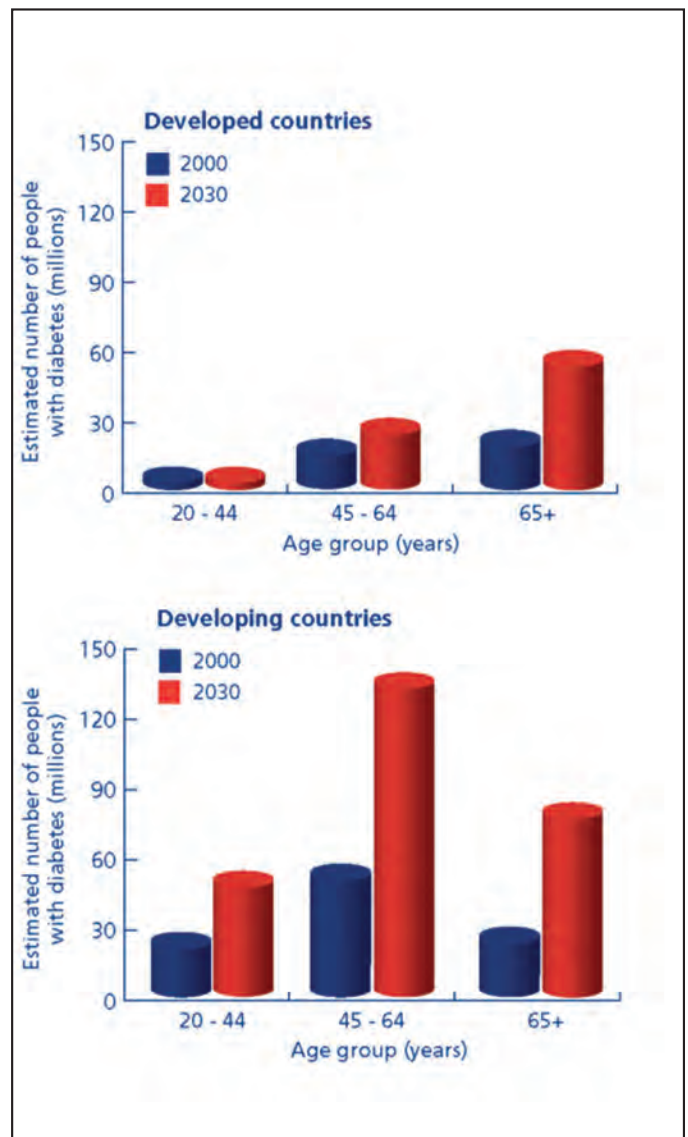
In developed countries, diabetes is the fourth main cause of death and the leading cause of blindness and visual impairment in adults. Diabetes is the most common cause of amputation that is not the result of an accident.

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.



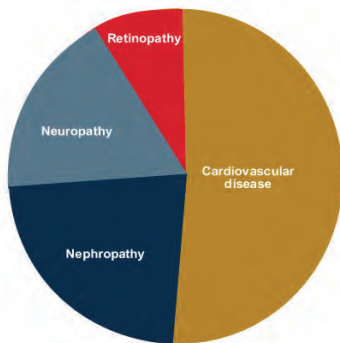
Source: World Health Organization

Source: IDF 2006

Defining the Problem: Costs of Diabetes

Estimated diabetes costs in the United States, 2007	
Total (direct & indirect)	\$174 billion
Direct Medical Costs	\$116 billion After adjusting for population age and sex differences, average medical expenditures among people with diagnosed diabetes were 2.3 times higher than what expenditures would be in the absence of diabetes.
Indirect Costs	\$58 billion (disability, work loss, premature mortality)

Source: American Diabetes Association



Distribution of estimated lifetime costs of managing diabetes complications	
Complication	Cost over 30 years
Cardiovascular disease (heart)	52%
Nephropathy (kidney damage/disease)	21%
Neuropathy (nerve damage)	17%
Retinopathy (eye damage)	10%

Source: National Committee for Quality Assurance

Healthcare spending on diabetes in the United States, 2011-2020	
Total national health spending on diagnosed and undiagnosed diabetes	\$2.75 trillion
Prediabetes-related healthcare expenses	Private Insurance: \$103 billion Medicare: \$204 billion Medicaid: \$111 billion Uninsured: \$166 billion

Source: United States of Diabetes

Defining The Solution: A New Diabetes Care Paradigm

Keypoint

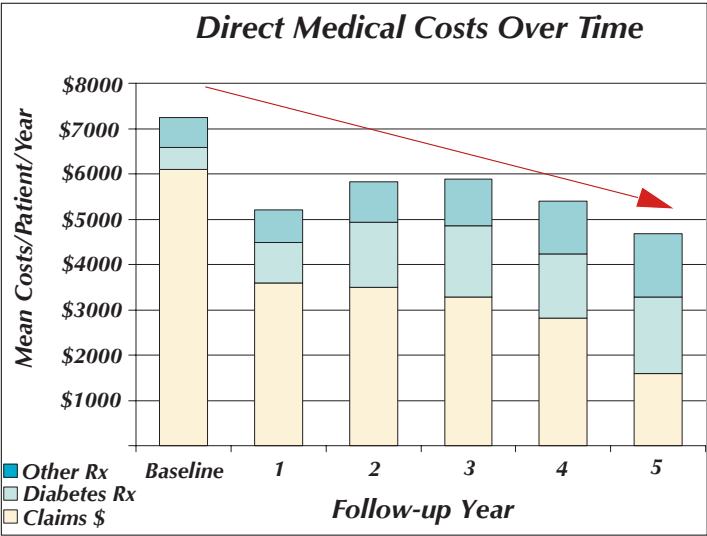
The Asheville Project first demonstrated that diabetes could be controlled by through a community program that centered on a monthly consultation between a diabetic and healthcare professional such as a pharmacist, nurse, or counselor.

Only in the past few years have governments, major health care providers, and pharmaceutical companies begun to respond to the scale of the looming diabetes disaster by focusing on finding effective programs for diabetes prevention and control. The way forward was indicated beginning almost 15 years ago, when the Asheville Project and the Diabetes Ten City Challenge demonstrated that a community-based prevention strategy based on monthly counseling improved patient outcomes, conserved expensive medical resources and more than paid for itself in reduced medical costs and increased worker productivity.



City of Asheville, North Carolina (Downtown)

Diabetes 10 City Challenge Participants
Charleston, SC
Chicago, IL
Pittsburgh, PA
Tampa Bay, FL
Colorado Springs, CO
Northwest, GA
Milwaukee, WI
Los Angeles, CA
Honolulu, HI
Cumberland, MD



Asheville Study Results (Cranor et. al.)

The National Prevention Strategy

Keypoint

The continuing implementation of the provisions of the Patient Protection and Affordable Care Act will create expanding opportunities for evidence-based prevention strategies.

The most significant impetus for the exploration and adoption of prevention-based approaches to diabetes is the passage of the Patient Protection and Affordable Care Act (PPACA) in 2010. The PPACA called for the creation of the National Prevention Council, which in turn released the National Prevention Strategy in June of 2011 – a document that outlines a detailed policy for the implementation of prevention-based programs that will improve health and significantly reduce healthcare costs.

Provisions of the National Prevention Strategy that are particularly relevant to diabetes prevention and management include:

1. A call for evidence-based preventive services, which may include screening tests, counseling, or medications used to prevent disease or to detect health problems early. While preventive services are traditionally delivered in clinical settings, some can be delivered within communities, work sites, schools, residential treatment centers, or homes.
2. Reimbursement mechanisms focused on proven interventions (e.g., those that support team-based care; use nonphysician clinicians such as nurse practitioners, physician assistants, pharmacists, and community health workers; and implement bundled payment systems) and measurable treatment outcomes can increase delivery of preventive services.
3. Federal support for the creation and expansion of prevention initiatives. A provision of the PPACA provides authority for

funding grants to model sites, the establishment of a training and outreach program for lifestyle intervention instructors, and a Centers for Disease Control (CDC) program to determine eligibility for those entities delivering services. The PPACA also provides grants to states to prevent chronic diseases, including diabetes, in the Medicaid population. Grant funding will

support initiatives that provide incentives to enrollees to participate in programs that improve health and outcomes through the adoption of healthy behaviors.

Finally, the PPACA requires the establishment of a national diabetes “report card” that will include information on health outcomes, risk, preventive care practices and quality of care provided to individuals with diabetes or prediabetes.

The federal government is also supporting a number of public policy initiatives to stimulate behavior change among populations prone to obesity, of which First Lady Michelle Obama’s “Let’s Move” campaign is the most recognized. These strategies aim to promote physical activity among the at-risk population or to encourage healthy eating.

Also in 2010 the UnitedHealth Group, one of the largest healthcare providers in the U.S., released a detailed report through its Center for Health Reform & Modernization, titled “The United States of Diabetes: Challenges and Opportunities in the Decade Ahead,” with the intention of proposing “intensive, practical intervention strategies to reverse the trend and help prevent the impending health care catastrophe.” A major pharmaceutical company, Novo Nordisk, which has a significant presence in diabetes care, has also proposed prevention-based initiatives.



Current Diabetes Prevention & Control Programs

Keypoint

The successful model for diabetes control based on monthly consultation first demonstrated through the Asheville Project is being reproduced through a wide range of programs nationwide.

Several local, regional and national programs have recently come online, which reflect the growing partnership of government, healthcare management, and private industry.

The PPACA allows rewards for wellness programs of up to 30 percent of the cost of medical coverage, with the opportunity to increase this to 50 percent. In response, some employers now offer an array of incentives that reward employees for taking part in wellness programs and for health improvement that may include cash, gift cards, health insurance premium reductions, health savings account contributions, personal and vacation-time accruals and merchandise-based rewards.

LOCAL

The Diabetes Quality Care Monitoring System (DQCMS) provides clinicians with a tool to monitor care for individual patients and to track care for the overall practice. DQCMS is an office-based patient care tracking system that allows clinicians to monitor and evaluate the level of care provided to persons with diabetes and identify areas for quality improvement efforts. It includes pre-programmed reports to identify patients in need of preventive care and clinical follow-up services. The DQCMS is programmed in Microsoft Access and tracks diabetes indicators noted in the American Diabetes Association's (ADA) Clinical Practice Recommendations.



National Diabetes Prevention Program

COMPONENTS



Training: Increase Workforce

Train the workforce that can implement the program cost effectively.



Recognition Program: Assure Quality

Implement a recognition program that will:

- Assure quality.
- Lead to reimbursement.
- Allow CDC to develop a program registry.



Intervention Sites: Deliver Program

Develop intervention sites that will build infrastructure and provide the program.



Health Marketing: Support Program Uptake

Increase referrals to and use of the prevention program.

Current Diabetes Prevention & Control Programs

Keypoint

The estimated result of full adoption of diabetes prevention programs is a net reduction of around \$250 billion in medical costs (\$357 billion gross) and a gain of \$239 billion in productivity.

REGIONAL

The YMCA (now known as the Y) has been in the forefront with an expanding commitment to promoting community health. Over a period of four years, the YMCA of Greater Indianapolis participated with researchers at Indiana University School of Medicine (IUSM) to design, implement, and evaluate a group-based adaptation of the highly successful Diabetes Prevention Program (DPP) lifestyle intervention. Subsequently, the CDC provided funding for research to translate the original DPP into a group model and gave funding to the Y for 10 sites to implement the program. The group-based model program offers a 16-session core program that is delivered over 20 weeks, with monthly maintenance sessions for reinforcement. It encourages healthy eating, structured physical activity, and behavior modification, such as stress management and motivation.



NATIONAL

Following on the success of the DPP program (a 58% risk reduction in progressing from prediabetes to diabetes), the UnitedHealth Group has collaborated with the Y and CDC to scale the DPP model nationally. This decision led to the formation of a national network of community-based lifestyle coaches who deliver the DPP to identified people with prediabetes.

In 2010, UnitedHealth Group introduced a national version of the Asheville pilot called the Diabetes Control Program (DCP). This expansion of the Asheville model is the first scalable health service intervention that targets the population with diabetes using advanced identification tools, a proven clinical intervention and a broad network of well-trained provider pharmacists. As with the DPP, UnitedHealth is implementing the DCP in cooperation with employer groups and health plans, and provides incentives for members.

The DCP is a prime example of how the United States can use non-physician providers such as pharmacists to support primary care practices and provide continuous and intensive support for people with diabetes, through ongoing education and behavioral interventions, risk factor reduction, health promotion, and detection for early signs of complications.



New programs to increase the availability of primary care are now being implemented to provide another avenue for community-based diabetes care. Pharmacy chains such as CVS and Walgreen's have begun to offer walk-in medical care, a program that will be expanded nationwide. Diabetes counseling will be an important function of these in-store clinics.

YMCA DPP State Participants

Alabama	Missouri
Arizona	Nevada
Connecticut	New Jersey
Delaware	New York
Florida	North Carolina
Georgia	Ohio
Idaho	Oregon
Illinois	Pennsylvania
Indiana	Rhode Island
Iowa	Texas
Kansas	Vermont
Kentucky	Washington, DC
Massachusetts	Washington
Michigan	Wisconsin
Minnesota	

The Financial Stakes of Diabetes Prevention

Keypoint

The financial incentives that will drive effective programs for diabetes prevention and control are enormous. The UnitedHealth Group report provides a detailed estimate of the potential savings opportunity offered by effective diabetes prevention. The scope of these savings will drive the market to search for and implement the most effective means of realizing these benefits.

The analysis prepared by the UnitedHealth Group clearly shows how much is at stake, and how large the benefits could be if the diabetes epidemic were to be brought under control.

If all U.S. adults with prediabetes were to enroll in the DPP (Diabetes Prevention Program):

Diabetes prevalence could be reduced by 8 percent by 2020.

The number of individuals expected to convert from prediabetes to diabetes would be reduced by three million individuals over the next decade.

Cumulative health system savings will be about \$105 billion (net of the estimated implementation costs).

\$61 billion would be realized through savings to the federal government through a reduction in Medicare and Medicaid spending and exchange subsidies.

A more comprehensive program would yield even more substantial benefits and returns. Based on a simulation of a combined medical compliance intervention and lifestyle intervention focused on weight loss for people with diabetes model:

The potential to reduce diabetes-related complications would be about 10 percent by 2020.

Diabetes prevalence would be reduced by 9 percent by 2020.

Prediabetes prevalence would be gradually lowered on net by 7 percent by 2020.

Projected Savings with a Monthly Diabetes Management Program

Estimated projections made specifically in conjunction with a program of diabetes management based on monthly consultation with a pharmacist (the Asheville Project model) would produce estimated health care savings of \$34 billion over the next ten years. Savings would accrue from a reduction in the number of diabetes-related complications resulting from improved health status (as measured by a reduction in A1c and LDL levels) among people with diabetes moving from non-compliant to compliant status. Savings to the federal government were estimated to be \$21 billion over the period.

If a program based on monthly consultation with a diabetes professional were administered to all diabetes patients, new cases of diabetes complications could come down significantly. Cost savings estimates rise to \$88 billion in health care savings over 10 years. Savings to the federal government might be \$53 billion over the period.

For a combination of all projected interventions the United Healthcare Study estimates a net reduction of around \$250 billion in medical costs (\$357 billion gross) and a gain of \$239 billion in productivity.

Two Integrated Paths to Diabetes Control

A comprehensive program to stem the onslaught of diabetes will require a coordinated effort along two broad lines of attack: screening and monitoring. Patient empowerment will be at the heart of any successful effort – all of the studies and success stories to date point to the combination of patient involvement and effective counseling as key to improving health and patient outcome. These are also the methods that have proven the most cost effective.

- People in the prediabetes stage need to be informed that they are at risk in order to provide them the time and methods to make the behavioral and lifestyle changes that will prevent or postpone their condition from becoming full-blown diabetes.
- People who have been identified as at risk or who already have diabetes need to have a way that they and their health-care support system can monitor their condition. Are the actions they are taking effective, leading to improvement, or are different or additional approaches to care required?

Glycated Albumin: The Solution for Diabetes Monitoring

Keypoint

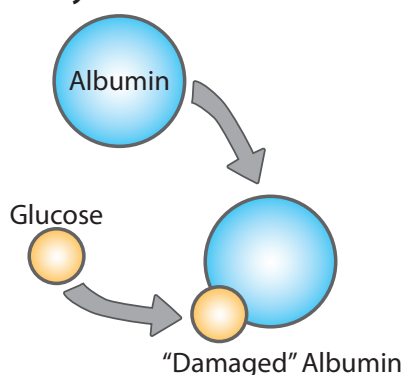
People who are at risk of developing diabetes need to have a simple and effective way to diagnose, monitor, assess risk, and measure compliance that is easy to administer, cost effective, and provides the best available information.

The key to monitoring diabetes, whether for diagnosis and screening or for compliance, is the measurement of glycation, the degree to which the excess sugar in the body is binding to various proteins and causing the damage that leads to diabetes complications. The ADA and all medical authorities have come to complete agreement on this point. (The spot testing of glucose levels as performed by individuals using the diabetes meters currently sold by the pharmaceutical companies [SMBG] does NOT provide information about glycation, and many studies have confirmed that SMBG alone is ineffective in controlling type 2 diabetes for those not using insulin [85% of diagnosed diabetics].)

The first test to become widely available that measured glycation and provided useful clinical information was the HbA1c test (A1c), which measures glycated hemoglobin. The A1c test has become the default standard for monitoring diabetes, and has recently been advocated as a diagnostic and screening tool. Although the A1c test has enabled physicians to assess glycation:

- It cannot be meaningfully administered more often than every three months, due to the lifespan of red blood cells. In clinical practice, it is frequently done every 6 months. This makes it a poor tool for monitoring short term changes in diabetes management.
- Although point-of-care instruments, and even a rapid test for A1c are available, the test is still mostly referred to the clinical laboratory, due to performance limitations and variations of the devices. This limits the opportunity for timely feedback.
- The test is not accurate for certain subpopulations of diabetics, including those with blood disorders and impaired kidney function.

Glycation Process

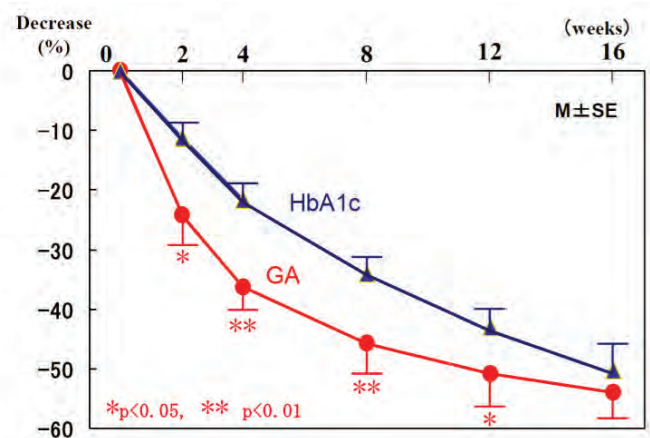


Researchers and medical authorities across the world are increasingly calling for a shift to a better marker for diabetes control: Glycated Albumin (GA). Some of the advantages of GA testing include:

- GA measures changes in glycation over a 3–4 week period and can be administered as a monthly test. It provides a better way to track diabetes treatment.
- GA is a direct marker for several of the major complications associated with diabetes, including retinopathy, nephropathy, and cardiovascular disease.
- GA is unaffected by conditions that affect hemoglobin production and has been shown to be more accurate than A1c for many diabetics.
- GA testing has been strongly recommended for monitoring of gestational diabetes.
- GA has been shown to be a potentially useful marker for diabetes and prediabetes screening.

Despite the advantages of GA, it has not been widely adopted because it has been only available as a clinical laboratory test. Due to the delayed turnaround time of laboratory tests and the relative short half-life of GA, delayed results may not accurately represent the patient's current state. A point of care version would allow instantaneous feedback.

Glycated Albumin reflects changes in glycation faster than HbA1c



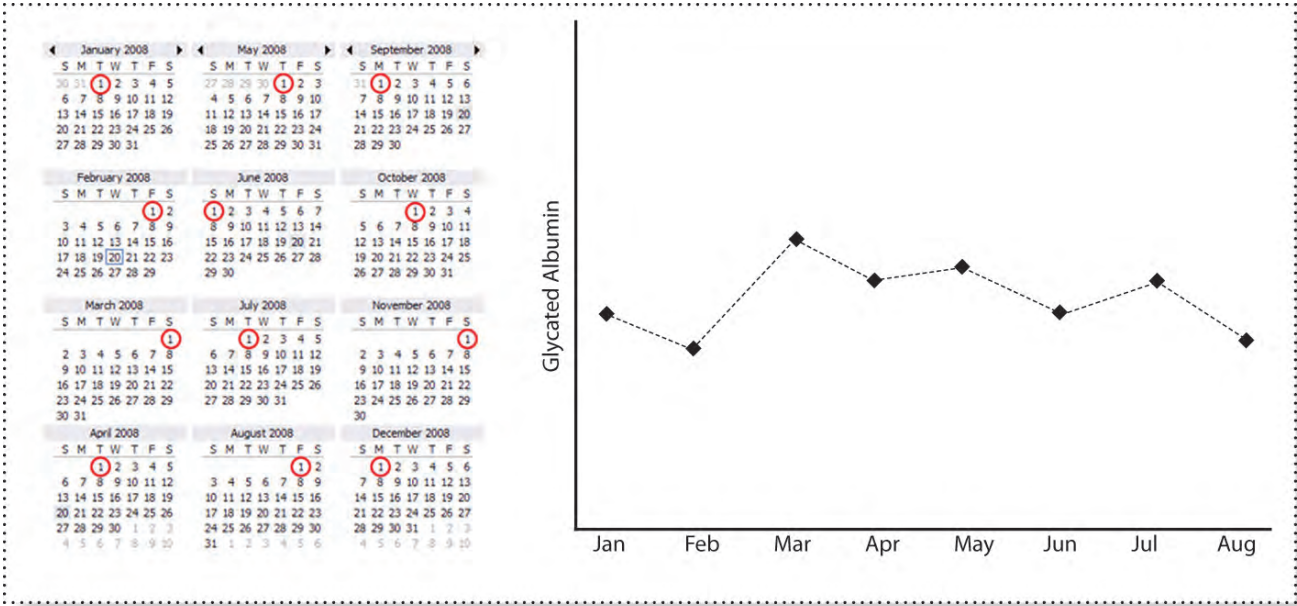
Source: Takahashi et. al.

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.

Glycated Albumin as a Monthly Report Card for Diabetes



FILLING THE GAP

Albumin Half-life
~25 days

RBC Lifespan
~120-240 days

Daily
Blood Glucose Testing
(SMBG)

MONTHLY
Glycated Albumin Testing
(G1A™)

Quarterly
Glycated Hemoglobin Testing
(HbA1c)

D 1	D 2	D 3	D 4	D 5	D 6	D 7	Wk 2	Wk 3	Wk 4	MONTH 2	MONTH 3	MONTH 4	MONTH 5	MONTH 6
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Keypoint

The most effective methods to control diabetes are based on monthly counseling. A glycated albumin test is an ideal marker to synchronize with this proven approach.

Compliance and Control

The programs that have proven successful in improving the health of diabetics and controlling the cost of care have all had a **monthly** consultation as the key to their efficacy. The Asheville Project and Diabetes Ten City Program used pharmacists, and the Y-DPP project used trained counselors. These are the projects that are now being scaled to the regional and national level. The UnitedHealth Group simulation model suggests that if similar improvements could be achieved among all people with diabetes and was maintained over the 10-year projection period, new medical complications among the diabetes population could be significantly reduced.

However, a critical component has been omitted from these programs. The Federal Government is demanding that new solutions for preventive care be evidence based. What has been missing is a way to generate that evidence, a way to precisely track patient progress and provide a clearly understandable marker that will guide diabetes counselors and empower patients to take responsibility for improving their health. Glycated albumin, in the form of a monthly rapid test that can yield immediate results at the point of counseling is the ideal choice for such a marker.

Diabetes Screening and Diagnosis

Large-scale screening for diabetes and prediabetes would make it possible to begin to reduce the onslaught of full-blown diabetes and its complications. Present barriers to effective implementation of widespread screening include:

1. Testing for diabetes or glucose impairment (prediabetes) requires fasting.
2. Several different tests are used, which can give different results.
3. The test must be performed twice to confirm the diagnosis.
4. The test must be processed in a clinical laboratory, so results are not immediately available and follow-up is more difficult.

5. The sheer number of tests to be performed is very large.

The American Diabetes Association has recently advocated for adoption of the HbA1c test as a diagnostic and screening tool, especially now that this test is becoming available as a rapid test. However, while the A1c test may solve some of the issues of access and standardization, it will still carry all the disadvantages already discussed: it does not reflect recent changes in glycation and it can be inaccurate for many groups.

Glycated Albumin is a superior option. A test based on glycated albumin has the potential to meet all of the challenges for diabetes screening and diagnosis, a concept that is backed by recent activities in the medical community:

- The Japanese Red Cross has introduced the use of GA testing to screen all blood donors for diabetes or prediabetes, with over 3 million tests done to date. The group found that when donors are informed of their GA levels:
 - More than 50% of pre-diabetic and diabetic donors showed decreased GA levels on the second testing date.
 - More than 60% of normal-high donors showed decreased GA levels on second testing date.

This study indicates that GA testing can be cost-effectively used to screen for diabetes and encourages preventive self-care behaviors from the patients.

- The Bill and Melinda Gates Foundation is sponsoring the development of a glycated albumin rapid strip test specifically to implement testing for gestational diabetes, in both the developed and underdeveloped world.

Glycated Albumin is the best choice for diabetes screening.

What is needed now is a rapid test for Glycated Albumin.

G1A™: The First Rapid Test For Glycated Albumin

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.

Epinex Diagnostics, a biotechnology company based in Tustin, California, has developed the first rapid test for glycated albumin. The patented Epinex G1A™ Rapid Diabetes Monitoring Index Test simultaneously measures albumin and glycated albumin and gives an indexed result of the percentage of glycated albumin in only a few minutes. The G1A™ test will provide timely results in a variety of clinical and point-of-care (POC) settings, allowing for patient interaction and feedback. Initially set up for use with a POC reader device, the test will be subsequently developed for over-the-counter (OTC) use.

With the growing acceptance of glycated albumin as a superior marker for monitoring glycation, the Epinex G1A™ test is poised to become a standard for care for diabetes screening, diagnosis, and control. The rapid test strip format and ease of use will make the test easy and efficient to use in point-of-care settings such as doctors' offices, pharmacies and diabetes counseling centers, and, later, with the roll-out of the over-the-counter reader, for home use that will further empower people in their efforts to control diabetes.

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
- More frequent monitoring = better control, lifestyle modification, and better long-term patient outcome

The Epinex G1A™ Rapid Diabetes Monitoring Index Test has the potential to close the information gap that exists now between the data provided by daily blood glucose testing (SMBG) 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.

Comparison of 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	test fluctuations in blood glucose levels
HbA1c	4-6 month average	once every 3-6 months	measure of long term glycation
Glycated Albumin (Epinex G1A™ Test)	1 month average	once monthly	Specific index for monitoring monthly glycation

Physician Response to the Glycated Albumin Test

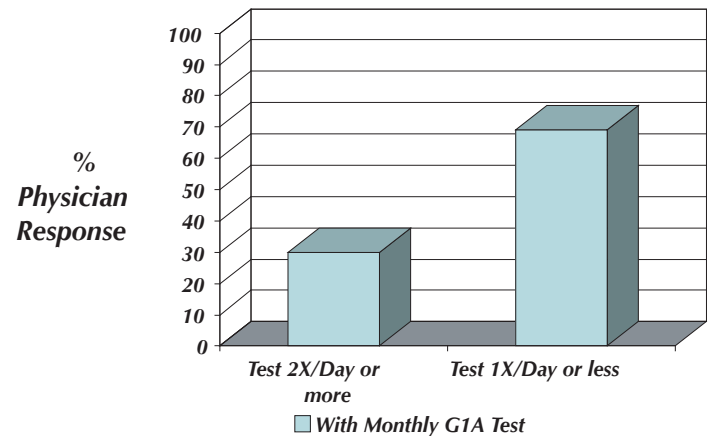
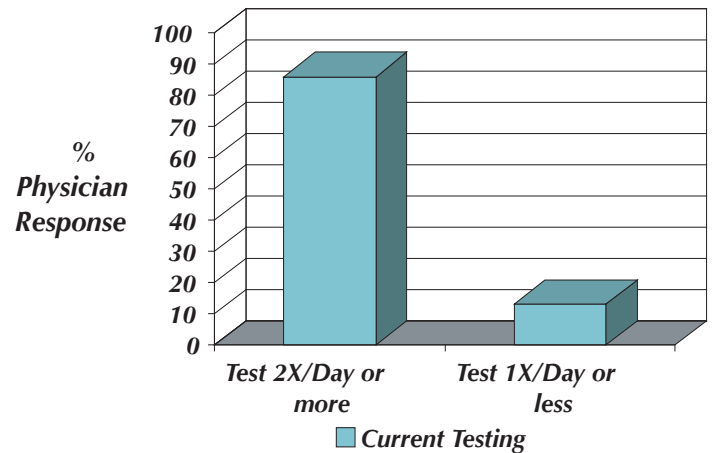
EpineX Diagnostics surveyed more than 3,500 clinical and research endocrinologists and diabetes specialists worldwide about their current diagnostic practices for type 2 diabetes patients and their opinion of the utility of a monthly test for glycation based on glycated albumin.*The Company received a highly positive response to the product concept and technology from survey respondents.

Physician Support for the G1A™ Test	
Would recommend G1A™ test for gestational diabetes	89%
Would recommend G1A™ test for diabetic patients	67%
Interested in learning more about test	90%
Physician Support for G1A™ Concept to Screen for Diabetes	
Prediabetic 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: $\pm 6.5\%$ 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.



Immediate Market Applications

Monitoring for Type 2 Diabetes

Articles demonstrating the utility of using glycated 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 levels.

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 glycated albumin testing for gestational diabetes.

Coronary Artery Disease

A clinical study published in 2007 concluded that there is “a strong and specific connection or association between elevated glycated albumin levels and coronary disease, with no correlation to HbA1c levels.” The article suggested that testing for glycated 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 glycated albumin was a better indicator of glycemia than glycated hemoglobin (the HbA1c test) for diabetes patients on hemodialysis. The authors strongly recommended glycated 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 glycated albumin (GA) and glycated 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.

Prediabetes 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.

The scale of the challenge posed by diabetes management and prevention is becoming evident to all of the stakeholders involved: governments, insurers, medical providers, and the people whose lives are directly affected - patients and their families. And now, after years of study, indecision, and detours down dead-end pathways, a consensus is emerging as to how we, as a society, can address this challenge with a meaningful opportunity for success.

We have known for a long time that the keys to managing diabetes are prevention and, when it becomes necessary, self-management of the diabetic condition. The search for an effective strategy to accomplish these goals has been long, and at times elusive. Now, at last, an effective and reproducible paradigm for diabetes monitoring and control has been demonstrated: based on monthly counseling in conjunction with evidence-based benchmarks that puts simple and easy-to-understand tools in the hands of diabetics, under the guidance of their counseling partner. Empowering diabetics provides incentives for them to meet their treatment goals, while shifting the front line of diabetes control from doctors to pharmacists, nurses, and trained counselors lowers costs significantly. These programs more than pay for all their costs through reduced medical expenses and increased productivity. This strategy has been aimed initially at people who already have diabetes, with the goal of slowing or reversing the degeneration of physiological functions affected by diabetes, and postponing or eliminating the onset of the many serious complications associated with the disease.

The success of the Asheville Project, the Diabetes Ten City Challenge, and similar programs has prompted healthcare giants like UnitedHealth to begin investigating the feasibility of expanding from diabetes control to diabetes and prediabetes screening, with the aim of using the same kinds of healthcare delivery structures to catch incipient or potential diabetes at an even earlier stage and, hopefully, reverse the condition before further treatment is required. This will be the ultimate achievement. It will be very difficult to reach this goal, but the financial analysis of both the negative and positive consequences makes the stakes of either failure or success brilliantly clear.

While we are now seeing a major advancement in our understanding of what kind of structural changes in healthcare delivery can make an impact on diabetes care, we have not yet seen a parallel advancement in the tools available to help healthcare workers and patients understand where they are and where they are trying to get to. The available tests, for blood glucose and A1c, are decades old, and have been put through many transformations as we have attempted to adapt them to new understandings and conditions. They have made a tremendous contribution, but their limitations have also become increasingly evident. They are no longer the best option, from the perspective of both information provided and cost.

Glycated albumin testing has been increasingly coming to the forefront of diabetes monitoring. It is a measurement of a marker directly linked to several of the most serious complications of diabetes. It has been shown to be a better reflection of the efficacy of treatment than other tests. It has recently been shown to be an effective marker to screen for diabetes at an early stage. And it has the potential to be tied directly to the monthly treatment paradigm that is proving effective at controlling diabetes, where it can provide the evidence-based scientific result that will reinforce treatment. The remaining step is to provide this superior test in a rapid, convenient, and cost-effective format; something that is only now becoming available. We believe that the Epinex G1A™ Rapid Diabetes Monitoring Index Test will provide this essential tool that, in conjunction with the new treatment paradigm, will transform diabetes care.

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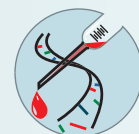
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