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EDITORIAL

Business and Economics of Diabetes

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The many medical and engineering dimensions to diabetes technology that *Journal of Diabetes Science and Technology* focuses on are matched by an equal number of business, economic, insurance coverage, and reimbursement problems that must be solved in order for device manufacturers to develop and provide these technologies for people with diabetes.

Good science decisions are necessary to develop diabetes technology, but good business decisions are also necessary for this process to succeed. In order for the field of diabetes technology to advance and in order for products containing novel technologies to be developed and utilized, these products will need to survive economically. After a product is conceived the company must accomplish a demanding set of tasks, including creating a business plan, securing intellectual property rights, obtaining funding, selecting management, hiring staff, and developing an infrastructure. Every one of these specific tasks necessary to develop and market a new technology must be accomplished if the product is to evolve from a concept to an actual product that will be used to help people with diabetes.

A great number of correct business decisions are necessary to bring a product containing new technology to fruition.[1] A new product containing a new technology must be developed, tested in-house, tested in a real world environment, approved by the Food and Drug Administration, manufactured on a commercial scale, distributed, marketed, and sold. If third-party reimbursement is part of the business plan, then arrangements must be made for the product to be covered by insurance and adequately reimbursed. The economic climate where the patient lives will greatly affect whether the technology will ultimately be available. Many large institutions can affect this climate. Economic and business policies set by any patient's government regarding factors can directly affect the ability of a company to succeed. Such factors subject to governmental regulation include intellectual property, patent protection, sales of generic products, product safety and liability, regulatory approval, postmarked surveillance, and taxation. Economic and business policies set by payors of technology related to coverage and reimbursement will play a major role in whether a technology will become available to large numbers of patients.[2] Improved diabetes care affords economic benefits to health plans, as well as important quality of life benefits to patients with diabetes.[3]

For workers with diabetes, corporate activities to improve diabetes care and education will help maintain productivity, decrease diabetes-related complications, and reduce diabetes-related costs. For inpatients with diabetes, the evolving roles and functions of hospitals are increasingly affecting the types of services available to diabetes patients who sustain a severe acute breakdown. Individual companies face unique pressures to produce new products profitably in a competitive environment

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where intellectual property is often disputed and generic products offer savings to consumers but might stunt the development of future products in some cases. Thus, multiple economic factors on the national level, on the industry-wide level, and on the level of the individual product manufacturer will affect the availability of new products for diabetes.

Diabetes is a worldwide disease. Economic conditions and policies of national various regulatory bodies that control access to medical technologies must be favorable in order for a patient in that country to have access to a technology, and these policies are often different in each country. With approximately 250 million people affected by diabetes worldwide, diabetes is extracting an increasing toll from the world economy. People with diabetes incur medical costs that are two to three times higher than those without diabetes. Furthermore, diabetes leads to significant indirect costs to the economy through early retirement and a disproportionate requirement for sick days and disability. As the U.S. population grows older and fatter, it might be anticipated that diabetes prevalence rates and future costs of this disease might grow at even faster rates than would be extrapolated from current prevalence rates.[4]

The practice of screening for undiagnosed diabetes or impaired glucose tolerance has been proposed because of potential public health and economic benefits to society. This practice affords the potential for preventing future diabetes and cardiovascular disease in these groups with lifestyle modification, drugs currently used for treating known diabetes, and statin drugs.[5] Further research is needed into the duration of states that precede diabetes and whether the rise in blood glucose levels in these states is linear throughout or whether there may be a slower initial phase followed by acceleration around the time of a clinical diagnosis.

Lifestyle interventions have been shown to prevent diabetes and obesity in high-risk individuals. These interventions may also be cost-effective (compared to other interventions providing similar health benefits that are generally accepted as worthwhile investments of societal resources) or even cost-saving in some groups.[6] Other interventions for people with known diabetes might be economically as well as medically attractive, such as control of hyperglycemia, blood pressure, and lipids, as well as routine pneumococcus and influenza vaccinations and aspirin prophylaxis therapy.[7] A pay-for-performance incentive has been shown to increase the provision of support for smoking cessation and has been associated with a reduction in smoking prevalence among patients with diabetes in primary health care settings.[8] These types of initiatives will become increasingly attractive from the economic perspective, if not the public health perspective, if the nation's health care dollar expenditures come under increasing pressure.

In this issue of *Journal of Diabetes Science and Technology* we will launch a new section devoted to business and economic trends in diabetes. This will be the first section in a medical journal devoted to this topic. The section will be edited by Ogan Gurel, M.D. The section will contain opinion pieces and analyses by experts in business and economic aspects of diabetes, and the section will shed light on how to spark the development and utilization of new diabetes technology from the business perspective.

Dr. Gurel received an A.B. from Harvard University, an M.Phil. in Biochemistry and Molecular Biophysics from Columbia University, and an M.D. from Columbia University. He then trained in surgery at Massachusetts General Hospital. Dr. Gurel is chairman of the Aesis Group in Chicago, which provides strategic marketing, international marketing, market forecasting, technology assessment, and business research services to life sciences and health care corporate and investment decision makers. His clients include startups, hospitals, health systems, private equity firms, venture capital funds, and hedge funds. Dr. Gurel has taught structural biology, computer science, cellular and molecular biology, neuroanatomy, bioinformatics, and mathematical modeling at NYU, Columbia, Roosevelt, and Harvard universities and is presently an Adjunct Associate Professor of Bioengineering at the University of Illinois in Chicago. *Journal of Diabetes Science and Technology* welcomes Dr. Gurel to the journal. He is an accomplished leader in the diabetes technology community.

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