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Does Medtronic’s Veo insulin pump reduce the risk for nocturnal hypoglycemia? Can an anti-CD3 therapy help prevent or delay the onset of type 1 diabetes?

One of February’s biggest medical stories was the FDA Advisory Committee’s recommendation to approve Qnexa, a new anti-obesity drug. One could argue that Qnexa represents a small change, since it is simply two existing medications (phentermine for short-term weight loss and topiramate for migraine/epilepsy) combined in a single, once-daily pill. But bringing such a change to the real world is a big process with big implications – clinical development has involved thousands of patients over several years, and the FDA’s review (which began in early 2010) will continue until at least this April. The FDA has been especially cautious so far because so many people might want to try Qnexa; in one-year trials, patients on average lost nearly 10% of their body weight when they used Qnexa along with a diet-and-exercise program. We discuss Qnexa more in this month’s NewNowNext, but suffice it to say that this small change could benefit millions of Americans as they work to lose weight and improve their health.

Another recent example is Bydureon, which uses the same active ingredient as Byetta – except in a once-weekly injection instead of twice-daily. Thanks to this small change (which also decreases the nausea associated with the drug), many people, including me, think that the launches of Bydureon in the US (this month) and in Europe (last summer) could be “game-changing” moments in diabetes care.

Although many more examples of small, positive changes are happening every day in diabetes care, I’ll close with just one more. Since we began publishing diaTribe in November 2006, we’ve made many tweaks: switching to a once-monthly format with longer issues, founding dQ&A to give you a direct voice to diabetes companies (write richard.wood@d-qa.com if you’d like to be part of this multi-thousand person panel), and expanding to platforms like Twitter (if you don’t already, follow us at @diaTribeNews). After 40 issues, diabetes has become a bigger worldwide problem than ever, and we are still just one small team working against the tide. But we hope that diaTribe has been a small change for the better in your own life, with many more small changes to come.
quotable quotes

“If we were discussing any other disease that affects 70 million Americans and will kill 100,000 by the end of the year, what would we consider acceptable risk?”

-Dr. Arya Sharma (University of Alberta, Edmonton, Canada) on the importance of recognizing obesity as a disease at the second FDA Advisory Committee meeting on Vivus’ weight loss drug Qnexa in White Oak, MD on February 22, 2012.

“In under 10 years, we’ve gone from no devices to studies outside the hospital. It’s incredibly exciting. It’s so close now I can taste it.”

-Dr. Stu Weinzimer (Yale University, New Haven, CT) on the progress achieved toward the development of an artificial pancreas at the 2012 JDRF Type 1 Diabetes Research Summit in Bethesda, MD on February 18, 2012.

“What are we doing to prevent type 2 and type 1 diabetes? Working to improve outcomes for those with diabetes is imperative, but we need to place a priority on prevention as well. We will not be able to sustain this pace. Obesity and diabetes will not only cause terrible damage to our economy, but to citizens that are trying to hold onto jobs and to contribute to society. It’s not just about health and healthcare, it’s about our society and our families.”

-Dr. Ann Albright (Centers for Disease Control and Prevention, Atlanta, GA) on the gravity of the obesity and diabetes epidemics for health, society, and the economy at the 12th Annual Rachmiel Levine Diabetes and Obesity Symposium in Pasadena, CA on February 15, 2012.

fingersticks

“"We are just about out of time but I am happy to take more questions at the dessert social up next."
FDA Advisory Recommends Approval of Obesity Medication Qnexa

After an intense day of deliberations earlier this month, an FDA advisory committee delivered an overwhelmingly positive vote (20-2) in favor of the approval of Vivus’ Qnexa for the treatment of obesity. The FDA now has until April 17 to consider the panel’s recommendation and to make a final decision on whether to approve Qnexa or ask for additional data. While approval is by no means guaranteed, the outcome of the panel looks very good for Qnexa. No other obesity drug has received such strong endorsement from an advisory committee in nearly 15 years (the last time was the unanimous recommendation to approve Roche’s Xenical in 1997). Members of the committee agreed that Qnexa works very well – in a one-year trial, participants taking Qnexa averaged weight loss of approximately 25 pounds; while those taking placebo also lost weight, it was much less, relatively speaking.

While panelists initially expressed greater concern about the potential long-term safety issues associated with the drug, including the risk of birth defects (especially cleft lip or cleft palate), and cardiovascular risk (due to the slight increase in heart rate), they were clearly reassured by the end of the meeting that the benefit/risk clearly worked in patients’ favor to recommend approval. While the FDA decided not to approve Qnexa in its first review in 2010 (see our NewNowNext in diaTribe #26), clearly the panel felt obesity was a major health risk and that patients needed an effective medical alternative to “Weight Watchers and bariatric surgery”. Overall, panelists expressed strong reassurance that the potential risks could be reduced through what is called a Risk Evaluation and Mitigation Strategy (REMS), through which Vivus would provide education to patients, physicians, and pharmacists on the appropriate use of the drug and its associated risks, have measures in place to restrict the drug’s use only to approved types of patient, and be able to closely monitor the drug’s safety. The exact REMS has yet to be finalized, but will be a focus of conversations between Vivus and the FDA leading up to Qnexa’s potential approval date.

Panelists also were comfortable that Vivus could conduct an “outcomes” trial to better understand cardiovascular risk after it was approved, rather than before (which would mean a long delay or that development of the drug would stop altogether). They acknowledged that there is inherent harm in doing nothing to make treatment options available, which should be balanced against the risks. This is an encouraging sign that obesity may finally be coming closer to being recognized as on par with other diseases, worthy and in great need of additional treatment options. At the panel, diaTribe editor Kelly Close had the opportunity to speak on behalf of diaTribe during the open public hearing session. To see Kelly’s comments on how important the day’s decision would be for obese individuals and for companies working to develop new treatments, please visit http://bit.ly/wPHp3w. To view her PowerPoint presentation, please visit http://bit.ly/zpPHeK. – VW

Bydureon Now Available in the US

Following the US approval of Bydureon late last month, the drug became available at pharmacies across the nation in mid-February. Bydureon is the first once-weekly drug to be approved for the treatment of type 2 diabetes. It belongs to a class of drugs called GLP-1 receptor agonists, which stimulate the body to produce insulin and reduce glucose production only when blood glucose levels are too high. Because of these effects, GLP-1 receptor agonists can help people with type 2 diabetes improve blood glucose control without increasing the risk for hypoglycemia (low blood sugar). GLP-1 receptor agonists also suppress appetite, which helps some patients achieve significant weight
loss. Besides Bydureon, two other GLP-1 receptor agonists are available in the US – Victoza (injected once daily) and Byetta (injected twice daily). Amylin, the manufacturer of Bydureon, is offering eligible patients a co-pay savings program (called the Bydureon Steady Savings Card), which can offset co-pay costs by up to $50 per month for two years (making many co-pays free). A patient assistance program is also available to eligible patients without prescription drug insurance coverage (for those paying out of pocket, Bydureon will cost $323 per month). For more information on Bydureon and GLP-1 receptor agonists, see the NewNowNext in diaTribe #39 and visit the Bydureon website (which includes a video on how to inject the drug) at www.bydureon.com. –BK

JDRF Research Webcast on March 5 to include renowned Dr. Judith Fradkin from the National Institute of Health

On Monday, March 5 at 8:15 am EST, JDRF will hold a live research webcast in conjunction with its annual Government Day. We’re extraordinarily excited that the National Institute of Health’s (NIH) renowned Dr. Judith Fradkin will discuss how JDRF and NIH research are jointly making progress to cure, treat, and prevent type 1 diabetes. Dr. Fradkin is a notable figure in the diabetes world and this represents a highly exceptional opportunity for patients to hear her speak and ask her questions. The webcast can be viewed at www.jdrf.org/livewebcasts and questions can be submitted via live chat, email (webcast@jdrf.org), Twitter, or Facebook. For those who can’t view it, the 90-minute webcast will also be recorded and made available after the live event. --AB

Dexcom and Tandem Partner to Combine Gen 5 CGM Sensor with Tandem’s t:slim Insulin Pump

In early February, Tandem Diabetes Care – the manufacturer of the t:slim insulin pump – announced plans to build a new version of the t:slim that can sync up with Dexcom’s fifth-generation continuous glucose monitoring (CGM) sensor (note that the currently available Seven Plus is the third-generation sensor). With the new device, users will be able to both dose their insulin and monitor their glucose sensor data using a color touchscreen.

Unfortunately, this Tandem/Dexcom product won’t be approved for at least two years, perhaps three. The standalone t:slim pump is set to launch in the US in the first half of 2012. Meanwhile, the fifth-generation Dexcom sensor, which will also feature open connectivity to devices like smartphones, tablets, and computers, is on track for FDA submission in mid-to-late-2013. The combination Tandem pump/Dexcom fifth-generation CGM product could be filed 100 days later, and the actual FDA review process typically lasts about six months. Thus, we expect the Tandem/Dexcom product will be available around mid-2014 at the earliest. (A similar timeline applies to the CGM-integrated pumps being built by Roche, Dexcom’s second-most-recently announced partner.) In the nearer term, Dexcom is continuing to move ahead with its fourth-generation sensor, which will offer notable accuracy and reliability improvements over the Seven Plus. The major trial to get the sensor approved was just completed, and we expect it could be on the market as soon as late 2012/early 2013.

To learn more on pump/CGM development, see past diaTribe articles on the Medtronic Paradigm REAL-Time Revel (the only combo product currently available in the US), the Animas Vibe (an upcoming system that unites the Animas Ping with Dexcom’s fourth-generation CGM, currently available in six European countries with a slightly earlier-generation sensor), and a combination product featuring the Insulet pump and the Dexcom CGM (an upcoming integration of the second-generation OmniPod and the fourth- or fifth-generation Dexcom CGM will be coming soon). – JS/AB
Two New DPP-4 Inhibitor/Metformin Combination Therapies Approved in the US

In late January, the FDA granted approval to two new combination therapies for the treatment of type 2 diabetes — Merck’s Janumet XR and Eli Lilly/Boehringer Ingelheim’s Jentadueto. Both therapies combine a DPP-4 inhibitor and metformin (both already approved therapies for type 2 diabetes) into a single pill, increasing convenience over taking each drug separately. As background, DPP-4 inhibitors help prevent the destruction of the gut hormone GLP-1 in the body, which improves glucose control with minimal risk for hypoglycemia or weight gain. Meanwhile, metformin lowers blood glucose levels by decreasing glucose production by the liver. With the recent approval of Janumet XR and Jentadueto, there are now four different DPP-4 inhibitor and metformin combination therapies available in the US. Jentadueto is a combination of the DPP-4 inhibitor Tradjenta and metformin and is taken twice daily. Janumet (approved in 2007), and Janumet XR both contain the DPP-4 inhibitor Januvia, but differ in the formulation of metformin that is used. For this reason, Janumet is taken twice daily, whereas Janumet XR can be taken once a day. The only other currently approved once-daily DPP-4 inhibitor/metformin combination therapy in the US is Bristol-Myer Squibb/AstraZeneca’s Kombiglyze XR (saxagliptin plus metformin XR). For more details on Kombiglyze XR, see the NewNowNext in diaTribe #28). We note that none of these combination therapies should be used in people with impaired kidney function because of increased risks for certain side effects (such as lactic acidosis). The manufacturers of both Janumet XR and Jentadueto have indicated that the drugs will be available at pharmacies shortly. --LR/BK

Dexcom to Acquire SweetSpot Diabetes Care, Developer of an Online Diabetes Data Platform

On February 23, Dexcom announced that it had acquired SweetSpot Diabetes Care, an IT company with an online platform for uploading and processing data from diabetes devices. The sleek web-based system will eventually allow patients to share data on blood glucose, CGM, and insulin delivery devices with their healthcare providers, enable online data storage, generate detailed reports, and even integrate the data into electronic medical records. Additionally, the new SweetSpot/Dexcom software will feature advanced data analysis capabilities like pattern recognition and glycemic variability statistics. Ideally, these features should make understanding an often-overwhelming amount of CGM data much easier for patients and providers. At this time, the companies have not announced when the new system will be launched and we expect that it will certainly take some time to develop. Nevertheless, we see the new platform as a major upgrade over Dexcom’s current PC-only, non-Internet-based DM3 software.

Looking to the future, Dexcom’s plan is to have their fifth-generation CGM sensor (the current Seven Plus is their third-generation sensor) enable the use of a smart phone as a receiver. This would allow Dexcom to remotely and seamlessly send CGM data from a smart phone to SweetSpot’s online-based data management platform. Such technology could be exciting from both a remote monitoring perspective (e.g., parents could monitor their child’s CGM while at school) and for its potential to reduce the hassle associated with downloading devices. Here at diaTribe, we have followed the excellent team at SweetSpot Diabetes Care since 2008 (see our coverage in NewNowNext in diaTribe #12) and are very glad to see them partnering with Dexcom. We’ll certainly be anxious to hear more updates on the development of the new software and when patients might be able to try it. --AB

www.diaTribe.us
Registration Now Open for the Students with Diabetes 2012 National Conference

Students with Diabetes will be hosting an exciting conference for young adults (ages 18-30) with type 1 diabetes from June 1-3 in Tampa, Florida. The weekend will feature speakers, activities, social events, sessions about the realities of living with diabetes as a young adult, and connection opportunities. Additional conference highlights include speeches by diabetes celebrities and team building activities at theme parks and ropes courses. Registration for the conference is $40 before the end of February and $55 thereafter. More information can be found at www.studentswithdiabetes.health.usf.edu and on Facebook at facebook.com/studentswithdiabetes. To register, please contact Nicole Johnson at nicolej@health.usf.edu or visit the event’s Facebook page. --LR

Avoiding Complications of Diabetes

by Mark Yarchoan

The word “pancreas” is bound to appear somewhere in this issue of diaTribe, and is probably found in every issue that precedes it. That is because diabetes is often thought of as a disease of blood sugar, insulin, and the organ directly in charge of insulin secretion - the pancreas. Yet I’ve never once met anyone with diabetes who came to the hospital saying, “my pancreas is acting up again.” Diabetes affects every single organ in the body, and most of the time it’s complications of diabetes in other organs that send people with diabetes to the hospital. Appreciating how diabetes affects other organs is essential to understanding how to avoid diabetes complications and for comprehending why blood sugar control is so important.

Three areas of the body that are often affected by diabetes are the eyes (diabetic retinopathy), the kidney (diabetic nephropathy), and the feet (diabetic neuropathy). It may seem strange that these three areas of the body that are physically and functionally far apart are nonetheless similarly vulnerable to damage from diabetes. The reason for their shared susceptibility is that all three tissues receive blood from very small blood vessels, called the microvasculature (micro- small, vasculature – blood vessels). Over time, high blood sugar can damage these blood vessels, leading to damage in tissues that rely on the blood supplied by these vessels. Damage to the eyes, kidney, and nerves of the feet from diabetes is collectively called “microvascular complications of diabetes.”

The good news is that with appropriate prevention, screening, and treatment, many people with diabetes can avoid diabetes complications altogether. High blood sugar is believed to cause microvascular complications of diabetes in three different ways: 1) high blood sugar can directly cause damage by sticking to the proteins that are the building blocks of the tissues, forming what are called “advanced glycosylated end products (AGEs)”; 2) high blood sugar can cause “free radicals” and “reactive oxygen species” – the opposite of “antioxidants” – that can damage or destroy cells; and 3) high blood sugar can lead to the accumulation of sugar-alcohol in cells such as sorbitol, which stresses cells and causes them to swell with water.

I’ve intentionally used the term “high blood sugar,” rather than diabetes, because the eyes, kidney, and nerves don’t know whether or not a person has diabetes. High blood
When blood sugar is well controlled, the rate of diabetes complications falls dramatically. For example, in the Diabetes Control and Complications Trial (DCCT), a landmark trial that was conducted from 1983 to 1993 in people with type 1 diabetes, there was a 60% reduction in kidney and eye damage in people treated to an A1c of 7.0% compared to an A1c of 9.0%. In type 2 diabetes, a 1% decrease in A1c has been shown to cause a 37% decrease in the risk in eye or kidney complications.

Reducing the rate of microvascular complications of diabetes is one of the main goals of current diabetes treatment guidelines. Below are some tips that can help reduce the risk of developing these complications:

**Glucose Control:**

- The A1c (widely referenced in this article) is a test that reflects your average blood glucose level for the prior two to three months. A goal of less than 7.0% is desirable for most people with diabetes, which corresponds to an average blood glucose level of 150 mg/dl. However, more or less stringent A1c goals may be appropriate for some people with diabetes. Some people believe striving for a more “normal” level is appropriate, especially if they have access to CGM, which can help significantly in recognizing signs of or in helping avoid hypoglycemia.

**Vision and kidney screening, and foot care:**

- People with diabetes should receive an annual comprehensive eye examination by an ophthalmologist or optometrist (less frequent exams may be appropriate for some people), an annual urine screening for albumin (a protein that when present in the urine can be a sign of kidney disease), and annual comprehensive foot examinations.

- Never cut off calluses or corns on the feet (calluses may safely be controlled by rubbing a wet pumice stone daily using a lotion after using the stone), and wear well-fitting protective shoes.

**Blood pressure and cholesterol:**

- People with diabetes should monitor blood pressure and cholesterol, and should aim for a blood pressure level below 130/80 mmHg and LDL cholesterol (the bad kind of cholesterol) of less than 100 mg/dl.

Our knowledge and understanding of diabetes and its complications is continually growing, and the available treatment options for diabetes have improved over the years. With careful self-management and support from your healthcare provider team, serious complications of diabetes can be avoided. Although glucose control will always be the best way to reduce diabetes complications, a number of breakthroughs in the management of diabetes complications are on the horizon. These include a remarkable anti-inflammatory therapy called bardoxolone methyl that has shown great promise in treating chronic kidney disease caused by diabetes, and several new treatments for diabetic macular edema including Roche’s Lucentis (already approved for age related macular edema). We look
Encouragingly, the artificial pancreas system in the study kept individuals in the target range 60-70% of the time without hypoglycemia.

The Artificial Pancreas Moves into the “Real World”

An artificial pancreas continuously monitors glucose levels (via CGM) and automatically delivers insulin in response (via an insulin pump and a computer algorithm; for more information, see the Artificial Pancreas section of our free e-book, Targeting a Cure for Type 1 Diabetes). ATTD 2012 featured updates on the first two artificial pancreas trials that have taken place outside the hospital and allowed patients to use the system in more real world, less heavily monitored scenarios. We note that at this point, these types of trials are more concerned with demonstrating safety and technical feasibility than achieving superb glycemic control.

The first AP update at ATTD came from a European study sponsored by JDRF. Participants wore an Insulet OmniPod pump, a Dexcom CGM, and used an Android cell phone that runs a computer algorithm and controller application. The system, called the Diabetes Assistant, was developed at the University of Virginia and was first demonstrated at the Diabetes Technology Meeting in November 2011 (see conference pearls in diaTribe #38). As part of the trial reported at ATTD, six participants wore the artificial pancreas for 18 hours outside the hospital, including sleeping in a hotel and dinner at a restaurant. While it is not fully automated (i.e., users still had to bolus for meals), it does “control-to-range” – meaning that based on a series of CGM values, it infuses the appropriate amount of insulin to keep users in a glycemic zone such as 70-180 mg/dl. Encouragingly, the artificial pancreas system in the study kept individuals in the target range 60-70% of the time without hypoglycemia. The Diabetes Assistant was not able to demonstrate that it is superior to completely manual blood glucose control in this trial. However, it has shown it is safe and we have no doubt that systems in the near-term future will perform even better.
We also heard inspiring results from an overnight study of the artificial pancreas that has now taken place at three diabetes camps in Europe. Fifty-six patients were studied over a two-night period. On one night, participants wearing an insulin pump and CGM controlled their diabetes as they normally would (known as “open-loop control”). On the other night, participants wore an artificial pancreas (“closed-loop control”), which included an insulin pump, a CGM, and a bedside laptop (the researchers are currently developing a smaller, more portable system to hopefully run on a cell phone). All patients were simultaneously monitored overnight from a central command and control center – we think this is one of the coolest and most impressive parts of the system. Compared to standard open-loop therapy, those wearing the artificial pancreas spent more time in range and had a lower rate and duration of hypo- and hyperglycemic events. The researchers even screened a dramatic video documenting the first phase of the study in Israel, with a focus on the children who bravely entrusted their sleep to science. Those interested can view the video at: http://youtu.be/9HMx8yy2nVw.

Finally, ATTD gave us a glimpse into the near-term and long-term future of artificial pancreas research. In the near term, we heard about an intriguing study planned to begin at Mass General in Boston this summer. Participants will wear two Tandem t:slim insulin pumps (one to deliver insulin, one to deliver glucagon), a CGM, and use an iPhone 4S to control the artificial pancreas system. This is known as a bi-hormonal system, which will automatically infuse insulin if the blood sugar is too high (either in response to a basal rate being too low or in response to too little insulin being taken as bolus) and infuse glucagon if the blood sugar is too low. Participants in the study will wear the artificial pancreas for five days and be permitted to roam freely around the Massachusetts General Hospital Campus – they will have free access to the gym, a nurse chaperone for safety during the day, and no set schedule or diet. At night, participants will sleep in the hospital with frequent blood glucose sampling. This initial trial will enroll adults, although future studies are planned for 12-17 year olds at a diabetes camp (2013) and newly diagnosed patients (2013-14). We are certainly glad to see that artificial pancreas research is moving out of the hospital and into more real world environments. These types of studies are essential to perfecting the systems and identifying any faults before they can be fully developed, submitted to regulatory authorities, and brought to market.

In the more distant future, we enjoyed hearing a full session on combining insulin infusion and CGM sensing into a single site (“single port”). This was a unique topic that we had not previously seen or heard much about, although it would certainly be a boon for patients. The data is still very early stage, but it’s a sign of what we can look forward to as diabetes technology continues to improve.

**Impressive Data from the T1D Exchange**

One of the other major highlights from ATTD was a full session on the T1D Exchange, a cohort of 25,000 people with type 1 diabetes in the US. The registry was launched through a $26 million grant from the Helmsley Charitable Trust and gathers data on patients from 67 clinical centers across the United States. The T1D Exchange will also include “Glu,” (https://www.myglu.org/), which will serve as a social networking site for people with type 1 diabetes once it is launched in the coming months. One of the major ideas behind the T1D Exchange is to gather “real life” data to help answer which treatments and practices actually improved patient outcomes, and perhaps to even challenge or confirm many of the assumptions held about diabetes care. Of course like any observational dataset, the Exchange cannot directly address important questions of causality (e.g., is therapy X beneficial, or is it just more likely to be used by the type of patients who tested their blood glucose ≥10 times versus 0-2 times per day were seen to have nearly 2.0% better A1c.
Insulin pumps and CGMs were associated with notable benefits as well, including better A1c (~0.5%) and lower rates of severe hypoglycemia and DKA.

The exchange also revealed areas where diabetes care and technology can improve. For instance, only about 2% of patients over 13 years old perform weekly downloading of data. CGM use was also quite low in the dataset – at most 3% in patients under 25 years and 14% in patients over 26 years (we believe actual use nationally is even lower). Rates of severe hypoglycemia and DKA were also quite high in the Helmsley dataset, suggesting that diabetes care and technology still has ample room to improve the day-to-day lives of those with type 1 diabetes. We are grateful for the brainpower put into the T1D Exchange thus far, and we look forward to seeing how the data will benefit future patients, physicians, and researchers, particularly in shaping policy and payments.

logbook

An American in Malawi: Madonna’s First School, Glucose Meters, and Baseball

by James S. Hirsch

I am sleeping in a mud hut in an African village, lying beneath a mosquito net on an unforgiving dirt floor, thankful that rest has finally come. But it doesn’t last.

“Arrrghh!” A loud groan comes from the adjacent room, quickly followed by two defiant whacks. Then the voice of my friend, Jim Ziolkowski: “I’ve been bit!”

He grabs his head light and shines it on his assailant: a fat 15-inch rat. It had begun to gnaw on his left ring finger when he awoke and slammed his hand to the ground. Now Jim Z, as he is known, looks right into the bulky rodent’s beady eyes before it waddles off into the dark. Blood smears his wedding band, and the flow doesn’t stop until he stanches it with toilet paper.

It’s our first night in the Village of Kankhumbwa, in the Central Region of Malawi, without electricity or running water or even a cot to sleep on. I understand what a soldier feels when he survives a round of fire but his friend next to him is killed – despair over the death but grateful for his own survival. I’m mortified for Jim Z but relieved that I wasn’t bit. I’m not sure I could “survive” an African rat bite; I might have gone home right then. Actually, as we soon discover, we aren’t sure Jim is going to survive either.

I’ve taken many business trips in my life, from Paris and Amsterdam to the Philippines and Bangkok. Because I have type 1 diabetes, I have to take extra care in my planning. Swift changes in diet, schedules, sleeping and activity patterns are enough to throw the most conscientious patient into glycemic turmoil, but I’ve always managed.
Then came Africa. You can go to any country on the continent and find modern accommodations. I’ve heard Americans talk about their “African experience” – going to safaris during the day, to safely gaze at the lions, elephants, and zebras, while staying in comfortable, even luxurious digs at night. That’s not the Africa I experienced, and it’s not the Africa most Africans experience either. I stayed in impoverished rural villages for almost two weeks. Despite my best efforts, I had several diabetes-related mishaps and near-crises, and I learned far more about the country’s primitive health care system than I bargained for. The trip overall was a surreal blend of the pre-industrial age and the digital age, of ancient customs and new opportunities, of haunted mountains, joyous dancing, and the crack of a baseball at twilight.

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I am in Malawi to research a book – a collaboration with Jim Z, a global youth advocate, on his memoir. His nonprofit organization, buildOn (www.buildon.org), constructs schools in developing countries while also running programs in the United States in which high school students volunteer for community service. Each year, some of these teens travel abroad to build schools, and 15 such students from the South Bronx were selected for this trek to Malawi.

BuildOn only assists the poorest of the poor countries, and Malawi easily qualifies. A former British colony, it is a small landlocked nation in southeast Africa, with one of the world’s lowest per-capita incomes – the average Malawian earns less than $1 a day. While its biggest cities have amenities such as electric lights and hot showers, those comforts do not grace the country’s rural areas, where 85 percent of the population lives. There, the men toil in the tobacco or corn fields, the women haul buckets of water on their head while balancing a baby on their back, and the children walk barefoot to school along dirt roads.

I had never been to Africa but tried my best, medically speaking, to prepare. My insulin, for example, would need to be kept cool for two weeks. There would be no refrigerators or cooling blocks in the village, but a friend told me about the FRIO carrying case, which can keep insulin cool and only requires water every two days to activate its cooling properties. I use the wireless OmniPod system, which means I only need a short-acting insulin (Novolog in my case). But the first rule of diabetic travel is that for every supply item, you need a backup. Not only did I bring two vials of Novolog, but in case my pump broke down, I brought a long-lasting, or basal, insulin (Lantus), plus syringes.

I packed my glucagon kit and showed Jim Z how to use it in case I ever passed out from hypoglycemia. I packed my backup batteries for my OmniPod “personal diabetes manager,” or PDM, the machine that both delivers the insulin and tests my blood sugar. I had backup plastic pods, backup glucose strips, backup glucose tabs, even backup granola bars. Medically speaking, what could possibly go wrong?

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The most memorable moment is our arrival at the village. We ramble in on an old school bus, along deeply rutted dirt roads that would be impassable in heavy rain. Today is bright, and as we chug along I see children from all different directions streaming toward us from four or five different villages. They’re chasing the bus, hundreds of kids, singing, smiling, dancing – as if this were the opening shot of a movie, a sweeping panoramic
across the African fields. The students from the Bronx step down into the unconditional embrace of these nameless, exuberant children. Some of the students dance. Others cry. Many watch in amazement. The children know we are here to help the community build a school, but their love speaks to some deeper connection. No one just happens by this isolated community, and there is no evidence the government pays it much heed. Our arrival signals an important message: you matter.

The new school, which will replace an older, dilapidated one, has another distinction: it is sponsored by Madonna. The pop star has an adopted child from Malawi and a foundation for the country; she recently gave money to buildOn to construct 10 schools here, and this will be her first.

But that means little to the American students, who just want to be accepted in the village. At a lengthy opening ceremony, our trek coordinator, Rosann Jager, gives each of us an African name. I am Kadammanja, which means “black hand.” I appreciate the literary touch but can’t absorb all the syllables. I introduce myself as “Jim.”

The Americans are assigned to a host family, and I room with Jim Z and our translator, Chris, a smart, friendly college student who only speaks when spoken to. It takes 35 minutes to walk to our mud hut, and the skies suddenly open as we trudge along. Some of our clothes will stay damp for the rest of the trip. We reach the hut by nightfall, and I have my first real glimpse of how barren my next two weeks will be. The hut, its thatch roof leaking, has two front rooms in which the three of us are to sleep. But there are no beds, no chairs, no benches, no tables, no shelves, no nightstands, no lights, no mirrors, no nothing.

Check that. The hut has one thing: cockroaches, which crawl brazenly along the wall. Jim Z believes they can fly, but I don’t have the good fortune of seeing one airborne. I decide to sleep in the smaller room, by myself. I lay my thin inflatable mattress on a hard wooden mat, then hang my mosquito net from a rafter. It dangles over and around the body so that when you open your eyes, you are literally enmeshed. The only light comes from a flashlight. Inside the hut or out, the darkness is unremitting.

All of this has repercussions for diabetes. Have you ever changed an infusion set, drawn up insulin, or tested your blood sugar in the dark? It’s not fun. I don’t appreciate until now how many moving parts there are to diabetes care.

The darkness brings to mind one more peril. What if my blood sugar crashes in the middle of the night? I’ve shown Jim Z how to use the glucagon kit if I’m unable to revive myself. Under ideal circumstances, it would be asking a lot for a neophyte to use it correctly – mixing the powder with the solution and giving the injection. But in the darkness, with no shelf on which to place the kit, he wouldn’t even be able to find it, let alone administer it.
As I fall asleep on that first night, I’m beginning to think this whole trip may have been a mistake. Then I hear Jim Z’s scream. His pain tolerance is probably as high as any person I know, so when he curses the “bastard rat,” I know it’s serious. Jim Z wasn’t using a mosquito net, which may have deterred the rat. The host family later tells us that it knows it has rats, which usually feed on sacks of corn but have bitten their children in the past.

We leave the hut that night and transfer to upscale sleeping quarters – the school headmaster’s new house. It has concrete floors instead of dirt, which probably means fewer rodents. Jim now sleeps with a mosquito net.

The next day, we head into town and find a clinic at a private school. Jim Z needs a vaccine, which is a series of five shots over 28 days. A nurse gives him his first shot. We then talk to a doctor provided by FrontierMEDEX, a travel insurance agency. He tells Jim Z that he needs to also take a second vaccine as well, immune globulin, which would be injected right into the potentially infected finger. He says Jim’s chances of having rabies “are low but not zero.” A rat on its own wouldn’t carry rabies, but if it were bitten by a rabid cat or dog, it would then be infected, and a 15-inch rat would be large enough to survive such a bite.

“If I do get rabies,” Jim Z asks, “what are the symptoms.”

“You die,” the doctor says.

Silence. “Okay, before I die, are there any symptoms?”

“You become irritable.”

Before leaving the clinic, I enter the washroom, desperate to clean my hands. There is hot water, but no soap.

He explains that three years ago, he came to Kankhumbwa to establish a health clinic, but it consists of nothing more than two trees, where he talks to villagers seeking care. He has no medical supplies and no diagnostic equipment.

The problem is that the district he services – eight villages and about 1,600 people – is too poor to afford care. Midwives deliver babies in homes, and herbalists brew concoctions to ward off disease. A more substantial clinic, which has refrigerated vaccines, is about four miles away, and a hospital stands about 30 miles away. But no one in the village has a car, so reaching either, by foot or bicycle, is difficult.

The most severe health problems are easily prevented. Malaria, for example, kills about 12 people a year in the district, with children under five the most vulnerable. They would be protected if they had mosquito nets, but most households don’t have them. A net only costs about $5, and several Western aid organizations supply them to developing countries. But Frackson says that the nets that are sent to Malawi never reach his villages. “They are sold on the black market,” he says.
Malnutrition, AIDS, and tuberculosis are the next biggest killers, he says. I ask about diabetes. He says the district has about 15 people with the disease and that some use insulin, some don’t. I ask whether they have type 1 or type 2, but he is unfamiliar with the terms.

I then show him my PDM and test my blood sugar – 190 mg/dl. He’s never seen anything like it.

He asks me what the normal “temperature” should be for someone without diabetes.

I explain that the machine doesn’t measure body temperature but determines the amount of glucose, in milligrams per deciliter of blood, and a fasting blood sugar should be no higher than 120.

“Ohhhh,” he says. Frackson is fascinated, and if I teach him how to recognize an elevated blood sugar, then I’ve made a small contribution to Malawian health care.

Three days after receiving his first rabies vaccine, Jim Z needs his second injection. The buildOn staff has no medics, so I am asked to administer the injection. My qualifications? I’ve taken thousands of shots because of my diabetes. The vaccine is assembled in the same way as the glucagon, with two vials, one liquid and one powder. I give the shot without incident – bevel side up for the needle, as I was taught years ago – and realize this is one of the few times in my life that having diabetes is an asset.

Next, we need to take a very long road trip south, to the village where Jim Z built his first school in Africa 19 years ago. But first we stop in the capital city of Lilongwe at the African Bible College, whose private hospital – we are told – has the immune globulin shot. But when Jim Z arrives, the doctor says the hospital has no such shot, and he’s not aware of any other clinic or hospital that might have it.

Jim Z’s window is narrowing. The shot is only effective if taken within seven days of the bite. He has four days left. Before we leave, I go into the washroom – but once again, no soap. It is a luxury that even hospitals cannot afford.

We have a daylong drive ahead of us. In addition to our translator, we ride with three women – a photographer, a videographer, and a producer – who are developing social media campaign for buildOn. They specialize in working for nonprofits for humanitarian causes. They are high-tech, multi-media missionaries, equipped with highly sophisticated digital and video cameras, smart phones, chargers, and laptops, trying to capture the sights and sounds of a land that seems passed over by modernity. We see the beauty of the landscape and the people, but also the primitive conditions: the shacks and shanty-towns, the rusting hulks of nothingness, sagging in the mud, selling trinkets and snacks along the road; the conspicuous signs for coffin makers as reminders that death is a booming business; the thinned-out dogs and cats, goats and cows, as hungry as their owners; the many walkers along the highway, without the resources to travel any other way.

I myself feel like a technological oddity, with my Star Wars insulin delivery device, as if I’ve walked back in time to tell the locals what the future of diabetes care will hold.
BuildOn’s country director tells Jim Z there is no immune globulin in Malawi, and the doctors at Medex are urging him to evacuate to South Africa or Kenya for the shot. He should also be seen by an infectious disease doctor. But evacuation would mean he would lose two days from this trip, whose stories and photos will be used for fundraising later in the year. But if he doesn’t get the shot and develops rabies, he’ll probably die. The doctors are vague about what those chances are, but driving along the road, Jim Z tries to calculate the possibility of death: less than 5 percent? Less than 1 percent?

He has always seen life as a series of risks and rewards and, in working and traveling from Haiti and Nicaragua to Senegal and India, has been exposed to far greater risk than this one. Indeed, he almost died from malaria in this very country 19 years ago. His only hesitation now is that he is a husband and father, with two young boys. “I love them so much,” he says. He worries that his wife might not find another husband if he dies. “She’s beautiful but introverted.”

He nixes the evacuation plans, confident that the risks of death are low, and continues on with the trip.

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We arrive in the Village of Misomali and see the remarkable legacy from Jim Z’s first school in Africa. There are now five schools – the village received money from the Malawi government as well as the European Union – educating more than 1,000 students, half of whom are girls. Jim Z had planted a dozen eucalyptus saplings, no more than six feet high, and they now tower over a courtyard garden adjacent to the schools. Signs of progress abound. Electric wires have brought power to some of the huts. Telephone polls have been erected. Concrete homes with corrugated roofs have been built for teachers. Satellite dishes dot some of the structures. Bicycles carrying sacks of grain roll over dirt roads. Of the five sub villages, four have female chiefs – unheard of in Africa. A baby girl that Jim Z once held is now a beautiful 19-year-old woman who, thanks to her education, is teaching a new generation of students in Misomali.

Jim Z reunites with three of the men he had worked with on the school, but the reunion is quickly tempered when he is told that three other men from this volunteer crew have died. They were his friends, including the village chief, who courageously worked on the school in the face of politically motivated lies by some in the village. Devastated, Jim Z tries to learn what happened to the chief and hears a disturbing tale that resulted in unfounded corruption charges against him. He was sent to prison and, after his release, died from AIDS.

Night falls as we walk back to our house, and the village suddenly takes a menacing cast. We are next to Mount Mulanje, one of the highest peaks in Africa and beautiful to behold in the day. But the locals believe it is haunted by evil spirits, and they must perform juju, or witchcraft, to fend those demons off. Jim Z recalls his own experience here with malaria – he was lucky to survive, but so many others have perished.

“This place is a death trap,” he tells me.

Moments later, we’re at the house to eat dinner with our team. I test my blood sugar, and it’s 144. Then I press the buttons on my PDM to deliver my bolus . . . but nothing happens. I try again, and the meter reads “error message.” Again, same result. And again. I have plenty of battery power, but the machine won’t work.
I am outside at the car gathering my supplies when it suddenly dawns on me: my PDM was also my glucose meter, and I didn’t bring a backup meter. I’m now in the middle of Africa with no way of testing my blood sugar.

tells me to call a toll free number for assistance. Both my son, who also has type 1, and I have used these PDMs for about five years, and I can’t recall one ever just dying. But now it has.

I blame the evil spirits.

I don’t panic. I have backups – my Lantus for a basal insulin, and my syringes. Bevel side up. This regimen will require at least four injections a day for the next week, but I can manage. I am outside at the car gathering my supplies when it suddenly dawns on me: my PDM was also my glucose meter, and I didn’t bring a backup meter. I’m now in the middle of Africa with no way of testing my blood sugar.

Okay. Now it’s time to panic.

When I return inside, I tell Jim Z and friends all that’s gone wrong. I’m blessed with an understanding audience. The photographer’s sister-in-law has type 1 diabetes. The producer’s sister also has it. We’ve been joined by Brett McNaught, buildOn’s vice president of International Programs, and his nephew has type 1. That’s one upside to an epidemic: everyone knows someone with diabetes. Brett says I can buy a glucose meter at a pharmacy in Blantyre, which we’ll be passing through tomorrow.

I say I don’t want to slow us down.

Jim Z says if I don’t get a new meter and strips, he’s going to evacuate me to South Africa or Kenya.

I’m practically moved to tears by their support.

I’m still in uncharted waters. I have to make the transition to Lantus, which I haven’t taken in seven years. I receive a basal insulin rate of 0.5 units an hour, or 12 units for every 24 hours. A once-a-day insulin, Lantus is supposed to last 24 hours, so I assume I should give 12 units before I go to bed. I draw up the syringe but am horrified by the huge volume – I can’t recall the last time I gave 12 units of any type of insulin. My pre-meal boluses are usually around 4 units. What if I’ve miscalculated or if I’ve not remembered correctly how Lantus works? I have no one to ask. A mistake could be fatal. I inject the fluid and wonder if I should learn some juju.

Meanwhile, my insulin pod – the one that I was using when the PDM died – starts beeping right before I go to bed. Why it’s alarming, I have no idea, but I know of only two ways to silence it. Stick a paper clip in it, or put the pod in a plastic bag and shove it in the refrigerator. I have neither a paper clip nor a refrigerator, but I can’t allow the pod to cause a racket indefinitely.

So I go outside and heave it into the black African night. It lands deep in a cornfield. In weeks or months or maybe even years, someone will pick it up – still beeping, perhaps – and believe it was dropped from the sky by an alien. Which I am.

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It’s a strange feeling. I began testing my blood sugar on a regular basis in 1979 or 1980, so for the first time in more than 30 years, I have no idea where I’m at. I wake up in the morning, and I can’t tell if I’m hungry or hypoglycemic. I eat two granola bars just in case.
We leave Misomali and make it to Blantyre for lunch. I stop at the Mudi Pharmacy, ask for a glucose meter, and am handed SD Check Gold, which looks like a Roche product. It costs about $34. The pharmacist speaks English, so I ask him if many diabetic patients in Malawi test their blood sugar.

“No,” he says. “The meters are too expensive. We sell very few.”

“What about insulin?”

He points his thumb straight up. “Oh, yeah, we sell a lot more insulin now. We have generic insulin.”

I had already read reports on the Internet about the rise of diabetes in Sub-Saharan Africa, of which I am now a beneficiary: without a market, there would be no glucose meters.

The new machine works fine, but the box only comes with 10 strips, and the pharmacy doesn’t sell strips individually. So I’m only given a temporary lifeline. Does Malawi sell strips alone? It’s Sunday, and the other pharmacies in Blantyre are closed. After a day of driving, we reach Lilongwe. I visit a pharmacy, but it doesn’t sell strips. The other pharmacies are closed. I could survive on 10 for the rest of the trip, using one a day, but I’d rather not.

Before heading back to our original village, we get gas. But when Jim Z drives out of the station and onto the road, the car inexplicably stops with a loud thump, and tilts downward. Chris jumps out of the back, inspects the scene, and yells to me, “Jim! Get out! Get out!”

I open the door and step down, but there is no ground. Jim Z had driven into a four-foot wide open trench – invisible in the darkness – and now I’m falling into it. I step out and reach over the opening, and Chris pulls me across. With the help of others, we push up the front end of the car, and Jim Z is able to back out.

I’m beginning to realize, that’s Africa at night. You never know when the ground below is going to disappear.

Someone from the village goes into Lilongwe the next day and finds strips for me, which I very much need, because I spend the rest of my time in Africa battling low blood sugars. Specifically, I’m crashing overnight and waking up in the 50s and 60s.
Building a school, it turns out, is hard work. But everyone pitches in, the Bronx students and the villagers, and the foundation is dug, the cement is mixed, the sand is hauled, and the bricks are carefully laid. Two walls begin to rise.

Besides a new school, I think what this village needs is baseball, so at the end of the work day, I bring a bat and ball to the dirt yard next to the work site. Baseball is played at the universities in Malawi, but it hasn’t reached the rural areas, and this appears to be a first at Kankhumbwa. Brett and I demonstrate the basics of hitting and catching, and the kids from the village immediately line up and want a turn swinging the bat.

Each time, whether they strike the ball or miss, they squeal with laughter. Baseball as it should be – for its pure joy. The kids aren’t big, but they haven’t spent a single minute of their lives watching TV or playing videos. They are lean, strong, and coordinated; soccer is their game, but they swing the bat with gusto and hit the ball hard. One girl in a green skirt – she can’t be 7 years old, but she rolls her top wrist like Henry Aaron and consistently whacks the ball over a tree in left field. (Early scouting report on the Malawians: they’re dead pull hitters.) Another boy whips the ball like a young Roberto Clemente. Another flags ground balls like Ozzie Smith.

On our last night in the village, I give the bat and ball to the girl in the green skirt. She seems confused at first but soon understands that this is a gift. I hope she’ll remember me by it.

Our farewell to the villagers is emotional, as some of the American kids have grown close to their host families, and they to them. The school bus rolls out of the village, with Jim Z, Chris, and I trailing in a Toyota Corolla. Alas, nothing is easy. We end up taking a more difficult route to town, and our car doesn’t have the size to handle the ditches in the road. The car gets stuck, and for the second time in Africa, I’m trying to push a car out of a hole.
We succeed, but we’re still in trouble. Our cell phones have no battery, and we’re in the middle of nowhere, so if the car becomes disabled, we’ll have a long walk before we can find anyone for help.

Chris finds a smoother route, and we eventually find our way to town and reconnect with the bus. Jim Z says he wasn’t worried because even if the car broke down, it would have only been a two hour walk. That’s the difference between those who have diabetes and those who don’t: I don’t measure a crisis by, say, the distance needed to walk, but by whether I’d have enough granola bars and glucose tabs to make it. I wouldn’t have.

That’s just the way it is with diabetes. When you travel, you live on the precipice – as I find out one last time in Africa. Jim Z has to get gas on the black market, so he gets it with one of buildOn’s country coordinators. I leave my glucose meter in the car but stay behind. When Jim Z returns, I check the car to make sure my meter is still there. I think I see it. But after we drive off, I double check. The meter’s gone. I assume the country coordinator inadvertently had it in her hand when she left the car. It was my fault for not being more careful, and now I have to buy yet another meter.

My life in Africa: chasing lows, chasing glucose meters.

But those are quibbles. All in all, it was a memorable trip.

Madonna’s first school is being built.

Misomali’s school children are thriving.

Jim Z lived.

And in 20 years, I hope to return to this village and see five schools across every grade level, a clinic that dispenses essential medicine, and a ball field with sturdy bases, an electric scoreboard, and two white foul lines that stretch beyond the cornfields, over the dirt roads, and into the heart of villages unseen.

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**trial watch**

**T1**

*Outpatient Study to Evaluate Safety and Effectiveness of the Low Glucose Suspend Feature (ASPIRE)*

*ClinicalTrials.gov Identifier: NCT01497938*


Although a fully integrated artificial pancreas is still a ways away, investigation into the first step towards it, a low-glucose suspend feature (LGS), is rapidly progressing. In an LGS system, an insulin pump stops dosing insulin when the glucose sensor a person is wearing detects hypoglycemia. Medtronic’s Veo – the first commercially available device containing LGS technology – has been available internationally since 2009, but is not yet approved in the US. This study, which will assess the safety and efficacy of the Medtronic LGS system “at home” (i.e., in the environments in which people will regularly wear it), is meant to provide support for an eventual US approval. It will be conducted at seven sites around the United States (in AR, CA, FL, GA, OH, TX, and WA). In the study, participants with type 1 diabetes will be randomized to wear either 1) the Medtronic Veo with LGS...
or 2) the Revel 2.0 with no LGS feature for five months. Those wishing to enroll must, among several criteria, have had type 1 diabetes for more than two years, and be willing to perform sensor calibrations and at least four finger stick blood glucose measurements a day. Individuals who have had two or more episodes of severe hypoglycemia in the six months prior to screening, have had a myocardial infarction (heart attack), unstable angina, or several other cardiac conditions within the year prior to screening, and/or are pregnant or planning to become pregnant during the study are not eligible to participate in the study. Full inclusion and exclusion criteria can be found at http://1.usa.gov/zAG7-KK. Those who are eligible and interested can contact Thomas Troub at (818) 576-3142 or thomas.troub@medtronic.com. -- LR

Teplizumab for Prevention of Type 1 Diabetes in Relatives At-Risk
ClinicalTrials.gov Identifier: NCT01030861
http://www.clinicaltrials.gov/ct2/show/NCT01030861

Certain white blood cells, known as T-cells, are involved in the body’s immune response. They are also thought to play an important role in the development of type 1 diabetes. These cells present a protein on their surface called CD3 that is critical for their activation and function. It is thought that neutralizing this protein with an antibody may stop the destruction of beta cells in the pancreas, which is the cause of type 1 diabetes. This approach is called ‘anti-CD3 therapy’ (for more details on the role of T cells in type 1 diabetes and anti-CD3 therapy see our free e-book, Targeting a Cure for Type 1 Diabetes). In initial clinical studies, an anti-CD3 therapy called teplizumab was shown to have positive effects for people treated within six weeks of diagnosis. Unfortunately, in a larger phase 3 trial that completed last year, teplizumab treatment did not help recently diagnosed type 1 patients meet targeted A1c and insulin dose reduction goals. But researchers are hoping that teplizumab could be useful in those at risk for type 1 diabetes. Accordingly, this study will examine whether teplizumab can help to prevent or delay the onset of type 1 diabetes in relatives determined to be at very high risk for developing the disease. It will be conducted at 14 sites around the country (in CA, CO, CT, FL, IN, MN, NY, PA, TN, TX, WA), as well as one site in Canada (in Ontario) and will recruit subjects between the ages of eight and 45 years old. Study participants will be randomized to receive either teplizumab or placebo infusions for 14 consecutive days; each infusion takes about 30 minutes and is followed by a two-hour observation period. In order to be eligible, participants must have a relative with type 1 diabetes (first-degree relatives must be between the ages of eight and 45, while second-degree relatives must be between the ages of eight and 20), have at least two confirmed diabetes autoantibodies, and have abnormal glucose tolerance that has been confirmed by an oral glucose tolerance test. Those who have had type 1 diabetes previously diagnosed or detected at screening, have abnormalities in blood counts or liver enzymes, and/or are currently pregnant or lactating are ineligible to participate in this study. Visit http://1.usa.gov/xKgfMb for full inclusion and exclusion criteria. If you are eligible and interested in participating, please contact Dr. Jay Skyler at 305-243-6146 or jskyler@miami.edu or Lisa RAFkin at 305-243-6146 or lrafkin@miami.edu. --LR

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