

Treating the Diabetes Infrastructure

A White Paper by Close Concerns¹

Introduction

The rising toll of diabetes complications are costing the U.S. taxpayers far more than previously realized. We believe these costs represent a major contribution to the rise in overall health care costs that will be virtually unsustainable by 2020. Therefore, it is time to re-examine how diabetes prevention and treatment is managed. Presented in conjunction with the Avalere Health Forum in Washington, D.C., this white paper provides new information concerning the direct and indirect costs of treating diabetes, a forecast of its serious implications, and what the “diabetes infrastructure” — which includes patients and patient advocates, doctors, educators, employers, payers and insurers, government agencies and the life science industry — can do to address the crisis. Additionally, we point to hurdles that must be overcome to accelerate drug development and market approval by the life science industry and its chief regulatory agency, the U.S. Food and Drug Administration (FDA).

Rather than giving a detailed master plan, our intent is to provide a blueprint for action, especially as President Obama lays the foundation for his new administration. The major challenge of treating a chronic disease such as diabetes is to provide patient-centered treatment, while controlling the inefficiencies and excessive administrative expenses of the larger health care system.

In order to treat the patient effectively, we also need to treat the shortcomings of the diabetes infrastructure to ensure access to care, while addressing the nation’s fiscal challenges. Our goal is to stimulate a productive dialog between policy makers, care providers, payers, patients, and industry leaders within the emerging health policy debate, and to help diabetes advocates ensure that their priorities gain traction during this critical policy window.

During his election campaign, President Obama’s health-reform agenda focused mainly on giving Americans access to care. But in his first formal address to Congress, he underscored health care reform as an issue central to the economic health of the nation: “Fixing what’s wrong with the health care system is no longer a moral imperative, but a fiscal imperative.” We strongly support this view, and we are ready to take the necessary actions to make diabetes the national priority it deserves to be.

¹ Close Concerns (www.closeconcerns.com) was founded in 2002 by Ms. Kelly Close, a person with diabetes since 1986. She is the editor-in-chief of the diabetes publications *Closer Look*, *Diabetes Close Up*, and *diaTribe*, and serves on the boards of the SF Juvenile Diabetes Research Foundation, the Children with Diabetes Foundation, and tuDiabetes.

Key Findings: The Alarming Rise in Diabetes Complications

Diabetes is all about the body's inability to manage blood sugar. It is a chronic disease that develops in response to diminished production of insulin by the pancreas (type 1) or gradual resistance to its effects (type 2 and gestational). Few people actually die directly from the disease. Poor control of the insidious complications of diabetes is what creates its chronic morbidity, mortality and skyrocketing costs. Based on our recent examination of the data, diabetes complications — cardiovascular disease, kidney failure, blindness, and amputations — are costing the U.S. health care system far more than we realized.

The national Centers for Disease Control and Prevention (CDC) reported that in 2007 the United States spent more than \$174 billion in direct and indirect costs to care for the approximately 24.4 million individuals diagnosed with diabetes — representing one out of every eight dollars of the \$2.4 trillion in federal health care costs.² In addition, another 57 million people are estimated to have pre-diabetes, putting them at increased risk. Our new estimates suggest that diabetes prevalence will jump to nearly 32 million by 2020 — nearly double the toll of 2002 if the increase in the rate of obesity persists at the current rate of 5 percent per year.³

The number of new diabetes cases is highly correlated with demographics — in particular, the growing size of the baby boomer generation now reaching about 63 years of age. Our analysis of prevalence rates shows a sharp rise of diagnosed diabetes among people in their mid-50s to mid-60s, peaking at about age 65 and then leveling off.⁴

What is striking in our analysis is that the cost of treating diabetes complications reached nearly \$40 billion in 2007 — double that in 2002. Moreover, assuming this rate remains constant, the trend will continue with \$52.6 billion projected in 2012, and \$75.1 billion in 2020 (Fig. 1). The growing rate of complications imposes a significant burden on the country's health care costs. Data from the Medical Expenditure Panel Survey (MEPS) showed that in 2003, 6.3 percent of adults were receiving diabetes care, but expenditures for diabetes care totaled 17 percent of health care expenditures.

While the total spending stands as a major concern, the sharp rise in spending on diabetes complications is especially disturbing. *Although the direct costs of diabetes rose 26 percent between 2002 and 2007, the complication costs increased 110 percent.*

² Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, 2006 National Health Care Expenditures Data, January 2008.

³ Based on data provided by The Lewin Group.

⁴ Ibid.

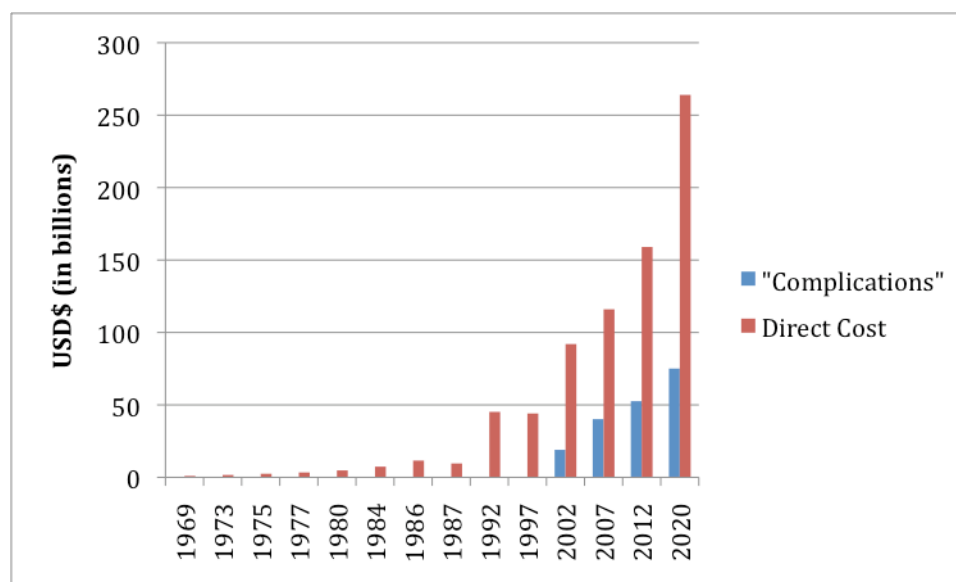


Fig. 1. The Cost of Treating Diabetes — The cost of treating diabetes complications reached \$40 billion in 2007 — double that of 2002.

The Skyrocketing Cost of Complications

The costs of complications are rising rapidly because more patients are developing the disease earlier, and more patients are experiencing long-term complications that require costly treatments. By the time an individual is diagnosed with Type 2 diabetes, the most common form of the disease, the development of complications has often already begun. The reality is that these poor outcomes are largely preventable with proper management and treatment.

Diabetes prevention and treatment, more than any other disease, is about education, training, and proper management. Yet the government only spends \$4 billion on diabetes prevention and health promotion — or 3.5 percent of the \$116 billion in direct costs to treat diabetes.⁵ Patients need help in learning how to adjust their medications so they don't join the 50 percent of those who fail to take their medicine in the first year of therapy. In addition, they need help with managing their diet, overcoming social and psychological burdens, leading healthier lifestyles, and integrating the constant demands of an unforgiving disease into their lives.

From Acute Care to Chronic Care Management

Although there has been a gradual shift to diabetes prevention during the past few years, the U.S. health care system is still geared toward acute or episodic care. Rather than covering the costs for education, early disease management and preventive care, payers are more apt to cover a discrete injury or temporary illness that can be resolved

⁵ Based on a 2007 study by Mathematica Policy Research, Inc., for the National Changing Diabetes™ Program, created by Novo Nordisk.

through rapid intervention. As one physician said, “You get paid more to spray a wart for five minutes than for spending 30 minutes educating a diabetes patient.”

Microalbuminuria illustrates the point: If small traces of protein (albumin) are found in the urine, the estimated per annum “state cost” (the annual additional cost of care following such an event) is \$14. However, if left undetected and untreated, the condition can lead to a per annum “state cost” of \$53,660 due to end-stage renal failure and the need for kidney dialysis. In 2001, 142,963 people with diabetes were living on chronic dialysis or with a kidney transplant. Assuming half of these patients were on dialysis, the cost would be nearly \$4 billion to keep this group alive. This cost is especially noteworthy because this patient group represents less than 1 percent of all people living with diabetes.

Recommendations

As health care reform is once again on the national agenda and a top priority for President Obama, now is the time to examine how government at all levels can be a major coordinating force for diabetes prevention, detection, treatment and management of complications. Although there are many agencies dedicated to diabetes at the



Fig. 2. Treating The Diabetes Infrastructure — In this model the patient is the focus of positive support, health and wellness. The patient is seen not as a “self-management problem,” but rather as the focus of a shared solution driven by social responsibility throughout the network.

federal, state and local levels, we believe there is also a need for stronger leadership and coordination throughout the diabetes community — what we call “Treating the Diabetes Infrastructure.” In this model the patients are the focus of positive support, health and wellness — and are not treated like an unfortunate victim (or even a pariah) of a chronic disease for which they are sometimes blamed (Fig. 2).

In addition to advocating for a more tightly coordinated diabetes network, we recommend treating the patient not as a “self-management *problem*,” but rather as the focus of a shared health solution driven by social responsibility — a theme that underlies President Obama’s agenda for aligning all of our nation’s programs for economic recovery. Accordingly, we advocate “health management” rather than “disease management,” where the “treatment modality” is based on providing the diabetes infrastructure with positive incentives for promoting *wellness* rather than sickness.

One reason why Barack Obama’s presidential campaign was so successful was that he understood the collaborative power of community and social networking — both in real space and cyberspace. Can the nation develop and leverage a similar network for diabetes health? Can we apply this vision of health management to other chronic diseases? Beyond the expediency of electronic patient records, the promise of health-care information technology may also hold the key to making the diabetes infrastructure a viable network for improving our health and well being.

Earlier Prevention and Treatment of Diabetes Complications

- ❖ **Patients** — Type 2 diabetes can be prevented in two-thirds of people by improved physical activity and diet. Early detection and treatment is key to reducing the cost and progression of diabetes complications. More resources are needed for diabetes education across all socio-economic groups. Since obesity is a major risk factor in people with pre-diabetes, we need to provide incentives for supporting “slow food” vs. “fast food” at home, in schools, and in the work place. We also need to de-victimize overweight individuals and positively support lifestyle changes that emphasize appropriate exercise programs at home, at school, and in the community for people of all ages. Although lifestyle modification programs may be expensive, they are a bargain compared to the cost of treating patients who have had cardiovascular or renal problems.
- ❖ **Government** — Leadership across federal, state, regional and city agencies must be better coordinated with a sense of shared social responsibility. Consideration should be given to establishing a central coordinating agency to ensure objectives are being met. Fund more NIH-sponsored translational research aimed at accelerating new technologies for diabetes detection, prevention and treatment. Additionally, provide incentives for medical students (physicians, specialists, diabetes educators) to major in diabetes specialties.

- ❖ **FDA** — The challenge for FDA regulators is to balance a drug's risks vs. benefits, ensuring patient safety while not being an impediment to innovation and commercial development of novel products. Unfortunately, these objectives are not always aligned. The FDA's recent guidance, which places an increased focus on cardiovascular (CV) risk and drug safety of diabetes therapies, is a case in point.
- ❖ New regulatory guidance requires pre-registration data to show exclusion of significant adverse CV risks, and pre-marketing CV outcomes studies may also be required, which means more years of drug testing and millions of dollars more to the cost of developing a diabetes drug.

We believe the current regulatory environment for diabetes drugs is too stringent for drugs that do not exhibit cardiovascular signals. Furthermore, it may be helpful for the FDA to consider more input from health care providers and patients who are close to the "front lines" of disease management. These individuals may be able to share with the FDA critical information regarding the patient's experience with diabetes drugs, especially as they relate to patient adherence – many current treatments cause troublesome side effects, leading to low adherence. Often this information is not available from clinical trials. Notably, we also strongly support more funding for an under-resourced FDA so that the agency can consider more alternatives for patients with diabetes.

- ❖ **Universities, Medical Schools** — Not enough attention is paid to educating general practitioners and allied health-care providers such as diabetes educators. Additionally, there are few incentives for physicians to become endocrinologists — in 2009 18% of endocrinology fellowships remained unclaimed. The response to these problems should include a reassessment of medical school curricula with regards to diabetes, and a re-examination of the requirements for CDE certification. Create financial subsidies and other incentives for students to pursue the endocrinology specialty, and provide educational loan subsidies or forego a certain percentage of the loan payback.
- ❖ **Payors** — Too often, insurers and payors have a short-term view of disease management, rather than a long-term focus on health and wellness. Successful wellness programs are being implemented, and we should examine what works (e.g., the Kaiser Permanente *Thrive* program) and what doesn't. Focus on value-based health insurance, and reward healthy behaviors such as gym memberships, educational workshops, and non-smoking with reduced premiums — similar to good-driver car insurance programs.

- ❖ **Drug and Medical Device Companies** — The pharmaceutical and medical technology industry can work more closely with universities to help fund translational research programs. Pfizer's multimillion collaboration with the California Institute for Quantitative Biosciences (QB3) represents an emerging model for accelerating drug discovery and innovation from the university to the marketplace. Since the venture capital industry is virtually absent from funding life science start-ups, federal and state governments could consider establish seed venture funds to help finance development-stage companies that show promise.

Many diabetes drugs elicit serious side effects that impede patient adherence. Current treatments, while tolerable and effective in some, are not suited to all patients. For example, in some patients metformin can cause nausea (40 percent reported drug intolerability in the DREAM study) and kidney dysfunction; sulfonylureas can cause hypoglycemia (low blood sugar), weight gain, and nausea; TZDs (thiazolidinediones) can cause liver problems, weight gain, edema, and fractures, and they have been associated with increasing the risk of congestive heart failure. Thus, drug companies should be encouraged to develop next-generation and additional classes of drugs for diabetes that have less deleterious side effects.

- ❖ **Doctors and Educators** — While the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) recommend starting metformin and lifestyle treatment immediately after diagnosis, then continuing on to combination pharmacotherapy as the disease progresses — this recommendation does not always translate into clinical practice. Often a patient's regimen is not adjusted when his disease starts to progress, and the patient does not always adhere to the prescribed regimen. Titration can also be a major problem, especially with primary care doctors who do not have enough time to spend with each patient. Although there are several different types of diabetes medications, each drug may be more or less effective for a given patient, and many patients are unable to take certain drugs without experiencing intolerable side effects. Lifestyle modification is often difficult for patients to sustain without close support. We support more education for patients, especially through diabetes educators working in tandem with physicians.

Conclusion

Our health care system has created a cruel irony for people with diabetes: they are underserved when trying to stay healthy. Only after developing full-blown complications — a foot requires amputation, kidneys require dialysis, a blood vessel needs to be unplugged — are they treated generously. Cooperation and coordination among all

members of the diabetes infrastructure is required. The system needs to be re-examined to make sure enough money and resources are invested in keeping these patients healthy before they develop serious complications. This can be said of everyone, regardless of their health condition — preventing disease is more cost-efficient than treating it.