Journal of Diabetes Science and Technology
Volume 3, Issue 6, November 2009

The Business of Intensive Insulin Therapy for Type 2 Diabetes Patients: Where It All Began for Me

Evan Norton, B.B.A, M.B.A.

Abstract

Ideally, it would be easy for physicians with Diabetes Control and Complications Trial data in hand to convince type 2 diabetes mellitus (T2DM) patients on insulin to move toward intensive insulin therapy (IIT), but in actuality, patient compliance remains a significant issue. One of the statistics that best illustrates this point is that 89% of T2DM patients on insulin do not inject themselves outside of the home (according to the National Health and Nutrition Examination Survey). The market has responded to poor compliance by developing insulin pens and different insulin formulations to improve compliance. But the fact remains that most T2DM patients on insulin are out of control. I would suggest that, in addition to better education, an opportunity exists for a medical device approach to better facilitate an easy-to-use, discreet approach to moving from conventional to IIT.

J Diabetes Sci Technol 2009;3(6):1521-1523

Earlier this decade, I worked for J&J's LifeScan division, managing its OneTouch® Ultra® blood glucose monitors and test strips business. I vividly remember the day the sales of the test strips surpassed one billion (yes, one billion) dollars. The product joined an elite group of brands, such as Coca-Cola®, that reached one billion dollars in sales in a calendar year. While obviously a clear business milestone, it made a lasting impression on me regarding the chronic nature of diabetes.

Additionally, my time in the blood glucose monitoring business allowed me to learn the significant difference in value from a business perspective between people with different types of diabetes (type 1 versus type 2) and the treatment regimen of these patients. For example, of the one billion dollars in OneTouch Ultra test strip sales, approximately 30% of the sales, or nearly $300 million, came from 18% of the patient population who were either type 1 or type 2 diabetes patients on intensive insulin therapy (IIT). Without question, winning with this small but valuable segment of the market was critical to any successful strategy. I was struck by how different type 1 diabetes (T1DM) patients were versus T2DM patients in this population. Market research suggested that T1DM patients become well accustomed to using insulin pumps or giving themselves multiple daily injections. Type 1 diabetes patients also have more information and motivation that is typically provided or at least enhanced by diabetes education programs and diabetes educators. Additionally, people with T1DM typically have more diabetes education and a better understanding of their disease because of increased glucose monitoring. Type 2

Author Affiliation: ONSET Ventures, Menlo Park, California

Abbreviations: (DCCT) Diabetes Control and Complications Trial, (HbA1c) hemoglobin A1c, (IIT) intensive insulin therapy, (T2DM) type 2 diabetes mellitus

Keywords: business, diabetes, intensive insulin therapy, type 2 diabetes

Corresponding Author: Evan Norton, B.B.A, M.B.A., ONSET Ventures, 2490 Sand Hill Rd., Menlo Park, CA 94025; email address *evan@onset.com*

diabetes patients, who typically develop the disease later in life, can struggle with the transition to insulin and especially IIT. Because of the rapid growth and progression of the disease among T2DM patients, more and more of them are ending up on IIT. Intensive therapy for T2DM patients increased dramatically between 2002 and 2006—increasing from 20% of T2DM insulin users being on intensive therapy in 2002 to 31% of T2DM insulin users being on intensive therapy in 2006.[1] These numbers suggest a total T2DM intensive insulin population between 1.2 million and 1.4 million. While significant, the total number of T2DM patients on insulin was estimated to be 4.5 million.[1] Even more startling, of the 4.5 million on insulin, 60% (or 2.7 million people) were not at their hemoglobin A1c (HbA1c) goal (or, stated another way, were "out of control"). These out-of-control people with diabetes represent a significant business opportunity.

There are a number of ways to look at the market potential. Oversimplified, you could think about the number of patients in the target audience, approximate an annual usage, insert the revenue per device or drug to determine the market size, and calculate a total potential market value. Another way to look at the opportunity, which I found more compelling, was to analyze the potential health care cost savings associated with moving a T2DM patient on insulin from out of control to in control.

A Model for Estimating Cost Savings

The Diabetes Control and Complications Trial (DCCT) Study Group demonstrated the benefit associated with intensive insulin therapies. Patients moving from conventional to IIT had a median reduction in HbA1c range going from 8.7–9.2 to 6.7–7.2.

Assuming that moving an out-of-control T2DM patient on insulin from conventional insulin therapy to IIT would result in a two-point reduction in HbA1c, the analysis shown in **Figure 1** can be created to demonstrate the cost savings potential.

As illustrated in **Figure 1**, it is clear that there is a significant business opportunity and, more importantly, better health outcomes associated with moving T2DM patients on insulin from conventional to IIT.

How Do We Get There?

Ideally, it would be easy for physicians with DCCT data in hand to convince T2DM patients on insulin to move toward IIT, but in actuality, patient compliance remains a significant issue. One of the statistics that best illustrates this point is that 89% of T2DM patients on insulin do not inject themselves outside of the home.[6] The market has responded to poor compliance by developing insulin pens and different insulin formulations to improve compliance. But the fact remains that most T2DM patients on insulin are out of control. I would suggest that, in addition to better education, an opportunity exists for a medical device approach to better facilitate an easy-to-use, discreet approach to moving from conventional to IIT. A few technologies are emerging to target this patient population, including I-Port® (Patton Medical), Click-It (Calibra Medical), and V-Go™ (Valeritas, Inc.). All of these devices are mechanical only, with no electronic parts. I break the products into three groups (**Figure 2**), acknowledging that physicians and patients themselves will help to determine which product is a best fit for managing a patient's disease.

While the medical device market for enabling T2DM patients on insulin to move to IIT is just emerging—you never know—one of these emerging technologies might join OneTouch Ultra as a brand with over one billion dollars

Average per capita annual costs of health care for people with diabetes[2]	$11,744
Reduction in health care costs associated with 2.0% HbA1c reduction[3,4]	11%
Annual cost savings	$1,291.84
Estimated life expectancy of person with type 2 diabetes[5]	between 13.2 and 21.2 years
Lifetime cost savings using the lower range (13.2 years)	$17,052.29
Estimated number of type 2 diabetes patients on insulin who are out of control	2,700,000
Total estimated cost savings potential for moving patients to in-control group	$46,041,177,600

Figure 1. Demonstration of cost savings potential.

	Baby Step	Half Step	Full Step
Product	I-Port	Click-It	V-Go
Description	Injection port for basal and bolus injections	Pump/patch for basal insulin	Pump/patch for basal and bolus insulin
Short Commentary	Helps to overcome needle phobia	Easy, discreet for postprandial insulin	Most physiological approach
Website	www.pattonmd.com	N/A	www.valeritas.com

Figure 2. Product breakdown.

in sales in a single year. Let's hope this is the case, and most importantly, let's hope improved compliance will also be a runaway success.

Disclosure:

The author is an employee of ONSET Ventures, a venture investor in Valeritas, Inc.

References:

1. Roper Global Diabetes Program, 2006 U.S. Diabetes Patient Market Study, management summary report. March 27, 2007.
2. American Diabetes Association. Diabetes statistics. *http://www.diabetes.org/diabetes-statistics.jsp*. Accessed on September 24, 2009.
3. Gilmer TP, O'Connor PJ, Manning WG, Rush WA. The cost to health plans of poor glycemic control. Diabetes Care. 1997;20(12):1847–53.
4. Diabetes Control and Complications Trial Study Group. Implementation of treatment protocols in the Diabetes Control and Complications Trial. Diabetes Care. 1995;18(3):361–76.
5. Leal J, Gray AM, Clarke PM. Development of life-expectancy tables for people with type 2 diabetes. Eur Heart J. 2009;30(7):834–9.
6. Hoerger TJ, Segel JE, Gregg EW, Saaddine JB. Is glycemic control improving in U.S. adults? Diabetes Care. 2008;31(1):81–6.