diaTribe®

research and product news for people with diabetes

in this issue

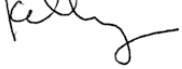
from the editor

A few days ago, I received the most amazing news. As you may recall from Jim Hirsch's extraordinary logbook in *diaTribe* #45, Jay Ward is a prisoner at Leavenworth's medium-security penitentiary who has been receiving dangerously substandard care for his type 1 diabetes. Jay was receiving NPH and regular insulin hours after his meals instead of the recommended 15-30 minutes before meals, causing his glucose levels to spike to 300 or 400 mg/dl and putting him at a significantly increased risk for diabetes complications. But now, thanks to the inspiring, tireless advocacy of Jay's father, of *diaTribe* contributor Jim Hirsch, and all of you who so wonderfully declared your support by signing our petition, Jay is now receiving a combination of Lantus and rapid-acting insulin. This is unquestionably a huge step forward, especially because he is now getting these newer insulins before lunch and dinner. While his care still isn't perfect – Jay still gets his morning insulin shot after breakfast and Leavenworth doctors are still refusing to treat the hepatitis C he previously contracted during his incarceration – it's moments like these that give me hope that, if we work together, we can help those who need it most. Thank you, again.

Indeed, Jay's story is a dramatic illustration of a more basic point: in the daily management of diabetes, we all face challenges and roadblocks. Encouragingly, technology is making our efforts easier, in both obvious and less noticeable ways. For instance, look no further than this month's *diaTribe* dialogue with Jeff Hyman, founder and CEO of Retrofit, a data-driven weight loss start-up. Retrofit is all about aggressively helping people lose weight – either 10% or 15% over the course of a year. Retrofit provides a team of experts – a dietitian, an exercise physiologist, and a behavior coach – whose job (via personalized live appointments on Skype) is to keep people on that path to weight loss and, ultimately, to weight management. As Jeff told us, the secret to success is his team just won't allow Retrofit users to quit. Speaking of technology, some big news this month for people with type 1 and type 2 on insulin (albeit those with good insurance) is the launch of Tandem's new touchscreen insulin pump, the t:slim, which is the first insulin pump with a touchscreen. See Adam Brown's test drive for our take on what makes the pump's features different from others on the market.

Still, for all the amazing resources available and all the loved ones and experts there to offer their help, it's easy to feel overwhelmed by the personal responsibilities and burdens of your own daily diabetes care. That can mean either going overboard in your self-management or letting things slide and forgetting critical parts of your care. Diabetes educator Gary Scheiner devotes his latest think like a pancreas column to how best to work through and ultimately avoid these issues. Anyone who has ever struggled with how best to manage their insulin will benefit immensely from Gary's common-sense tips. We know diabetes requires optimum resources to help ease the stress – and that's why we're always working to make *diaTribe* one of the best resources available.

very best,



diaTribe staff

diaTribe advisory board

quotable quotes

"The First Lady and I have met with four-star generals who say obesity may be our greatest national security threat…we hear stories of new recruits breaking bones and having joint problems because they have not grown up with all of the various cross-fitness activities that have made us strong and healthy."

- Mr. Sam Kass (White House Assistant Chef and Senior Policy Advisor for Healthy Food Initiatives, Washington D.C.) on the urgency of increasing physical activity and combatting childhood obesity, at the US Open, September 1, Flushing Meadows, NY.

"If people work in an environment where they believe there is meaning, they will put up with a lot. It goes beyond the significant personal consequences for an individual physician. It affects whom patients can see when they are sick, the quality of care they receive and their safety… Doctors are losing their inspiration, and that is a very frightening thing."

- Dr. Tait D. Shanafelt (The Mayo Clinic, Rochester, MN), from Dr. Pauline W. Chen's New York Times article "The Widespread Problem of Doctor Burnout."

"Only a quarter of doctors are self-employed – an extraordinary turnabout from a decade ago, when a majority were independent. They've decided to become employees, and health systems have become chains."

- Dr. Atul Gawande (Brigham and Women's Hospital, Boston, MA), from his New Yorker article "Big Med."

fingersticks

The chase is on…

new now next

Qsymia is now available from select mail-order pharmacies. The low 3.75 mg dose (above left) costs about $120 per month. The recommended 7.5 mg dose (above right) costs around $135 per month.

T1/2 **Vivus' Obesity Drug Qsymia Launches**

On September 17, Vivus announced that its obesity medication Qsymia (formerly Qnexa) is now available on the US market – this happened at least several weeks earlier than expected. Qsymia is a once-daily pill extended release combination intended to be used with diet and exercise by adults with a body mass index (BMI) greater than 30 kg/m2 or a BMI greater than 27 kg/m2 and a weight-related condition such as type 2 diabetes, high blood pressure, or high cholesterol (see new now next in diaTribe #45). As a reminder, the drug is available in four different doses to give users more flexibility and to ease the transition to the higher doses. The recommended mid dose of Qsymia will cost approximately $135 per month (about $5 per day), the lower dose will cost $120 per month, the three-quarter dose will be about$163 per month, and the high dose will be about $184 per month (about $6 per day), although these prices may be somewhat higher depending on where the drug is purchased. Since only around 30% of prescriptions for weight-management drugs are paid for by private insurers and Medicare Part D does not cover weight-management medications as yet, it is likely that people who want to use Qsymia will have to pay these costs out of pocket initially. However, Vivus is optimistic that some employers will soon take on at least some of the cost of the drug. The company is also working with private insurers and the government to get Qsymia covered in the future. Initially, Qsymia will be available through certified mail order pharmacies from Walgreens, CVS, and Kaiser Permanente (for members only), though expansion to other pharmacies is expected soon. Vivus' ability to get Kaiser on board so early is particularly notable in our view, as it likely signals future potential for coverage by the very influential and cost-focused insurer. And indeed, we believe the Kaiser coverage speaks volumes about what may be available going forward – we suspect large employers over time who really want to help their employees will be covering it. For more information on Qsymia, speak with your healthcare provider or visit www.qsymia.com, and if you work at a company you would like to see cover it, speak with your benefits manager. *–AW*

The US Capitol Building.

T1/2 **Alert! Seniors on Medicare, Look For Access to the Diabetes Prevention Program**

Exercise and weight loss have been shown to significantly reduce a person's risk of moving from prediabetes to type 2 diabetes. However, insurance coverage for these lifestyle-based prevention programs is relatively rare, which often makes them too expensive for many who are at the greatest risk. To that end, Senators Al Franken (D-MN), Richard Lugar (R-IN), and Jay Rockefeller (D-WV) recently introduced the Medicare Diabetes Prevention Act of 2012, which if enacted would provide seniors access to the Diabetes Prevention Program (DPP) through their Medicare benefits (read full details of the bill here). A landmark clinical trial found that the DPP reduced the risk of diabetes by 71% in people over 60. The program is currently offered at over 300 YMCA branches in 30 states (see new now next in *diaTribe* #23). Over 16 weeks, the DPP sets two main goals for its participants: to reduce body weight by 7% and to participate in at least 150 minutes of physical activity each week. The ADA has strongly endorsed both the DPP and the Medicare Diabetes Prevention Act.

The bill suggests that extending access to the DPP to all Medicare beneficiaries could prevent as many as three million people with prediabetes progressing to diabetes between now and 2020. Because medical expenses for people with diabetes are more than double those without the condition, the total savings are estimated at over $190 billion over the next decade. The bill could also pave the way for further expansion of coverage so that even more of the estimated 67 million Americans with prediabetes can gain affordable

access to the DPP. Unfortunately, the congressional monitoring site GovTrack gives the bill a relatively low probability of being passed, though our fingers are crossed, and we will continue to keep tabs on its progress over the coming months. If you're looking for ways to advocate for the bill's passage, check out Kerri Morrone-Sparling's sum musings in *diaTribe* #46. *–AW*

Takeda's TZD medication Actos will now be sold in generic form by Mylan, Teva, and Ranbaxy.

T2 Takeda's Oral Medication Actos Goes Generic, Making it Significantly Cheaper

On August 17, the FDA approved Mylan's new generic versions of Actos (pioglitazone), a once-daily oral tablet for the treatment of type 2 diabetes originally sold by Takeda. Mylan, Teva, and Ranbaxy all plan to sell generic versions of the drug. The introduction of generic Actos should substantially reduce the price of the drug. One estimate suggests the current price of $270 for 30 mg Actos could drop to $153 this time next year, and by 2015 the price could be as low as just $15, and no more than about $90. This means Actos now has significant potential as a low-cost treatment for type 2 diabetes, which could mean healthcare providers will become more likely to recommend its use.

Actos belongs to a class of medications called TZDs (short for thiazolidinediones), which potently lower blood glucose levels by making the body more sensitive to insulin. First approved in 1999, Actos is currently the only drug in this medication class to be widely available in the US and Europe. The first drug in this class, Warner-Lambert's Rezulin, was pulled from the market in 2000 because of liver toxicity. GlaxoSmithKline's Avandia, was also approved at almost the same time as Actos but became restricted in 2010 due to concerns about an association with heart attacks (see new now next in *diaTribe* #24). Actos also has a number of side effects including weight gain and bone fractures, and clinical studies have more recently revealed an increased risk of bladder cancer in people taking Actos, (see new now next in *diaTribe* #34). An NIH-backed study found people taking Actos for more than five years were two to three times more likely to develop bladder cancer than those taking other diabetes medications. As a result, the use of Actos as a type 2 diabetes treatment has declined by about 40% in the past year. Despite these concerns, use of Actos at low doses is still endorsed by many leading diabetologists because of the drug's unique benefits on insulin resistance. Also, the link with bladder cancer is based on the five-year analysis of a Takeda-backed study – the more recent eight-year analysis suggests the link between Actos and bladder cancer was weaker than previously thought, and did not appear to be statistically significant for any of the groups tested.

Of the three companies selling generic versions of Actos, Teva and Mylan also plan to launch generic versions of Actoplus Met, a combination therapy that incorporates both Actos and metformin in a single pill.The FDA applies the same stringent safety requirements to generic drugs as it does to their brand name counterparts, meaning that the risk of bladder cancer is no different in the generic tablets than it currently is in Takeda's Actos. With these safety concerns in mind, we suspect many doctors and nurses will shy away from use – that said, the lower price is certainly attractive and some believe that much lower doses confer much lower risk for side effects. *–AW*

Nucynta ER is available in five doses, including 100 mg, 150 mg, and 200 mg.

T1/2 Chronic Pain Drug Nucynta ER Granted FDA Approval for Management Of Diabetic Peripheral Neuropathy

On August 29, J&J's chronic pain drug Nucynta ER (tapentadol) was granted FDA approval for the management of the pain associated with diabetic peripheral neuropathy (DPN). Diabetic neuropathy is one of the most common complications of diabetes, affecting about half of all people with diabetes at some point in their lifetimes. Peripheral neuropathy, which primarily affects the legs and feet, is one of the most common

forms of this condition. Improved blood glucose control can slow down and sometimes even reverse the damage to nerves, but medications and devices are often still needed to treat the pain and numbness of neuropathy. Nucynta ER is the third drug to gain FDA approval to treat DPN, following Eli Lilly's antidepressant Cymbalta (duloxetine) and Pfizer's anticonvulsant Lyrica (pregabalin). Last month also saw the approval of NeuroMetrix's pain management device Sensus for DPN (see new now next in *diaTribe* #46).

We recently had a chance to talk with Dr. Keith Candiotti, a professor at the University of Miami School of Medicine and consultant to J&J for Nucynta ER. Notably, he suggested that Nucynta ER could be particularly useful for people who are experiencing especially intense pain from DPN, or an exacerbation of their existing pain. Nucynta ER works by increasing the activity of the brain's opioid receptors, which are linked to pain relief. This means Nucynta ER treats DPN in a fundamentally different way than Cymbalta and Lyrica. This is great news because DPN affects so many different aspects of the brain and body, which makes it notoriously complicated to treat, and there's no guarantee a drug therapy that is successful for one person will work for others. Nucynta ER is specifically approved to treat the painful symptons of DPN when a continuous, round-the-clock opioid analgesic is required. Adding more treatment options for DPN is always needed, and we're hopeful Nucynta ER can provide some relief for those who have not had success with Cymbalta or Lyrica. *–AW*

Children play tennis using the USTA's specially designed, kid-friendly rackets, ball, and miniature court.

T1/2 **Partnership for a Healthier America and the US Tennis Association Join Forces against Childhood Obesity**

During the US Open tennis tournament earlier this month, Larry Soler of the Partnership for a Healthier America (PHA) announced a pair of new initiatives to promote fitness and combat obesity in children (see the *diaTribe* dialogue with Mr. Soler in *diaTribe* #35). Children should be getting at least 60 minutes of physical activity every day, but past estimates suggest just 42% of elementary school students and only 29% of high school students are at this benchmark – and those figures are likely overly generous estimates in our view. To help children be more active, Mr. Soler announced a major commitment from the United States Tennis Association (USTA): building 3,200 kid-sized tennis courts in 2012 in addition to the 3,000 it previously built in 2011, all of which improves both the availability and child-friendliness of the sport. These courts are a little over half the size of a regular court, and the USTA advises children to use specially designed kid-sized rackets and balls, which are significantly slower than those used by adults. Encouragingly, the USTA has already exceeded the 3,200-court goal and is on track to build an impressive 8,600 child-friendly courts by the end of the year. The Association is complementing that major achievement by providing child-specific training to 12,000 new and current tennis coaches, teachers, and volunteers, as well as $150,000 worth of new tennis equipment to programs for children ten and younger. Considering 30 million Americans played tennis in the past year, we hope this partnership can make a dent in the childhood obesity epidemic. We also very much hope to soon see an agreement with Partnership for a Healthier America and a life sciences company – we urge them to rally! *–AW/AB*

T1/2 **Latest WHO Statistics Reveal One in Ten People Have Elevated Blood Glucose Worldwide**

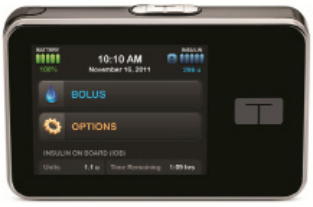
The World Health Organization (WHO) recently released its World Health Statistics 2012 report, compiling data from 194 countries. The report estimates that about 9% of women and 10% of men worldwide have elevated levels of fasting blood glucose – notably, this is the first major report to our knowledge that includes data on blood glucose levels. The report also offers a long-term outlook on the spread of noncommunicable

diseases (NCD), which includes diabetes and obesity. Diabetes is only directly responsible for about 3.5% of NCD deaths, although it bears pointing out that diabetes, elevated glucose levels, and obesity all increase the risk of even deadlier NCDs such as cardiovascular disease, cancer, and coronary heart disease. Indeed, elevated blood glucose, physical inactivity, and being overweight or obese are risk factors that combined account for an estimated 17% of global deaths.

About 12% of the global population is obese, although there's extreme variance between regions – in the Americas, 36% of people are overweight and a further 26% are obese, while only 11% are overweight and a further 3% are obese in Southeast Asia. Obesity currently accounts for about 2.8 million deaths every year worldwide, primarily due to its links with type 2 diabetes, high blood pressure, and cholesterol. The WHO hopes to act on this alarming new data by setting targets to prevent and control NCDs, including the development of a global monitoring system to pinpoint the regions most at risk. It is still early days for these efforts, but hopefully this latest confirmation of these disturbing trends will spur governments to action. We are not, however, holding our breath waiting for the US government to act in the near future. *–AW*

T1/2 **New Study Suggests Diabetes is Four Times More Common Among Chinese Teenagers than American Teens**

A new study from the University of North Carolina and the Chinese Center for Disease Control (CCDC) has found that diabetes is four times more common among Chinese teenagers (1.9%) than it is among their American counterparts (0.5%). This is despite the fact that, according to the researchers, type 1 diabetes is virtually unknown among East Asian youth. Although prediabetes remains much more common in American children (20%) than it does for Chinese children (8.4%), and the overall prevalence of diabetes in China (6.9%) is actually lower than that of the United States (9.3%), Hong Kong (9.8%), and South Korea (8.1%), the relatively high incidence of diabetes among China's youth may point to a serious national health problem down the road for the world's most populous nation. Worse yet, obesity and prediabetes appear to be significantly more common among Chinese children ages 7-11 than for adolescents ages 12-18, suggesting the country's youth diabetes crisis is skewed quite young and getting worse. *–AW*



Tandem's new t:slim insulin pump.

test drive

T1/2 Touchscreen Meets Insulin Pump in Tandem's New t:slim

by Adam Brown

"Design is a funny word. Some people think design means how it looks. But of course, if you dig deeper, it's really how it works ... To design something really well, you have to get it. You have to really grok what it's all about. It takes a passionate commitment to really thoroughly understand something, chew it up, not just quickly swallow it. Most people don't take the time to do that."

Those were the words of the late Steve Jobs in an interview with *Wired* in February 1996. More than a decade later, Tandem Diabetes Care took this idea to heart with its new t:slim touchscreen insulin pump, which it designed after conducting a remarkable 4,000 in-depth interviews with patients, healthcare providers, and caregivers. Tandem really wanted to get inside the minds of people who take insulin – pumpers and non-pumpers alike. The new pump was approved by the FDA in November 2011 (see new now next in *diaTribe* #38) and launched just last month. I was able to get trained on the t:slim at Tandem's San Diego headquarters soon after it launched, and what follows is my experience wearing the device over the past week. Three themes have emerged: some clear differences from other pumps, a focus on simplicity and convenience, and an attention to safety.

The t:slim home screen.

Part One: Differences from Other Pumps

Adam's Favorites

- iPhone-like touchscreen
- Rechargeable battery
- Highly customizable "personal profiles" for insulin delivery

From the minute I opened the shipping box, it was clear that the t:slim pump was somewhat different from other pumps I've used – included with the pump were a USB charging cable and adapters for both the wall and car. Even the included user manual comes on a credit-card-like thumb drive. But the most obvious difference between the t:slim and other pumps is the touchscreen. I found this to be the most compelling feature of the pump and a major departure from the button-driven devices I've used since I began pumping in 2002.

The Touchscreen

Most important, the touchscreen is easy to use, intuitive to navigate through, and responsive. I appreciated the screen's very bright, high contrast, full color design, which also incorporates highly readable bold font and large icons that make selection easy and mis-taps rare. Unlike some other medical device touchscreens, I also appreciated that the t:slim screen did not require a lot of finger pressure to use – it's right on par with using an iPhone or Android smartphone. The one minor shortcoming of the t:slim touchscreen is it doesn't have the smartphone swiping (i.e., to navigate up, down, left, and right) that I'm so used to. Instead, you must hit a down or up arrow key, though this was a fairly minor inconvenience because few of the menus take up more than one screen length.

The Battery

Another departure from other pumps is the t:slim's rechargeable battery, which lasts seven days on a full charge. A dead battery would take about 90 minutes to completely

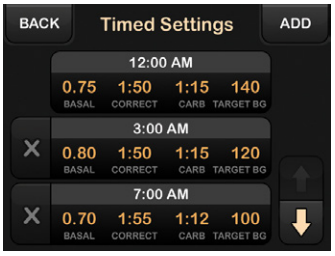
charge, and on average it takes about a minute of charge time for every percentage point of battery life (i.e., if the pump is at 80% battery life, that's about 20 minutes to fully charge it). Tandem recommends plugging in the t:slim for 10-15 minutes every day to "top it off" – I did this while I showered (see water resistant information below) or when sitting next to my computer, and the t:slim would always return to 100% battery life. The pump can be charged whether or not you are connected to it.

The t:slim battery recharging.

Although a rechargeable battery is new to insulin pumps, I found it refreshing and fairly easy to remember to plug it in – I'm used to doing it for my Dexcom Seven Plus CGM, my LifeScan OneTouch Verio IQ blood glucose meter, my cell phone, my laptop, my iPod, and pretty much everything else these days. The included charger cable is the very common micro-USB computer cable used for many consumer electronics, and I was happy to see Tandem include a wall adapter and car adapter. There are also a variety of battery packs, solar chargers, and the like for those who will not have access to electricity (Tandem is not currently selling these but they are easy to find online). I was glad to hear this is an option since I know many pumpers that are into outdoor camping and backpacking where charging would be a challenge.

Personal Profiles

The third biggest difference between the t:slim and other pumps is setting up the pump's insulin profiles and bolus calculator settings. Traditionally, a pumper sets up basal rates by time of day in one menu, an insulin to carb ratio by time of day in another menu, a correction factor by time of day in a third menu, and a target blood glucose or range by time of day in a fourth menu. The separate menus do not interact, meaning that a change in one parameter (e.g., the time a basal rate changes) is not reflected in the other menus. On past pumps, at least for me, this process has sometimes resulted in a disjointed insulin profile, with parameters that do not match up. Tandem has improved and streamlined this process, which is good news in our view because we worry a lot about optimizing glycemic management. In a recent dQ&A survey, fewer than 60% of patients and 50% of educators thought that their insulin pumps were configured optimally – very disappointing from a patient perspective!

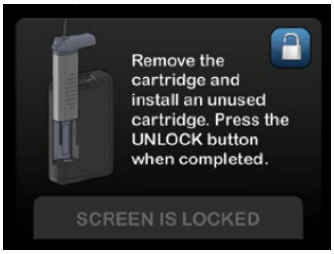


The t:slim offers an improved, streamlined approach to setting the user's personal profile.

In the t:slim's personal profile menu, all four parameters – basal rate, correction factor, insulin to carb ratio, and target glucose – are set for a particular time of day. These appear in a single menu and are saved together. The entire day's worth of settings is then saved within a particular profile, which you give a custom name and can easily and quickly duplicate. I have one profile called "Home" that is based on my level of activity at home and my normal diet and wake up time. But I also have a "Travel" profile with different settings, as well as a "Sleeping in" profile for going to bed later and waking up later. It's very easy to toggle between these profiles, and it's all located in one centralized menu. You can have up to six different personal profiles and up to 16 time segments within each.

A New Delivery Mechanism

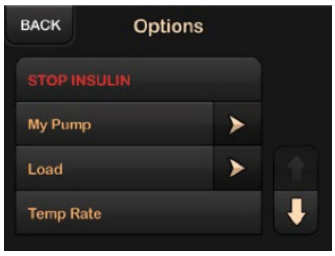
Instead of a conventional piston driven delivery, where a mechanical screw drives a syringe built into a reservoir (the way a Medtronic, Animas, Roche, or Insulet pump works), the t:slim uses a micro-delivery technology. This means that very small amounts of insulin are shuttled from the reservoir to the infusion set, and the full insulin supply is never directly exposed to the user's body (as it is with other pumps). Notably, the pump can deliver in increments of as little as 0.001 units, compared to 0.025 for the Animas OneTouch Ping and Medtronic Paradigm and 0.05 units per hour for the Insulet OmniPod. While I cannot say that I noticed a difference from these novel accuracy and safety features in my blood glucose numbers over the last week, I can say it was comforting to know that the pump has these innovations. Perhaps Tandem will eventually conduct studies to examine whether these are indeed beneficial for glycemic control.



Instructions for changing the t:slim's infusion set and cartridge.

Changing an Infusion Set and Cartridge

The one area where the t:slim was different from other pumps – but in a way that created more hassle – was when it came time to change a reservoir and pump set (the t:slim works with any luer lock infusion set). The process took me an average of around nine minutes with the t:slim, more than double the average of four minutes it took me on the Medtronic Paradigm and Animas OneTouch Ping. The process is slow for a few reasons: 1) the pump takes a bit of time to automatically clear air out of the new cartridge (I appreciated this, since air bubbles can cause some unexplained and frustrating highs); 2) because of the micro-delivery technology, it takes the pump a couple minutes to prime and fill the tubing with insulin; and 3) you are guided via step-by-step on-screen pictures and prompts, which take extra time to clear relative to the Animas and Medtronic pumps. As we understand it, the cartridge change process is a leading cause of calls into manufacturers' support lines and one of the reasons Tandem included this extra guidance. In the future, I think Tandem could improve the process by prefilling the cartridges with insulin (similar to the Asante Pearl) or perhaps speeding the priming process by allowing users to turn off the pictures once they have the process down. On the plus side, the cartridge does hold 300 units of insulin, a notable feat considering the t:slim is about 25% slimmer than the Animas OneTouch Ping and Medtronic Paradigm insulin pumps. As a reminder, only the Medtronic Paradigm 723 holds 300 units.



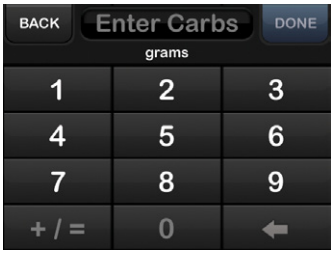
The t:slim Options menu.

Part Two: Focus on Simplicity and Convenience

Adam's Favorites

- Very simple menu layout, intuitive user interface, and fast navigation
- Bolus menu design
- Quick bolus feature

The marketing tagline for the t:slim is "touch simplicity," which is most evident in the device's user interface. The pump is very similar to the user interface concept and button design pioneered by the iPhone: 1) a touchscreen to use it; 2) a button on top that blacks out the screen and locks it; and 3) a button on the face of the device that immediately takes you back to the home screen at any time. Since the home screen is really the hub of the pump's software and the starting point to perform any action on the device, I really liked having a single button take me there immediately. It was much faster than on other pumps I've used, where you keep hitting a back button to exit a menu.

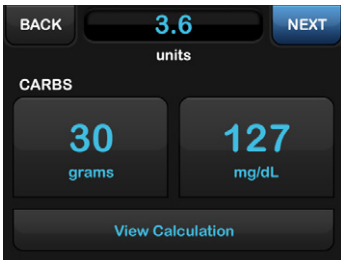


The t:slim carb calculator.

The Menu Design

I did not need to open the instruction manual to figure out the t:slim's menu layout, and the overall design made navigating through the pump quite fast. Taking a combination meal and correction bolus for 30 grams of carbs and a blood glucose of 165 mg/dl took me an average of nine seconds on the t:slim, compared to double the time (18 seconds) with the Medtronic Paradigm and nearly triple the time (26 seconds) with the Animas OneTouch Ping. I know a matter of seconds may not sound like a lot, but when you're bolusing multiple times a day (I take an average of six boluses per day), every day, that adds up.

The t:slim's home screen displays the most critical pump information: two large buttons called "Bolus" and "Options," a battery life indicator (in both percent and an icon), an insulin reservoir indicator (in both units and an icon), the time and the date, and insulin on board (IOB) in both units and time remaining. IOB is my favorite part of the home screen because I use it so religiously, and it's such a meaningful improvement for me over other pumps that only display IOB in units remaining and hide this in a status menu.



The t:slim bolus calculator.

The Bolus Calculator

Since bolusing is the most common interaction a user has with a pump, I appreciated that this was front and center on the home screen. Clicking the "Bolus" button immediately takes you into the bolus menu, where you can enter carbs and/or a blood glucose level if the carb calculator is turned on, or just insulin units and a blood glucose if the carb calculator is turned off. You can quickly override the calculator's dose by clicking a box at the top of the screen and inputting your own number of units. "Options" allows you to suspend insulin, set up profiles, load a new reservoir (what Tandem calls a "cartridge"), set a temp basal, and view history.

The bolus screen is a perfect example of how the t:slim's user interface is simple and convenient. The side-by-side, large block design makes it very clear what can be entered, while a running tally at the top totals the insulin dose. A tab at the bottom allows you to click and view the full delivery calculation in a nice vertical arithmetic layout. Entering a blood glucose value or number of carbs pulls up a touchscreen numeric keypad (like dialing a phone number), and cleverly, Tandem has included an addition sign that will tally the carbs from multiple foods. This struck me as a great addition considering how tiring diabetes math can sometimes be.

The quick bolus function.

Extending and Quick Bolusing

After entering the information for a bolus, the final screen before delivery gives you the option of extending the bolus – this was just a toggle switch and was available for every bolus, unlike on other pumps where you must preselect an extended bolus before entering anything into the bolus calculator. The t:slim also has a great quick bolus feature that uses only the screen lock button on top of the pump. Increments can be in units of insulin or carbs, making the t:slim the only pump that offers either option for a quick bolus. I used this feature to program and deliver a bolus without looking at the pump (!) and to very quickly take a bolus without unlocking the pump screen and using the carb calculator.

The t:slim confirms each bolus (above) and provides ten seconds to cancel (below).

Part Three: Safety

Adam's Favorites

- 10 seconds to cancel a bolus
- A plethora of confirmation screens, alerts, and warning messages

It's great to make a cool-looking, sleekly designed insulin pump, but it's also a medical device infusing insulin. As such, I was glad to see a vast array of built-in safety features – confirmation screens galore, alerts when you have not completed an action for 90 seconds (e.g., you were in the middle of calculating a bolus and forgot to deliver it), red bold text to draw attention to important items, an automatic screen lock following a bolus or when the screen is tapped three times in quick succession (e.g., to prevent accidental touchscreen taps while in your pocket), and a user interface feature called "dynamic error handling" that prevents the user from selecting illogical items in real-time (e.g., you can enter 100 grams of carbs, but the pump prevents you from adding another zero for 1,000).

My favorite safety feature of the pump was the cancel/stop bolus button. After programming and confirming a bolus, the t:slim gives you approximately 10 seconds to cancel the bolus before it ever starts delivering it. On other pumps, programming and confirming a bolus initiates delivery immediately, so unless you have lightning fast fingers, cancelling the full amount of the bolus is very challenging. I found this feature of the t:slim valuable when I had second thoughts about the bolus I just gave. The cancel bolus button also appears right on the home screen as a red "X" during the 10-second grace period, so there is no need to dig into a menu and hunt around for this feature.

Part Four: The t:slim's Durability and Cost

Durability

As an outdoorsy and active person, I was initially concerned about the t:slim's durability. Tandem has told me that if a user accidentally cracks the screen, the pump will be replaced under warranty. While I can't say I did my own extensive crash tests, I know that many young attendees at the recent Children with Diabetes Friends for Life conference had "contests" to try and break the trial t:slim pumps, and it was pretty challenging for them to do so – I think in the end it took one t:slim pump thrown at another one to crack it (and it was still fully functional)! The starter kit comes with a hard plastic case that wraps around the pump for additional protection, and the t:slim touchscreen also has a pre-applied protective film. I have not worn the pump long enough to have too many accidental drops, but the durability will be on the top of my mind as I get more experience with the device.

We field-tested the t:slim's water resistance!

Water Resistance

Unlike the Animas pumps and Insulet's OmniPod, the t:slim is not completely waterproof. According to the company, the t:slim has been tested in three feet of water for 30 minutes (what's known as an IPX7 rating, similar to Medtronic pumps) – essentially, it's "water resistant." However, I must confess that I've broken multiple pumps due to water damage, so this is a concern for me. The pump worked fine after I submerged it in a cup of water for ten minutes, though I will need to wear it for a longer period to fully test its durability and water resilience.

Cost and Insurance

And of course, the very, very important question is cost. Insurance companies typically pay for a new insulin pump once every four years, though this can vary. Tandem has already signed contracts with some major insurers, and is currently working with customers on a case-by-case basis to obtain insurance coverage. We understand that the t:slim has a higher list price (about $6,995) than the Medtronic Paradigm Revel (about $6,500), Animas OneTouch Ping (about $6,300), and Insulet OmniPod (only around $600 for the starter kit, although "pods" are more expensive than sets on an ongoing basis), so that is an important consideration for those who must pay co-insurance. However, Tandem has a large staff dedicated to reimbursement, so if you are interested in getting the t:slim pump, the best way to figure out your situation is to contact Tandem directly.

Closing Thoughts

I was impressed and plan to keep the t:slim assuming my insurance will help cover some of the cost (fingers crossed!), though the devil will be in the details since I changed to my current pump fairly recently. That said, I'm definitely still interested in trying the upcoming Animas Vibe (integrated with the Dexcom Gen 4 CGM), Insulet's smaller second-generation pod, and Medtronic's MiniMed 530G with low glucose suspend – as a reminder, all these devices are currently under FDA review or will be submitted to the FDA soon. Indeed, this is a great time for patients with so many innovations coming, and I had a great week trying out something so new. For more information on Tandem's t:slim, see new now next in diaTribe #38 and Tandem's website at www.tandemdiabetes.com/products/t-slim/.

Jeff Hyman, founder and CEO of Retrofit.

diaTribe dialogue

T1/2 Jeff Hyman Discusses How Retrofit's Data-Driven, High-Tech Approach Offers an Aggressive Solution to Losing Weight Long-Term

by Adam Brown and Alasdair Wilkins

Last November, high-tech entrepreneur Jeff Hyman and a team of leading weight-loss experts launched Retrofit, which offers one-year programs designed to help people lose 10% to 15% of their body weight. The company provides each Retrofit client with his or her own dietitian, exercise physiologist, and behavior coach – all of whom offer their guidance over weekly Skype sessions, meaning they're available anywhere and anytime. We've written before about how impressed we are by Retrofit's approach (see from the editor in diaTribe #41), and as the company approaches its first anniversary, we decided to check in with Mr. Hyman.

He visited our San Francisco headquarters to provide an in-depth explanation of how the Retrofit program works. Acknowledging the program is a significant investment for many who might be interested – the one-year Retrofit membership costs between $3,000 and $4,000 – he discussed how employers, insurance companies, and eventually the government could work to make it more affordable. While Retrofit doesn't feature a diabetes-specific program, Mr. Hyman said it has helped people with diabetes and prediabetes lower their weight and glucose levels. He closed by explaining why exercise is vital not only to short-term weight loss but keeping weight off long-term.

For more about Retrofit, check out the company's website at Retrofitme.com. As an exclusive offer to diaTribe readers, Retrofit is offering a special discount of $500 off its weight loss program. When purchasing a plan on the website, simply enter the exclusive discount code "OCTOBER" into the box marked "Referrer" to get this great savings. This code will expire on October 31, 2012 and cannot be combined with any other offers.

"The average diet is going to last nine weeks. This is not a diet. It's true commitment. It's a one-year program."

"It's not a diet, and we don't use the word "diet." We don't believe in starvation. We don't believe in restricting people from all their favorite foods. That's not sustainable, right?"

WHAT IS RETROFIT?

Adam Brown: To start, could you give us a quick background on how you came to Retrofit and started the company?

Jeff Hyman: I put on two pounds a year like a typical American. I'm 44. And I got to a point where I just was fed up with that. I tried everything – I would lose weight, gain it back, lose weight, gain it back. My wife eventually dragged me to a destination wellness resort, which changed my life. I worked with therapists, dietitians, and exercise physiologists. For me, it was a transformative experience.

But the problem is that it's $1,000 a day. So last year, I started thinking about how to make it scalable using technology. Retrofit is a one-year behavior change program delivered entirely online. There's nothing magical or mystical about it, other than it works because it's a very intensive, robust, and multi-dimensional program. It includes, of course, nutrition and exercise. And we believe most uniquely, behavior change. In our view, this aspect is responsible for about 50% of weight loss between the ears. The last important thing Retrofit includes is third-party accountability to a dietitian, exercise physiologist, and a behavior change expert.

The customer meets with their team of experts via Skype video conference. They arrange the day and time, from 6 AM until midnight, seven days a week. Each person gets their own registered dietitian, a behavior coach with ten years' experience and a Master's degree, and an exercise physiologist with ten years' experience and Master's degree. You work with those three people for a full year. It's not a random rotation call center type.

"People need to sleep at least six and a half hours a night in order to really be able to lose weight."

"Ninety-five percent of our customers are losing weight on the program. The majority of our customers are on track to lose at least ten percent of their weight. Experts have told me this has never been seen before in the industry."

"Dr. Robert Kushner, who has over 30 years of experience, identified 21 distinct personality types that prevent you from losing weight."

It's literally three people. They're on your speed dial. And each week you meet with one of them on a rotating basis for a half-hour session (e.g., my dietitian this week, my therapist next week, etc.). Between Skype sessions, you have unlimited access to your team for questions, comments, and concerns. So if you're going to this restaurant in New York, your dietitian will download the menu, and tell you what to order. It's a very high level of personal service with a lot of technology behind it. We have 65 of these experts now across the country that cover all states and all time zones. And our clients are across the country even though we're based in Chicago.

In addition to your team, you'll receive two wireless devices. The first is the Withings Wi-Fi scale. You connect this to your Wi-Fi network at home, you step on the scale, and it instantly sends your data to your team. We require customers to weigh in once a week. Our average customer weighs in five times a week. They get very addicted to the data and the progress, and half our clients are men.

You also get a wireless pedometer (Fitbit) that tracks the steps you take, miles per day, and calories per day. At night, it tracks how long you sleep and how well you sleep, which is a huge issue for a lot of customers. People need to sleep at least six and a half hours a night in order to really be able to lose weight. A lot of our customers will only sleep three hours a night, so with the pedometer, we can find it out and begin behavior coaching work to figure out what's going on.

All this data is wirelessly uploaded to us. You get your own private dashboard that your team is looking at every single day, and it's a very high accountability program in a very supportive way. They're not looking to catch you doing something wrong, and we don't expect perfection. The truth is we find we don't need to be perfect. We try to lose one pound a week, very slow, steady progress.

Adam: Many would call this just a high-tech "diet." What would you say to those individuals?

Mr. Hyman: It's not a diet, and we don't use the word "diet." We don't believe in starvation. We don't believe in restricting people from all their favorite foods. That's not sustainable, right? We can teach balance and portion control. Why am I eating a gallon of ice cream at night if I'm not hungry? That's not a food issue. That's a behavioral issue. Is that stress eating, emotional eating, binge eating, eating out of boredom, eating out of depression? We have all these reasons that we all turn to food – what we believe is almost an addiction. So we do this little by little over 365 days, and that's the program.

We were lucky to recruit Dr. Robert Kushner, who runs the obesity program at Northwestern, and Dr. Jim Hill, who runs the program at the University of Colorado. With Doctors Kushner and Hill, we have developed a protocol that 500 clients are on. If you do it in a sustainable way for enough time, changes take hold. The average diet is going to last nine weeks. This is not a diet. It's true commitment. It's a one-year program. After you have joined, we lock the door behind you. And so that alone, I think, weeds out people that aren't serious.

Adam: How successful are people at losing weight while on Retrofit?

Mr. Hyman: Ninety-five percent of our customers are losing weight on the program. The majority of our customers are on track to lose at least ten percent of their weight. Experts have told me this has never been seen before in the industry. It's transformative. But it's not rocket science. We're just keeping people on the straight and narrow for a year. We've got many, many hundreds of people who are slowly but surely succeeding on the program. Time will tell if they keep the weight off over time. But what gives us confidence is that based on our advisory board's experience, most people fall off the wagon after two to three months. So the fact that we've now kept these people on for six, nine, coming up on 12 months next month, is in and of itself remarkable because most people will have failed.

"A recent study found that 59% of employers are now contributing or giving employees some money to apply to wellness and weight loss."

Adam: You mentioned that the behavioral side of Retrofit is one aspect that makes it unique? Can you talk about that approach?

Mr. Hyman: The protocol that we use is really interesting. Dr. Kushner, who has over 30 years of experience, identified 21 distinct personality types that prevent you from losing weight. He calls them lifestyle patterns, which he summarized in a very good book called *Dr. Kushner's Personality Type Diet*. Couch potato, meal skipper, constant muncher, midnight snacker – all these are different eating patterns. And sure enough, you'll read it and say, "Yeah, that's me." Dr. Kushner developed a 50-question quiz that identifies your lifestyle patterns. It's on our home page and nearly 15,000 people have taken it. We email results to people totally free. And then if you choose to join Retrofit, that becomes the basis of your protocol.

It's a very, very personalized service, which is why you get better results than a group meeting where you often must dumb it down to the lowest common denominator. It's not possible to personalize because you have twenty people in the room. We have clients who have diabetes or are vegetarians or travel all the time. For the latter, as an example, you'd have to figure out how to exercise in their hotel room.

"It's my premise that eventually, the US government will have to do something about it. I can't say when. But if you look at the numbers, if we keep going at this rate, in 25 years our healthcare system is in trouble."

PAYING FOR RETROFIT

Adam: Is it possible you could obtain reimbursement either in the United States or in the UK or other countries?

Mr. Hyman: Yes. Right now, half of our business is direct to consumers. They come to the website and just put it on their credit card. The other half is through employers and most of that is subsidized. A recent study found that 59% of employers are now contributing or giving employees some money to apply to wellness and weight loss. They understand that that's way less expensive than treating diabetes later, especially self-insured employers. Now that we've got some outcome data, we are starting to get calls from insurance companies. That is the next level, and we're still having those discussions.

Insurance companies spend hundreds of millions of dollars treating all the diseases that are caused by obesity. Medications, gastric bypass, the list is endless. We're starting to engage in those discussions with insurers. It's my premise that eventually, the US Government will have to do something about it. I can't say when. But if you look at the numbers, if we keep going at this rate, in 25 years our healthcare system is in trouble.

So it strikes me that, at some point, the government will get involved. And in addition to starting to curtail this food advertisement to kids and a bunch of other things, I believe that the government will start to offer some kind of support, financial support, for effective programs. The programs will have to work, which is again why I'm maniacally focused on outcomes. I'm not trying to be the cheapest program. I just want to have the best outcomes, because ultimately, someone will pay for it, either the consumer or their employer or the insurance company or the government.

"Their blood glucose numbers are transformed in six months. And they didn't lose a ton of weight, but they lose enough to make a difference."

RETROFIT AND DIABETES

Adam: What about people with diabetes? Can you talk about that aspect?

Mr. Hyman: We have a number of people with diabetes on the program, and quite a few people with prediabetes, where their physician has told them they're on the wrong path. And we paired them up with dietitians who have expertise in diabetes, and with behavior coaches that have expertise in diabetes. So while it's not a diabetes-focused program, we leverage that expertise. We're always evaluating if we should have a diabetes-specific program, and maybe we will one day.

Adam: From an insurer perspective, it would be very compelling to show that Retrofit slows or halts the progression from prediabetes to diabetes.

Mr. Hyman: So many of our clients track their blood glucose numbers before the program, and then during the program they send us a copy of the report. We'll actually liaise with their physician if they want with no additional fee. Their blood glucose numbers are transformed in six months. And they didn't lose a ton of weight, but they lose enough to make a difference. So what I've learned from the experts on our team is that an overweight person losing 10% of their weight reduces their risk of many diseases by 50% to 80%. That's where you get the biggest bang for your buck. We get customers who lose 25 pounds or 30 pounds, but they're not going to become a cover model anytime soon. However, it's enough to make the difference such that their blood glucose numbers are transformed. They go off medications or they reduce them. That's why we focus on losing at least 10% of body weight.

"Dr. Holly Wyatt, in her research, has found that there's a trade off. Initially, you do it with food. But to keep the weight off over time, it's got to be through increasing activity, and more importantly, strength training. That's really the engine that burns calories throughout the day."

THE ROLE OF EXERCISE

Adam: We spoke with Dr. Arya Sharma, who's a weight loss guru. [See our diaTribe dialogue with Dr. Sharma in diaTribe #45.] It is his opinion that if you go on a calorie restriction diet, you will lose a certain amount of weight. But in order to maintain that weight loss over a long period of time, you have to maintain the diet. Is that realistic for anybody?

Mr. Hyman: Just so I'm very clear, to lose one pound per week, you need to create a net calorie deficit of 500 calories per day (i.e. 3500 calories a week equals one pound of fat). That is roughly what we work with our clients to do. Some of them lose two pounds, depending on their story.

Over time, you start seeing the curves plateau as it becomes harder and harder to lose weight. To continue to lose weight, you have then to begin to increase the exercise. There's no question about it. Dr. Holly Wyatt, in her research, has found that there's a trade off. Initially, you do it with food. But to keep the weight off over time, it's got to be through increasing activity, and more importantly, strength training. That's really the engine that burns calories throughout the day. Most Americans have no idea – they think you just go onto the treadmill. While that's great, you've got to do strength training twice a week. We teach clients how to do all that.

Once our customer gets to the goal weight, we're just working with them to maintain. That is in and of itself another process. So of the one-year product, roughly half of it is weight loss, and half is weight maintenance. And we actually think weight maintenance is the harder part, because now we created that deficit.

"We actually think weight maintenance is the harder part, because now we created that deficit."

Now, we need to teach you how to live within a band. You're not going to be perfect, but it's almost like a stock price chart that's kind of going sideways. You know you've got some fluctuations. And what the National Weight Loss Control Registry – which Dr. Hill developed – shows is that people that keep the weight off over time learn how to live within this span. They weigh themselves regularly, a couple of times a week at least. And they notice that they've gained a little bit, and then the alarm bells go off. And they start to lose weight, and then they gain weight, and they live within this very tight range.

And that's what we teach our clients how to do. It's an energy balance and all about balancing your calories in and out. You can't give an exact range, and it's a little bit different for everybody based on your metabolism, your starting weight, your gender, your age, and your percent muscle versus fat. So we can't just give people a number. We have to iterate to get there. But that's what the second phase of the program is all about.

"We have to teach people you can't out-exercise a poor diet. Most people don't understand that very basic concept."

Adam: What I've heard at obesity conferences and reading the literature is that if people try to lose weight by just burning off calories with exercise, and not changing their eating habits, they end up eating those calories back again. But at the same time, anybody who's sustained weight loss over a period of time has a very active exercise component. Could you talk a little bit about that?

Mr. Hyman: What your average person does is they go to the gym and exercise for an hour and a half and kill themselves. They think they burned a thousand calories – they've actually burned 300. And they go and have a bagel and a latte at Starbucks, right? We have to teach people you can't out-exercise a poor diet. Most people don't understand that very basic concept.

With that said, there comes a point in time where you just can't eat any less, where you don't want to eat any less. And so the only other option is starting to increase the exercise. The benefit you get from strength training is that it's powering your engine – muscle burns more calories than fat. So you get this lasting burn of calories throughout the day as opposed to just during a cardio session.

"When a customer first joins us, on average, they take 2,000 steps a day. Dr. Hill has found that if you take 10,000 steps a day, it's really hard not to lose weight."

But they're both important. We generally tell people that exercise is necessary to keep the weight off. When a customer first joins us, on average, they take 2,000 steps a day. Dr. Hill has found that if you take 10,000 steps a day, it's really hard not to lose weight. You've got to be eating a ton to outdo that.

So we notch them up from 2,000 to 2,500 a day, to 3,000 a day and kind of go from there. Just over the course of a few months – very gradual, and we're not trying to drop them in a gym and kill them. But then by month four and six, they've lost some weight. We're down this part of the curve. And now, we start to really introduce the exercise. They've got some self-confidence. They feel more energy. And then that becomes a huge part of the focus, and you're just finding that balance.

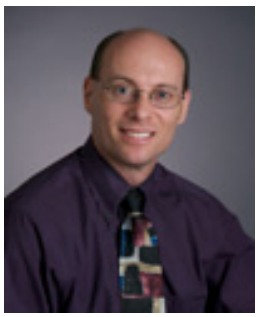
Adam: Jeff, thanks so much for taking the time to speak with us.

Mr. Hyman: I enjoyed it very much. Thank you.

thinking like a pancreas

T1/2 The Happy Medium: Finding Balance Between Diabetes Neglectus and Diabetes Overwhelmus

by Gary Scheiner, MS, CDE



From what I can tell, there are two ways diabetes can ruin your life. You can ignore it, let it run amok, and have blood sugars that are all over the place. Or… you can obsess over it and let it take over your every waking minute.

Take these two examples.

Jess is a 19-year-old college freshman who has had type 1 diabetes since she was in third grade. As is the case for many students living on their own for the first time, diabetes takes a pretty low priority in her life – somewhere between calling her parents and putting away her laundry. She checks her blood sugar each morning, but doesn't pay much attention to it the rest of the day. At mealtimes she takes rapid-acting insulin, basing the dose more on gut instinct than on the actual carbs in her meal. And there are lots of late-night snacks that just don't get covered at all. She changes out

"One question we all face in living with diabetes is, how much work should we put into it? It's similar to preparing for an exam in school: study too little, and your chances of success are low. But over-preparation can be a problem as well. Finding the right balance – that happy medium – is what it's all about."

her pump when it runs out of insulin rather than on a fixed schedule, and her usual workouts at the gym have been replaced by the walking she does between classes. Jess has also discovered the joys of long college weekends – featuring parties that run from Thursday afternoons through Sunday, complete with drinking and dancing.

Uncontrolled blood sugars are causing some unexpected problems for Jess. She's not sleeping well at night due to frequent trips to the bathroom, and she keeps getting yeast infections. She's having a hard time concentrating, and her once first-rate memorization skills have been failing her come exam time. The weekend fun came to an abrupt end last weekend when Jess had seriously low blood sugar at a party. Paramedics had to be called, and Jess said some things under the influence of low blood sugar that bothered many of her friends and classmates.

William, by contrast, has it all "under control." A 33-year-old software engineer and new father, William weighs and measures everything he eats and avoids eating out, out of fear that he'll get the carb count wrong. His wife isn't thrilled with the idea of never eating out, but she deals with it for William's benefit. He wears a continuous glucose monitor and also checks his blood sugar just about every hour in order to keep from going above or below target. His insurance company doesn't cover all the strips, so he pays out of pocket for about half of them, something that is a bit of a drain on the family budget.

A perfectionist by trade, William takes it personally when his blood sugar is above normal. He aggressively covers above-target readings with either insulin or a quick run on the treadmill. This has caused William to experience more than his share of lows, but he's more comfortable (and in a much better mood) when he's low than when he's high. William also keeps detailed records and analyzes them often, resulting in therapy changes several times each week. Despite his doctor's warnings about making changes too often, William feels that he knows his body better than anyone, and lets his tight A1c speak for itself.

There you have Jess and William. Two people with extreme approaches to diabetes management, and each with their own set of issues. One question we all face in living with diabetes is, how much work should we put into it? It's similar to preparing for an exam in school: study too little, and your chances of success are low. But over-preparation can be a problem as well. Finding the right balance – that happy medium – is what it's all about.

"Extreme approaches to diabetes management are clearly unhealthy and unwise. However, there is still a spectrum of effort that can produce desired results. Not everyone has to be right in the middle."

The Search For The Happy Medium

For most of us, the goal is to keep diabetes from interfering with our quality of life. There are several ways diabetes can, and does, interfere:

1) We can put so much effort into it that it gets in the way of enjoying our daily activities. In the example above, William's all-out emphasis on tight blood sugar control keeps him from taking his wife out to dinner, affects his moods, and creates a financial burden.

2) We neglect it to the point that the blood sugars are causing immediate problems. For Jess, poor control is affecting her sleep, her studies, and her friendships. She may have been trying to conceal her diabetes from others, but after the incident at the party, it is apparent that she doesn't just have diabetes, she has a problem dealing with it.

3) We put ourselves at risk for serious health problems by running our blood sugar too high or too low. Jess is setting herself up for eye, kidney, nerve and circulatory problems by letting her blood sugar run high so often. But William is also setting himself up for problems. His obsession with tight control has caused so many lows that he's lost the ability to sense when hypoglycemia is developing. It may just be a matter of time before he has a serious accident due to undetected hypoglycemia.

Extreme approaches to diabetes management are clearly unhealthy and unwise. However, there is still a spectrum of effort that can produce desired results. Not everyone has to be right in the middle. It's okay to gravitate toward the "Jess" or "William" approach, but with some common-sense modifications.

Jess, for example, doesn't have to check her blood sugar hourly the way William does. But checking before she goes to bed and taking appropriate action, such as snacking or taking insulin, could go a long way toward keeping her safe. And William might raise his target blood sugar slightly and expand what he considers his "acceptable" range. This would allow him more dietary flexibility and may keep him in a better mood.

> "By taking care of these few key "survival" responsibilities, you can keep yourself out of immediate harm's way and lay the foundation for more advanced management techniques – when you're ready, willing and able."

The Outer Limits

Whichever side of the spectrum you prefer, it's important to distinguish between essential, non-negotiable responsibilities of living with diabetes, and secondary behaviors that are not necessary for survival but are important for controlling blood sugar effectively.

For most people with type 1 diabetes, as well as those with type 2 who are on an intensive insulin program, essential "survival" responsibilities include:

- Taking basal insulin daily
- Taking rapid insulin with all meals and snacks
- Checking blood glucose before eating and at bedtime
- Recognizing and treating hypoglycemia properly

By taking care of these few key items, you can keep yourself out of immediate harm's way and lay the foundation for more advanced management techniques – when you're ready, willing and able. Examples of these "glucose management" responsibilities include:

- Counting carbs
- Matching insulin to carb intake
- Timing insulin doses properly
- Exercising regularly
- Adjusting insulin based on physical activity
- Keeping records
- Proper management of injection or (pump) infusion sites
- Seeing healthcare providers on a regular basis

A list like this could fill up the next 10 pages, but you get the idea. These are the types of things that let us do more than just survive with diabetes. They allow us to thrive as well. Nobody can or should be expected to do everything right all the time. Pick and choose the activities that are most pertinent to you, and don't overdo it. Diabetes management may be necessary for life, but there is a lot more to life than managing diabetes!

Gary Scheiner MS, CDE is Owner and Clinical Director of Integrated Diabetes Services, a private consulting practice located near Philadelphia for people with diabetes who utilize intensive insulin therapy. He is the author of several books, including Think Like A Pancreas: A Practical Guide to Managing Diabetes With Insulin. *He and his team of Certified Diabetes Educators work with people throughout the world via phone and the internet. Gary is also "Dean" of Type-1 University (www.type1university.com), an online school of higher learning for insulin users. See our Test Drive in diaTribe #29 for more information on this resource. Gary can be reached at gary@integrateddiabetes.com, or toll-free at 877-735-3648.*

trial watch

T1 Comparison of a New Formulation of Insulin Glargine With Lantus in Patients With Type 1 Diabetes Mellitus on Basal Plus Mealtime Insulin

ClinicalTrials.gov Identifier: NCT01658579
http://clinicaltrials.gov/ct2/show/NCT01658579

Can a new version of Lantus improve glucose control?

While Sanofi's Lantus (insulin glargine) has emerged as the standard for basal insulin, companies such as Novo Nordisk, Eli Lilly, and Sanofi itself are still working on new long-acting insulins that offer more flexible dosing options, less risk of hypoglycemia, and other novel features that distinguish them from Lantus. Sanofi previously announced its own new, clinically different formulation of Lantus was in phase 3 trials, and it is now undertaking an additional phase 2 study comparing the effectiveness of the current, FDA-approved version of Lantus with this new formulation. The trial is primarily focusing on the percentage of time participants spend in their target glucose range on either version of insulin glargine. Participants must have type 1 diabetes and an A1c no greater than 9.0%. The study is currently recruiting 56 participants at Sanofi's investigation sites in Minneapolis, MN (site #840001) and Temecula, CA (site #840002). For more information, please send an email with the number of your preferred site to contact-us@sanofi-aventis.com. *–AW*

T2 The Efficacy of Insulin Degludec/Liraglutide in Controlling Glycemia in Adults With Type 2 Diabetes Inadequately Controlled on GLP-1 Receptor Agonist and Metformin Therapy (DUAL III)

ClinicalTrials.gov Identifier: NCT01676116
http://clinicaltrials.gov/ct2/show/study/NCT01676116

Can an insulin/GLP-1 combo lower A1c?

IDegLira is Novo Nordisk's combination of its GLP-1 agonist Victoza and its ultra-long-acting insulin degludec, which is still pending approval from the FDA and other global regulatory agencies. By combining the two therapies in a fixed ratio – which means any increase in the amount of insulin would also require a proportional increase in Victoza – IDegLira has so far demonstrated improved glycemic control, potential for weight loss, and less risk of hypoglycemia than insulin alone. Last month, Novo Nordisk announced updates on its phase 3 IDegLira trials (see new now next in *diaTribe* #46), with the DUAL I trial producing favorable results and the DUAL II trial on track to complete by the end of the year. The company is now beginning work on the DUAL III trial, which will compare the change in participant A1c levels when taking IDegLira and metformin compared to taking metformin and either just insulin degludec or just Victoza. Participants must have type 2 diabetes, an A1c between 7.0% and 9.0%, a BMI no greater than 40 kg/m2, and be using a daily GLP-1 agonist as part of their treatment for at least 90 days before beginning the study. The study is recruiting 429 participants at 55 locations in 24 states (AL, AZ, CA, FL, GA, IL, IN, KY, MD, MI, MO, NE, NV, NH, NJ, NY, NC, OH, PA, TN, TX, UT, VA, WA) as well as additional locations in Australia, France, and Slovakia. For more information, call the Novo Nordisk Clinical Trial Call Center at 866-867-7178. *–AW*