diaTribe®

research and product news for people with diabetes

in this issue

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from the editor

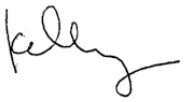
In a recent article in The New England Journal of Medicine, researchers found that only 52% of people with diabetes in the US are achieving an A1c less than 7.0%, a percentage that actually worsened since the last update. This is set against an important backdrop – the psychological barriers and stigma associated with taking insulin, despite its role as the most effective glucose-lowering therapy. Clearly, our available insulins and their associated delivery devices are not helping nearly as many patients as they could -- we need a greater variety of diabetes therapies, and more types of insulin and delivery devices in particular.

That brings me to MannKind's inhalable, ultra-rapid-acting insulin Afrezza, which will be the topic of an FDA Advisory Committee meeting on April 1. Afrezza has the potential to be an amazing alternative for people who aren't getting the desired results from their current insulin or are nervous about insulin injections. The sleek, compact Afrezza inhaler and discreet, hassle-free delivery is great news for people who are wary of taking insulin in public.

If approved, Afrezza would also be a first in the next-generation ultra-rapid-acting insulin. MannKind's product peaks after about 12-15 minutes, a massive improvement from the 60-90 minute range of current rapid-acting insulins like Humalog, Novolog, and Apidra. Such an ultra-rapid-acting insulin should improve control in after-meal glucose levels. This isn't the first time that Afrezza has been considered by the FDA; MannKind previously received a Complete Response Letter in 2011 requesting additional safety data for the drug. Over the past few years, MannKind has completed multiple such safety trials, and the data look compelling. These new phase 3 trials were designed to specifically address the FDA's concerns. The FDA would need a truly compelling reason NOT to let Afrezza move forward.

Assuming Afrezza is safe (we look forward to the expert opinion on safety discussed at the Advisory Committee), the failure to approve Afrezza will send a disturbing message – that the FDA is not prepared to approve innovative diabetes products. I dread a future in which companies will not invest in groundbreaking ideas for fear that any such innovation would lead to a regulatory dead end. I understand that the FDA's mandate is to place patient safety first, but sometimes that can go too far. As a patient, as long as there is good, strong evidence that a new medication is safe and effective, I am willing to take the risk in the name of improved glycemic control, better management of my diabetes, and higher quality of life. From where I'm standing, Afrezza is worth the risk.

Very Best,



quotable quotes

"CGM, if understood for its limitations, is the best tool to allow for quality of life and proactively managing your diabetes."

– A patient in Dr. John Pickup's (Guy's Hospital, London) survey on experiences with CGM, presented at ATTD in Vienna, Austria, on February 5-8, 2014.

"There's no better time to be an innovator in health than right now."

– Aneesh Chopra (Senior Advisor, The Advisory Board Company) on the field of mobile phone apps at the PHA Summit.

"We need you all with us. We're just starting to get traction. The biggest barrier to success is impatience."

– First Lady Michelle Obama on the goals of Partnership for a Healthier America (PHA) at the PHA Summit in Washington, DC, on March 11-17, 2014.

fingersticks

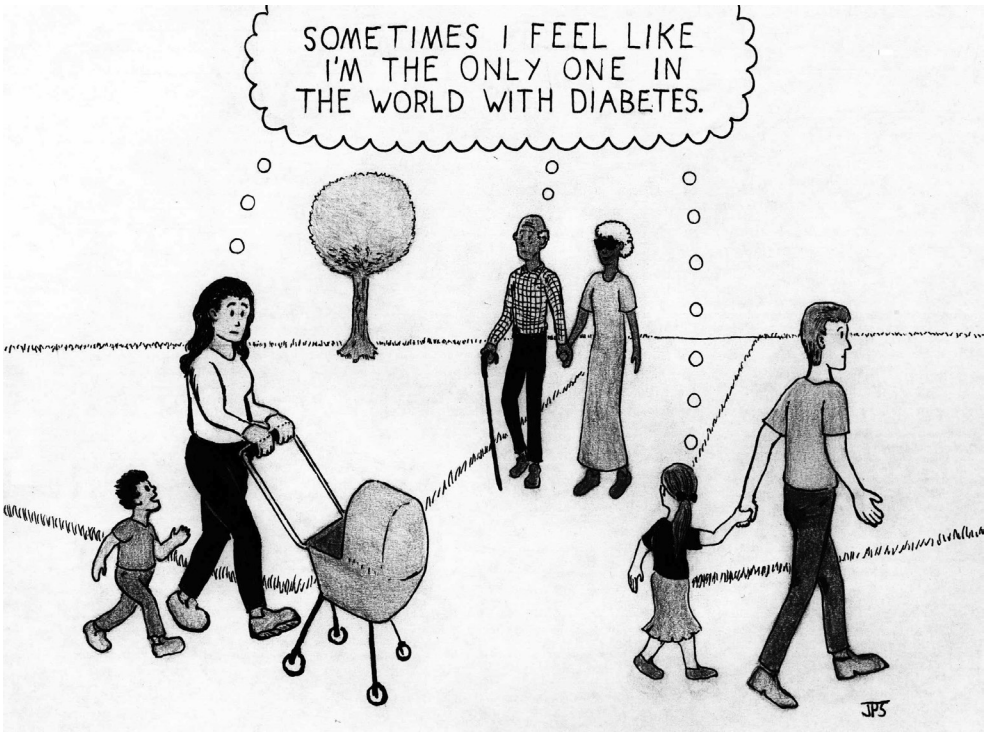
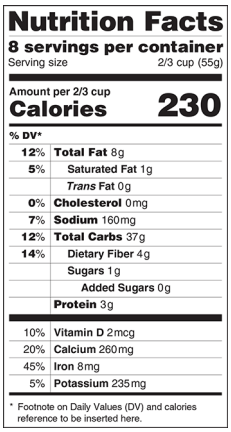


ILLUSTRATION: JOSEPH SHIVERS

new now next



FDA's proposned new label will include more noticeable calorie counts.

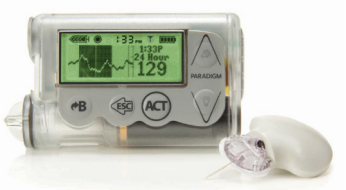
T1/2 FDA Proposes Updates to Nutrition Facts Labeling for First Time in Two Decades

On February 27, the FDA published proposed regulations to update nutrition fact labels that would make the familiar labels undergo a dramatic change for the first time in two decades. The changes include more noticeable calorie counts, an increased focus on added sugars, and nutrition information based on more realistic serving sizes. These are welcome changes for the public as well as for people with diabetes and will hopefully make it easier to get clear and understandable information about what we're eating.

The changes will emphasize the link between our food intake and chronic diseases such as obesity, heart disease, and type 2 diabetes. Labels will require information about the amount of "added sugars" from the production process above and beyond what is naturally present in foods. For the average American, added sugars account for 16% of total daily calories, with many of them from soda, energy drinks, grain-based foods, desserts, and sweetened fruit drinks.

The updated labels will also address the outdated serving sizes still used in labeling – a big win for people with diabetes. For years, the public has been confused by the need to adjust the nutrition information for serving size – for example, a 20 ounce bottle of soda that is usually consumed in one sitting is often labeled as 2.5 servings of eight-ounces instead of just one. This means that the whole bottle actually contains two or three times the sugars and carbohydrates mentioned on the label! The new label would reflect serving sizes that people currently eat instead of what they "should" be eating.

These changes are also in line with First Lady Michelle Obama's "Let's Move!" campaign, which aims to provide more information to consumers and make healthier choices easier. The proposed changes will be open for public comment for 90 days here. The FDA will consider these comments as they draft the final regulations. After the final publication, the food industry will be given two years to change their labeling, and as we understand it, the process could take three to four years before changes will be implemented. *–NL*



Participants in the pilot will receive a MiniMed Revel insulin pump as well as educational support.

T2 Medtronic and Aetna Partner to Provide Pumps for People with Type 2

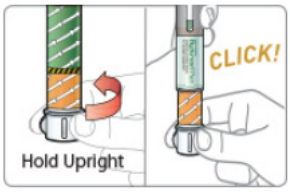
On March 4, Medtronic announced the creation of a new pilot program with Aetna to provide an insulin pump to up to 300 fully insured members with uncontrolled type 2 diabetes (those with an A1c greater than 8%). Participants in the pilot will receive a MiniMed Revel insulin pump as well as educational support to learn about insulin pump therapy. The companies expect the program to run for two years and will track the success of pumps in helping the wearer with glucose control, health outcomes, and healthcare costs. Hopefully, the information from the program may also benefit providers in identifying type 2s who can benefit the most from going on a pump (this important factor has long been debated, and the new data would help in figuring out what patients are best suited for pump therapy).

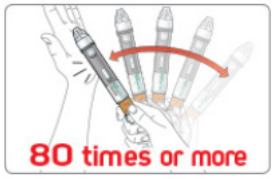
This is a much-needed initiative, as about 50% of type 2 patients are not at their A1c goal, and many dislike insulin injections or using needles in public. Currently, very few people with type 2 diabetes use pumps – this stems from a variety of factors, including the lack of data on the benefits of pump therapy for type 2, healthcare providers' comfort level with pumps for type 2, and reimbursement challenges. Luckily, there are several less expensive, easier-to-user insulin delivery devices currently approved or in development. Valeritas manufactures the V-Go Disposable Insulin Delivery Device (basal/bolus) for type 2 patients, which is currently available in the US. J&J/Calibra's very slim Finesse (bolus-only) has been approved by the FDA and is under further study. CeQur's PaQ device (basal/bolus) is currently being studied in Europe and is expected to launch there next year. Several other type 2 products are in development from companies like Insulet and Debiotech. *–NL/AB*

T1/2 San Francisco Soda Tax Takes Aim at Sugary Drinks

We're proud to see our home city of San Francisco taking a stand against soda and sugary beverages and recognizing their role in the rising rates of obesity and type 2 diabetes. The problem is that soda and other sweetened drinks are the largest single source of added sugar in the American diet, containing no nutritional value. People who drink soda also don't feel as full as if they had eaten the same number of calories from food, and research has found that the rising consumption of sugary drinks has been a major contributor to the obesity epidemic. This is a distressing fact when 32% of children and adolescents in San Francisco are obese or overweight, and at increased risk for type 2 diabetes, depression, and other issues.

San Francisco's proposed soda tax would add 2 cents per ounce to the cost of soda, energy drinks, and other sugar-sweetened drinks that contain more than 25 calories. Diet sodas and naturally sweetened drinks with juice will not be included. Data from the soda tax instituted in Mexico early this year and previous research show that raising the price of soda will decrease consumption. In San Francisco, this could mean better health outcomes as well as an increased $31 million per year raised from the tax that will be spent on improving school lunch programs, physical education, and food access across the city. We encourage you to learn more and get involved at Choose Health SF. *–NL*





T2 Bydureon Dual-Chambered Pen Receives FDA Approval After a Year-Long Wait

On March 3, AstraZeneca announced FDA approval for the Bydureon dual-chambered pen (once-weekly exenatide) to improve glycemic control in people with type 2. The device is a pre-filled, single-use pen injector, which eliminates the need for patients to manually mix the drug before injection ("reconstitution") and reduces the "hassle factor" of taking Bydureon once per week. Before, users of Bydureon had to go through six steps to prepare and inject the drug. AstraZeneca plans to make the pen available in the US later this year, and it is still under regulatory review in Europe with a decision expected by the end of this year.

The new pen will have to be refrigerated for storage and then must rest at room temperature for at least 15 minutes before use. The patient will then twist the

base of the pen to mix the drug and tap the pen firmly against the palm of their hand – the guide states that people may need to tap the pen "80 times or more" while rotating the pen until the solution is completely mixed. While this new process is a significant improvement from manual mixing, AstraZeneca is also working on a Bydureon suspension formula and auto-injector that will hopefully increase convenience further.

Bydureon is a once-weekly GLP-1 agonist, which stimulates insulin production when blood sugar becomes too high. Please read our previous new now next articles about the approval of Bydureon, the action of GLP-1s, and our previous update about the Bydureon Pen. –*NL*

Asante and Tidepool have announced an insulin pump data downloading partnership for the Snap.

T1/2 Asante and Tidepool Announce Data Downloading Partnership for Snap insulin pump

On January 27, Asante and Tidepool announced an insulin pump data downloading partnership for the Snap insulin pump. The agreement marks the first diabetes device company that has officially partnered with Tidepool and the company's in-development diabetes data platform. Under this partnership, development will begin immediately, and the launch could occur sometime in 2014, assuming the regulatory process goes well. Current Snap clinics will be able to download Snap pump data to the platform, and eventually, Asante hopes to provide a solution to download data at home.

Tidepool is an up-and-coming non-profit based in Silicon Valley that works to create open-source diabetes management apps. The organization has received lots of attention in the diabetes online community (read our conference pearls to learn more about its work). The Tidepool platform can currently read data from Medtronic and Animas pumps as well as Dexcom and Medtronic CGMs, with more partnerships in the works. The group has two apps in the works – blip and nutshell. We are particularly excited about blip, a web-based program intended to be a "hub for diabetes data." The application will take data from many devices (meters, CGMs, pumps, and even activity monitors) and aggregate in one dynamic, sleek online interface (see example pictures here). Blip is being tested at UCSF, and Tidepool is in talks with the FDA.

The move to universal palotforms will be beneficial to patients, providers, and companies alike.

It's encouraging to see Asante pursuing more partnerships for data downloading, as it just announced an agreement with Glooko last June and worked to allow health care providers to download Snap pump data to Diasend's web-based data management system. The move to using universal platforms will be beneficial for patients, providers, and companies alike, and hopefully this bold move by Asante will also push other companies to make their data protocols open and available on the Tidepool Platform. –*NL*

T1/2 Cellnovo Launches Mobile-Enabled Insulin Pump System in UK

Cellnovo recently launched its mobile-enabled insulin pump system in the UK, after receiving very positive feedback from a usability study that began in the UK in October of 2013. The company plans to make the system available in the Netherlands and France over the first half of 2014. Cellnovo previously announced that it planned to file its insulin pump system for approval in the US in 2014, but the company has not made any recent announcements.

As background, the new pump system is designed with the mobile experience in mind. It combines a small patch pump, a short infusion set, and a mobile touch-screen controller. Like the OmniPod, patients will remotely operate the insulin pump from the controller, which also serves as a blood glucose monitor. The controller connects to the web, uploads data in near real-time, and allows users the option to input information regarding their exercise and carbohydrate intake. The online data management system associated with the pump allows users to see their blood glucose levels, insulin use, activity and diet information. Notably, healthcare professionals will also be able to see real-time information. For more information on the Cellnovo insulin pump system and for the most current updates regarding approval and release in other areas, please see the company website. *–AF*

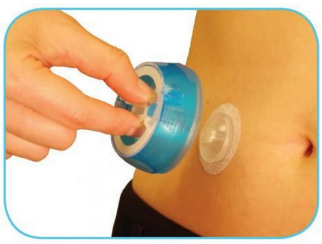
T1/2 In a Race for a New and Cheaper Insulin Glargine, Legal Troubles May Delay New Products From Coming to Market

Do you ever wonder why there aren't cheaper "generic" insulin products available?

Do you ever wonder why there aren't cheaper "generic" insulin products available? This may soon change as the patents for branded insulin begin to expire. In fact, the patents for Sanofi's top-selling Lantus (basal insulin glargine) are set to expire in the US in 2015, and other companies are racing to produce new "generic" insulins that could provide more choices for patients and importantly, push down the prices. The term "generic" traditionally applies to small molecules that are chemically and structurally equivalent to the original drug. Biosimilars created for products like insulin are biologically created products that tend to be more complex and sensitive. Thus it is difficult to completely prove that a biosimilar drug is identical to the original like a true "generic" drug.

The race has already started. On December 20, Eli Lilly and Boehringer Ingelheim announced the submission of a new basal insulin glargine to the FDA. The compound, called LY2963016, is under regulatory review in the US, Europe, and Japan. In January, we learned that Sanofi has filed a lawsuit against Lilly alleging patent violations of the original top-selling Lantus (insulin glargine) – the lawsuit could delay the FDA's decision on drug approval for up to 30 months, which would push back potential approval to 2016.

Other companies are getting into the game as well. Merck and Samsung Bioepsis announced a partnership to develop a "generic" insulin glargine, and phase 3 testing of the drug candidate will begin "soon" for its candidate MK-1293. India-based Biocon also has its own "generic" insulin glargine product, which is already approved in more than ten countries around the world and is beginning a phase 3 trial this year. Despite the uncertainty around legal matters, there is certainly a lot of interest in bringing a cheaper version of insulin glargine to market. *–NL*



The Metronic i-port could help address "needlephobia" for some patients.

T1/2 Medtronic i-port Advance Injection Port Helps Address "Needlephobia"

'Needlephobia' and the hassle of multiple daily injections can be a significant barrier to taking insulin. Encouragingly, Medtronic recently made its i-port Advance Injection Port available in the US for those who inject insulin more than once daily. The device eliminates the need to puncture the skin multiple times each day, instead allowing for the delivery of insulin through a small plastic cannula that the user inserts under the skin and wears for up to three days (similar to an insulin pump infusion set, but without the tubing). The port itself is about the

size of a US quarter coin and sits a third of an inch above the skin. Over the three-day maximum wear period, users would inject medication into the top of the i-port using a standard syringe or pen – the device allows a maximum needle size of 8 mm and cannot be used with needles shorter than 5 mm. Each i-port will sell for $12 dollars, translating to $4 per day and $120 per month. Medtronic is working with payers to establish a reimbursement policy and will provide customers with a toolkit to help pursue reimbursement from insurance companies.

The i-port is unique in the world of diabetes, as no other ports for insulin are currently available to our knowledge! We're most excited that it will reduce the pain of taking injections and make taking insulin a bit easier. Those interested in learning more should contact Medtronic's customer center at 1-(800)-646-4633 or visit www.i-port.com *–AF/AB*

The NovoPen Echo launched in the US on January 21.

T1/2 Launch of NovoPen Echo – The First Pen in the US with Half-Unit Dosing and Memory Function

On January 21, Novo Nordisk announced the launch of the NovoPen Echo in the US. This is the first and only pen device available in the US with half-unit dosing and a memory function that can record the dose and time passed since the last injection. The pen will be used with NovoLog (insulin aspart) prefilled cartridges and should be particularly useful for children who may forget doses or need finer adjustments in insulin. The NovoPen Echo received FDA clearance in August 2013. For more information, please read our new now next on the device. *–NL*

Abbott announced a recall of FreeStyle and FreeStyle Flash meters on February 19.

T1/2 Abbott Announces Voluntary Recall of FreeStyle and FreeStyle Flash Blood Glucose Meters

On February 19, Abbott announced a recall of FreeStyle and FreeStyle Flash blood glucose meters, which may produce low blood sugar results incorrectly when used with FreeStyle or FreeStyle Lite blood glucose test strips (e.g., the meter could read 70 mg/dl when the real glucose level is 100 mg/dl). Neither meter has been in production since 2010, and the recall of these two products will affect only about 1% of Abbott's US customer base. The recall will also affect the Freestyle meter built into the OmniPod Personal Diabetes Manager handheld.

The voluntary recall does not apply to any other FreeStyle brand blood glucose monitoring systems - the FreeStyle Lite, FreeStyle Freedom Lite, and FreeStyle InsuLinx systems can still be used with FreeStyle test strips. Abbott has asked all users of the affected products to call its Customer Service line at 1-888-345-5364 for a replacement meter that will be shipped overnight. People using the FreeStyle meter built into the OmniPod should only use the meter once receiving free replacement strips provided by Abbott and call the customer service line at 1-877-584-5159.

The consequences of faulty supplies for blood glucose monitoring are very serious, and it's important to see that Abbott quickly identified and communicated the issue to patients. However, not all companies have the necessary quality control process, which only highlights the importance of creating a formal postmarket surveillance program that could monitor meters and strips after they are on the market. For more information on this initiative, please read *diaTribe*'s latest updates on the Diabetes Technology Society surveillance program. *–NL*

T2 Eli Lilly and Boehringer Ingelheim's SGLT-2 Empagliflozin Delayed at the FDA

On March 5, Eli Lilly and Boehringer Ingelheim (BI) announced a delay in the approval of their new SGLT-2 inhibitor, empagliflozin, due to problems in manufacturing. SGLT-2 inhibitors are a class of type 2 diabetes drugs that cause users to excrete excess glucose through their urine (for more details, please see learning curve in *diaTribe* #24).

The companies originally submitted empagliflozin to the FDA in March 2013, and the FDA's response cited issues with manufacturing at BI's facility. On the bright side, the delay does not seem related to the mechanism or approvability of the drug, and will fortunately not require more clinical studies. It's unclear when the next FDA re-inspection might be or when the FDA will be able to make a decision on whether the issues have been resolved. In the meantime, this delay will likely also set back several exciting fixed-dose combinations (combining two or more pills into a single pill) expected to be submitted this year, including empagliflozin with Tradjenta (linagliptin, a DPP-4 inhibitor) and an empagliflozin/metformin fixed-dose combination. *–NL*

T2 The FDA Investigates Data from DPP-4 Inhibitor Onglyza (saxagliptin) Trials

On February 11, the FDA requested data from the widely publicized cardiovascular outcomes trial fro Onglyza.

On February 11, the FDA released a Drug Safety Communication requesting data from the widely publicized cardiovascular outcomes trial for Onglyza (saxagliptin). The trial, called SAVOR-TIMI 53, showed a 27% increase in the risk of hospitalization associated with heart failure in people using Onglyza (heart failure is when the heart does not pump blood well enough). Overall, the trial did not find an increase in death rates associated with hospitalization due to heart failure, and there was also no observed increase in other major cardiovascular risks (e.g., heart attack and stroke), as we noted in a previous article. The FDA considers the data from the trial to be preliminary, and suggests that people with diabetes currently taking Onglyza or Kombiglyze XR (a combination of Onglyza and metformin) continue to take the drug and speak to their provider if they have any questions or concerns. Healthcare professionals should also continue to prescribe Onglyza as they normally would. According to the FDA, the analysis of the Onglyza clinical trial data will be a part of a broader investigation of the cardiovascular risks of DPP-4 inhibitor drugs for type 2 diabetes.

Onglyza was one of the first drugs to be approved under stricter rules from the FDA for diabetes drugs regarding cardiovascular disease and events. If the FDA does determine that Onglyza is responsible for an increased rate of heart failure in people with type 2 diabetes, it might well result in a warning added to the drug label. This would only continue the controversial debate over whether DPP-4 inhibitors as a class may be associated with heart failure risk. We'll be back next issue with more from the American College of Cardiology conference taking place in Washington DC right now – there was really exciting news on EXAMINE and alogliptin, that might confer cardioprotection for women taking this compound as well as those diagnosed in the last five years and those with healthy kidney function *–AF/KC*

T1/2 The Childhood Obesity Bay Area Annual Conference in 2014

On February 22, Slow Food San Francisco hosted the annual Childhood Obesity Bay Area Conference, which featured Dr. Robert Lustig of the University of California, San Francisco, Todd Putman (Chief Marketing Officer of Bolthouse Farms, and previously of Coca-Cola), and other impressive speakers working to reduce childhood obesity through research and community action. We were incredibly inspired by The Bigger Picture, a collaboration between the University of California, San Francisco Center for Vulnerable Populations and Youth Speaks, to empower youth to combat the rising epidemic of type 2 diabetes. The organization screened a moving video called "Perfect Soldiers" about the destructive intergenerational effects of type 2 diabetes and its impact on vulnerable communities - it was a moving story and we highly recommend watching it! *–NL*

test drive

T1/2 The LifeScan OneTouch VerioSync – the magic of wireless blood glucose data to your iPhone/iPod/iPad

by Adam Brown

twitter summary: LifeScan's OneTouch VerioSync meter and Reveal app – wirelessly sending glucose data to your smartphone ...without needing an instruction manual!

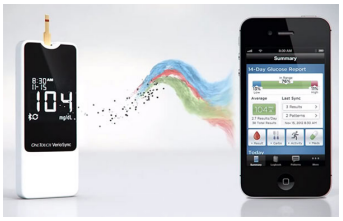
According to Pew Research (May 2013), 56% of Americans own smartphones, which is up substantially from 35% just two years prior. Given their dramatic rise in popularity, their usefulness, and their near-24/7 presence in our lives, it seems like a no-brainer that they should seamlessly interface with our diabetes devices. We've written about and tested several such products in past issues of diaTribe, including Sanofi's iBGStar, Telcare's meter, Glooko's MeterSync Cable, iHealthLab's Smart-Gluco Monitoring System, and Dexcom Share. LifeScan's OneTouch VerioSync, one of the newest connected meter offerings, was FDA approved in February 2013 and launched this past January.

It seems like a no-brainer than smartphones should seamlessly interface with our diabetes devices.

With the VerioSync, LifeScan took the very well-designed VerioIQ meter (which we test drove in *diaTribe* #41), stripped some of the on-meter functionality out (color screen, buttons, menus), added Bluetooth connectivity, and built a sleek accompanying iPhone/iPod/iPad app (called OneTouch Reveal in the iTunes store). After performing a glucose test, the VerioSync meter will automatically send the glucose value to the app (provided it is open on the smartphone) and incorporate it into statistics, patterns, a logbook, and more. This article reviews my experience using the meter and the accompanying OneTouch Reveal app over several weeks.

The VerioSync Meter

I really appreciated the VerioSync meter's minimalist design, which keeps it small and puts all the value in the accompanying smartphone app. To start, it's one of the smallest and slimmest meters I've ever used, at just half an inch thick, 3.9 inches



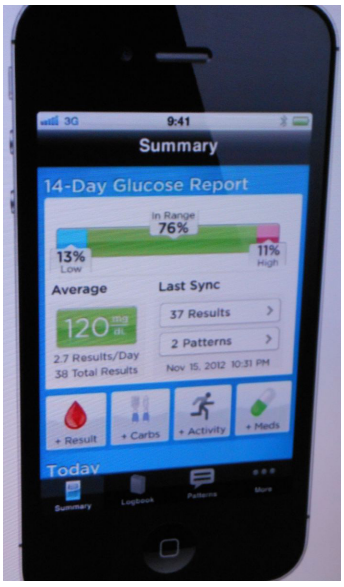
long, and 1.6 inches wide. The small profile made it incredibly easy to fit into pretty much any carrying case or pocket I could think of. After pulling it out of the box, it was immediately clear to me that this meter is designed for simplicity – it has no user interface to speak of and just a single button to turn the meter on/off and toggle the light and Bluetooth. All the history, pattern recognition, and settings are in the accompanying app. This was a disciplined design choice that I appreciated – I'd rather have a smaller, stripped down meter that does one thing really well (testing and displaying the current value) than a lot of things only moderately well.

Inserting a strip into the meter automatically turns it on, and after applying blood to the thoughtfully designed Verio strips (reviewed in our test drive of the VerioIQ), the result is displayed on the meter's high-contrast black-and-white screen in five seconds. It's truly a five second test, unlike other meters that count down from five but actually take more like seven or ten seconds. Though the screen is black-and-white, I found the high-contrast, large digits very easy to read. Some might prefer a meter with a color screen, but I thought the black-and-white display was fine given the colorful accompanying app.

It's truly a five second test, unlike other meters that actually take more like seven or ten seconds.

Unlike many other meters that run on AA, AAA, or coin cell batteries that last a very long time, the VerioSync is rechargeable via micro-USB. A full charge of the meter takes two hours and lasts one to two weeks. I didn't mind this part – I charge pretty much every device in my life, including my Dexcom CGM – but I recognize this could be a deal breaker for some patients. I was very glad to see that the VerioSync retained the VerioIQ's port light, which made it very easy to test in the dark. In my view, the port light is an underappreciated design feature on glucose meters, given how often I wake up and test in the middle of the night.

The OneTouch Reveal App



The VerioSync's accompanying app – OneTouch Reveal – is the major highlight of the system. Once downloaded and installed, you must Bluetooth "pair" the meter with the app, which took less than 30 seconds and did not require an instruction manual (that's my bar for well-designed diabetes technology!). The app even knew that the time on my meter was wrong and needed to be changed.

From there, I was off and running. I tested my glucose on the VerioSync meter, and within a few seconds after the test result, the number was transferred to the app. No cables. No fuss. No fingers crossed. It just worked. Magic! A popup window on the app showed the result (blue for hypoglycemic, red for hyperglycemic), the time of day and date, and allowed me to easily tag it pre- or post-meal. The result was also immediately incorporated into the app's statistics, logbooks, and patterns. The app is intuitive to navigate through and has four main menus: Summary, Logbook, Patterns, and More (settings, help, reminders, contact OneTouch).

I was a big fan of the Reveal app's summary home screen, which LifeScan clearly put a lot of thought into. To my excitement, the first thing you see is a colorful time-in-range chart (blue for hypoglycemia, green for in-range, red for hyperglycemia), which told me exactly how I was doing with my diabetes management. Seeing a 70% time-in-range figure let me know I was doing pretty well (motivational), while a 20% time below range was a red flag that I was experiencing too much hypoglycemia. (The time-in-range values are highly customizable in the app's settings). The summary screen also displays average blood glucose in large font, which was a nice high-level metric to see but far less actionable than time in range.

Back when I tested the VerioIQ, I was impressed with its novel high and low pattern recognition feature. This has been retained in the Reveal app and is another major highlight of LifeScan's new meter. After performing a sync, the Reveal app immediately notified me with a popup message if I had any high or low glucose patterns. Relative to the VerioIQ's small color screen, I thought that the app did a better job of summarizing patterns and giving me clear direction on what times of day to address.

Last but not least, the Reveal app makes it fairly easy to share results via email or text message.

Last but not least, the Reveal app makes it fairly easy to share results via email or text message. I simply navigated to any screen on the app, held my finger down for three seconds, and a "Share" button popped up. With two clicks, I had an email or text open with a picture of the screen I was currently on. The low hassle factor to Share results was great, though this part of the app could be significantly improved (see below).

Areas for Improvement

- **Automatic upload:** The Reveal app only downloads the values from the VerioSync meter when the app is open on your Apple device. In other words, it does not push the values to the app in real-time in the background. The meter can hold up to 500 tests in its memory, so there's really no fear of losing the data if you go some time without syncing the data to your Apple device. However, it would be great if the values went straight to the app or a web-based platform, where pattern recognition and statistics would happen in the background and notify me. There's no doubt that it was extremely easy to sync the meter with the app, but at minimum, I still had to remember to do it. This is one nice feature of the Telcare's meter, which sends meter results to the cloud automatically in near real-time.

An ability to send the raw numerical data for analysis in another program (e.g. Microsoft Excel) would have been useful.

- **Sharing:** Overall, I was disappointed that the Reveal app did not have a nice PDF report feature like the Glooko or mySugr apps – these summarize the data well, are easy to email or to print, and can be brought to a visit with a healthcare provider. I found the app's screenshot approach to be quite limiting, particularly because certain screens require scrolling and thus get cut off in the screenshot. It was also not particularly intuitive to hold my finger down and pull up the "Share" button – most apps have a dedicated on-screen arrow icon for sharing. Last, an ability to send the raw numerical data for analysis in another program (e.g., Microsoft Excel) would have been useful.
- **Meal tagging:** Meal tagging can only be done on the Reveal app once meter values are downloaded. When I hadn't synced the meter with the app in a few days, it was hard to remember whether values from two days ago were pre or post-meal. My normal meter doesn't have meal tagging, so I wasn't necessarily incapacitated without this feature. However, the VerioSync will only give high patterns if you meal tag, meaning that forgetting these tags skips out on half the pattern recognition's value (low patterns appear whether you tag or not). Ideally, meal tagging could be done on the meter with a single button.
- **Defaulting to 14 days:** Every chart, graph, and statistic in the app defaults to 14 days. It would have been nice to customize this for other periods of time.

Concluding Thoughts

Overall, I had a very good experience with LifeScan's OneTouch VerioSync. The system makes a huge stride in making it easier to quickly download glucose data, analyze it, and make some diabetes management changes. I really appreciated that

it didn't need an instruction manual, required limited set-up, and worked right out of the box. As I think about the future of diabetes technology, I'm confident that the VerioSync is a good sign of things to come – low hassle, easy-to-use, time-saving devices that work seamlessly with the other electronics we use on a daily basis.

Adam is the co-managing editor of diaTribe and Chief of Staff at Close Concerns. He is a graduate of the University of Pennsylvania and serves on the board of Insulindependence and the San Francisco branch of JDRF. He was diagnosed with type 1 diabetes at the age of 12 and has worn an insulin pump for the last 11 years and a CGM for the past three years. Most of Adam's writing for diaTribe focuses on diabetes technology, including blood glucose meters, CGMs, insulin pumps, and the artificial pancreas. Adam is passionate about exercise, nutrition, and wellness and spends his free time outdoors and staying active. He can be contacted at adam.brown@diatribe.org or @asbrown1 on twitter.

learning curve

T1 Top 10 Things I Wish I Had Told My Parents After I Was Diagnosed With Type 1 Diabetes

by Amelia Cooper, Adam Brown, and Tia Geri

Twitter summary: What I wish I could have told my parents after being diagnosed with type 1 #diabetes – life gets easier and I can still have fun!

Eighth grader Amelia Cooper and her father Blake recently stopped by the diaTribe office in San Francisco for her middle school career day. After publishing our learning curve last month on tips for patients newly diagnosed people with type 1 diabetes, we wondered Amelia wished she had said to her parents, friends, and the general public back when she was recently diagnosed. We learned a great deal from her, and then teamed up with Tia Geri, who was diagnosed with diabetes in early 2009 and who helped Amelia and Adam refine the advice! Adam of course was diagnosed in 1999 at the age of 12 – he remembered a lot as well!

1. **I'm going to feel and look a lot better.** Even though the diagnosis of type 1 diabetes is scary, it will not hold me back. Watching what I eat and how much I exercise makes me healthier, and these are important life skills that everyone should have. Though diabetes comes with plenty of hassle, it also builds a character – resilience, adaptability, responsibility, and so much more.

Trying to control blood sugars without testing iis like trying to fly an airplane without looking at your controls.

2. **If I'm irritable, it may mean that I'm low (or high).** When I am hypoglycemic, I don't feel well, can't think straight, and may have trouble expressing my thoughts. If I am not acting right, help me by giving me a source of glucose and then checking my blood sugar. It is important to check blood sugars frequently and regularly. Trying to control blood sugars without testing is like trying to fly an airplane without looking at your controls. If you are not regularly checking your altitude, it is likely that you will crash. (However, I am not always irritable just because of my blood sugars. Every kid has a reason to be mad sometimes.)

3. **Pizza and ice cream are still okay.** There is a time and place for everything in moderation. I have found that after having pizza, it is very difficult to control

my blood sugars. However, if I have pizza for lunch instead of dinner, I have more time to make adjustments to my insulin levels or exercise to help offset the spike. Other patients find that they do best just avoiding pizza altogether. Remember that diabetes is a very individual disease, so let's work as a team to find a diet that works for all of us – me, you, and my blood sugars!

4. **I am not a number, so don't judge me by one.** Blood sugars should be used as guidance to make adjustments and bring me back in range – they do not define me as a person. There is no room for shame and blame when I am trying my best to manage diabetes. There are so many variables that go into managing blood sugars, and it's impossible to control all of them. When a number is not in range, please don't view it as a mistake, but as an opportunity to figure out what needs to be changed.

Having friends that understand what diabetes is and what I'm going through will help keep me healthy and happy.

5. **Sleepovers are fun and still okay.** Having friends that understand what diabetes is and what I'm going through will help keep me healthy and happy. I am lucky to have a group of friends that have been with me every step of the way. I can be myself around them and never have to explain why I pick salad over fries. Loosening up and allowing me to have a sleepover away from home is a very scary thought, especially soon after diagnosis. But remember that things will be okay, and I will surprise you with my responsibility and diligence. A little bit of education goes a long way, and I will be just a phone call away.

6. **Counting carbs gets easier.** When I was first diagnosed, I didn't know what a carbohydrate was, but over the first few months I quickly learned how to read packaging labels, look at a plate of food, and have a good idea of what I was eating. Practice makes perfect and making it a game makes it more fun.

7. **Technology can make my life easier.** At the time of diagnosis, I had to learn how to check my blood sugar before and after meals, count my carbs, and give myself shots. It was very confusing and time-consuming. I now wear an insulin pump and a CGM, which both make it a lot easier and more convenient to keep an eye on my blood sugar and make small adjustments to keep me in range. Don't be afraid of technology – it can be one of your greatest allies as you work to manage diabetes.

8. **I may beep. And no, that is not a cell phone.** Often, my pump or CGM will beep when I am in public or at school. It is important to respond in an appropriate and timely manner to these alerts. Sometimes, there is a temptation for me to hide my pump or meter because you don't want to be perceived as different. Stay true to yourself! It is helpful for teachers and other people that I'm around to understand what diabetes is and what devices I'm using. Educating them will avoid any irritation when I fall out of range and my CGM starts beeping.

As Kerri Sparling says, "Diabetes doesn't define me, but it helps explain me."

9. **Diabetes is not an excuse.** Homework and household chores are never fun. Don't let me off the hook because you feel sorry for me. You can let me play the D-Card occasionally, but not all the time.

10. **I am still the same person.** As Kerri Sparling says, "Diabetes doesn't define me, but it helps explain me." Remember that the future is getting brighter every day and I will live and long and happy and healthy life – all I need is a little help and encouragement along the way.

conference pearls

Dr. Ed Damiano presents data from his bionic pancreas system.

T1/2 Dr. Ed Damiano Presents Next Set of Bionic Pancreas Study Results at ATTD

by Adam Brown and Nancy Liu

Twitter summary: Dr. Ed Damiano presents impressive results at #ATTD2014 from bionic pancreas trials – lowering average bg and reducing hypo!

This February 6, Dr. Ed Damiano shared the much-anticipated results from the 2013 Beacon Hill and Summer Camp outpatient studies of the bionic pancreas at the 7th International Conference on Advanced Technologies and Treatments for Diabetes (ATTD). We can say that even among a conference full of exciting new technology, these results stood out as exceptional.

As background, Dr. Ed Damiano and Dr. Steven Russell's bionic pancreas is a closed loop system that takes readings from a Dexcom G4 Platinum CGM, feeds them into a control algorithm running on an iPhone, and ultimately directs insulin and glucagon dosing through two Tandem t:slim pumps. diaTribe's Editor-in-Chief, Kelly Close, participated in the five-day Beacon Hill bionic pancreas study, and we wrote about the five-day Summer Camp study of adolescents 12-20 years old just last year. We've been following this exciting new technology very closely – you can read our last update on the bionic pancreas here.

Data from Beacon Hill and Summer Camp Impresses

In Dr. Damiano's presentation, the bionic pancreas dramatically improved average glucose levels and nearly eliminated hypoglycemia.

In Dr. Damiano's presentation, the bionic pancreas dramatically improved average glucose levels (predicted to result in a 0.9-1.6% A1c reduction!) AND nearly eliminated hypoglycemia (just <2% of the time spent <60 mg/dl) compared to when patients were not wearing the bionic pancreas (the "control" or "usual care" group). Those results are unheard of for any diabetes drug or device. In addition, the comparison to the control group was very challenging, as patients received far better care at the study sites than they would normally.

The tables below summarize the results of both five-day trials. On the left is the average glucose, A1c, and hypoglycemia rate while patients wore the bionic pancreas. On the right is the same data for the exact same patients when they were not wearing the bionic pancreas.

Beacon Hill Study Results (n=20 adults, 100 bionic pancreas days)				
	Bionic Pancreas		Usual Care	
	Mean Glucose	% CGM <60 mg/dl	Mean Glucose	% CGM <60 mg/dl
	133 mg/dl	1.5%	159 mg/dl	3.7%
Projected A1c	6.2%		7.1%	

Summer Camp Study Results (n=32 adolescents, 160 bionic pancreas days)					
	Bionic Pancreas		Supervised Camp Care		Baseline before the study began
	Mean Glucose	% CGM <60 mg/dl	Mean Glucose	% CGM <60 mg/dl	Mean Glucose
	142 mg/dl	1.3%	158 mg/dl	2.2%	189 mg/dl
Projected A1c	6.6%		7.1%		8.2%

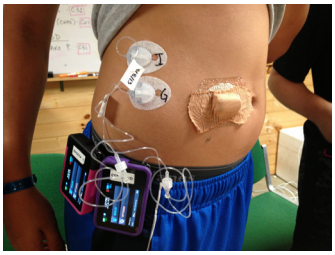
** Data in the table show combined data from days 2-5 during each study – the first day is excluded because the device must adapt and learn about the patients during that time and does not reflect the rest of the time spent on the bionic pancreas.*

The system also has some very patient-friendly features that aim to reduce the burden of diabetes management.

The system also has some very patient-friendly features that aim to reduce the burden of diabetes management – no carb counting, no required bolusing, control that adapts to each user and learns over time, and very little data entry to start the system. As Dr. Damiano noted, "This is diabetes without numbers."

Challenges for the Bionic Pancreas and What's Next

The strong results are a very encouraging sign of the potential of the bionic pancreas. However, there is still much to be done to realize Dr. Damiano's goal of having the bionic pancreas on the market by 2017 (when his son with type 1 diabetes goes to college). We described some of these challenges previously – most importantly, the development of a dual-chambered pump (insulin and glucagon) and a stabilized glucagon. We're glad to see progress on this front, as the bionic pancreas team is currently working with their industrial partners to create a dual-chambered pump platform and conducting trials for a stabilized glucagon candidate. However, large and long enough studies must be conducted with the system to convince regulatory authorities that these systems are safe and effective and can be worn by thousands of patients without close supervision.



The bionic pancreas team is currently working with their industrial partners to create a dual-chambered pump platform.

The upcoming timeline is to begin a four-center, 12-day study in adults, which will take place at Massachusetts General Hospital, Stanford University, the University of Massachusetts Medical Center at Worcester, and The University of North Carolina at Chapel Hill. The study is expected to start this spring and will run until early 2015. Participants must be students or employees of the centers and will be able to sleep at home and go through their daily routines. In other words, the bionic pancreas will control their blood sugar while they go about their normal lives. Very real world indeed! The researchers also plan on conducting another camp study in the summer of 2014 in 6-11 year olds at Camp Clara Barton for girls and Camp Joslin for boys in Boston. We imagine that camp slots this summer are already filling up fast!

With the recent approval of the Medtronic MiniMed 530G (read our test drive), all of us at *diaTribe* have been thinking a lot about the road to an automated insulin delivery system. What new challenges will have to be overcome? How fast will chronic use of glucagon be approved? How will patient use evolve? Will we be able to see these

systems on the market five or 10 years down the road? Although it frequently seems that progress cannot come quickly enough on the diabetes front, the data that Dr. Damiano presented on the bionic pancreas shows us that these devices are definitely worth waiting for.

SUM musings

T1/2 The Art of Compliance

by Kerri Morrone Sparling

Twitter summary: Kerri tackles the tricky question of compliance – is it offensive, out-dated, or misunderstood? Our readers weigh in.

com·pli·ance (noun) - the act or process of doing what you have been asked or ordered to do : the act or process of complying

The word "compliance," by definition, does a great job of putting my actions into specific categories. Am I doing what I was told, or not? Am I counting my carbs to the gram and calculating my insulin doses accordingly? Or am I relying too heavily on estimations? It's a word that comes with a simple definition, but with many connotations, especially in the world of diabetes care. "Compliance," for so many, can be a word loaded with shame, finger-pointing, and judgment. If my doctor calls me out for a lack of compliance, I feel terrible for disappointing her and not meeting her expectations. But mostly I feel discouraged with myself for my inability to follow directions. What makes it so hard to do what's necessary – the multiple glucose checks per day, the healthiest diet, the regular exercise? And why does this one word seem to make or break a mindset for so many?

Over the last almost-three decades, I've had some very compliant pockets of time with my diabetes duties (e.g.. pregnancy, where I followed every rule to the absolute best of my ability). I've also been decidedly non-compliant/apathetic at other times (e.g. during my parent's divorce, where I barely tended to my diabetes needs at all). During the tougher times, words like "compliant" weren't said out loud during my endocrinologist appointments. When my labwork and logbooks showed lots of out-of-range results, my endo didn't stamp my file with a big NON-COMPLIANT mark that was visible to me, even though there were several visits where the "uncontrolled" box was marked, or the notes recounted issues I was experiencing.

As people with diabetes, how does the word "compliance" strike you?

It wasn't until I entered the diabetes advocacy space and started reading a lot of anecdotes from other patients and healthcare professionals that the word kept jumping out at me. "Compliance," or the lack of it, was to blame for everything diabetes-related that plagued us: a non-compliant pancreas giving rise to a list of diabetes maintenance requirements, and non-compliant patients who didn't do all the things that we had been asked to do.

I posted an open question on my Facebook page, asking **"As people with diabetes, how does the word 'compliance' strike you? (Positively? Negatively? Apathetically?)"** Of the 133 responses, most associated the word with a mixed bag of negative emotions, ranging from "offensive" to "underhandedly judgmental" to "it

has no meaning [to me].” Briley Boisvert, diagnosed with type 1 diabetes at age two, offered, “I think it’s a results-based word for PWDs [people with diabetes] rather than an effort-based word.”

Jessica Collins, living with type 1 diabetes since she was ten, said, “I cringe when I hear the word ‘compliance’ used with diabetes. For me, it is a completely negative word. [It] elicits a knee-jerk, angry reaction. I don’t completely understand why, but part of it is the judgment. If you call someone ‘non-compliant,’ then you are judging that person, intentionally or otherwise. Support and encouragement are much more constructive.” “‘Noncompliant’ makes me think of toddlers refusing to eat their vegetables. At best the term is demoralizing and infantilizing, and at worst it implies deliberate sabotage of your self-care. I loathe, loathe, loathe the word,” said Karen Hoffman Anderson, living with T1D.

More education and listening to patient’s feedback are needed.

Caroline Sheehan, a fellow T1 PWD, agreed, but offered a solution, saying, “’Compliant’ feels like I am following commands by a medical professional, as though I am in lockstep in a one-way relationship. “Adherent” feels like following their suggestions, a two-way relationship in which I stick to or stray from recommendations, not rules. Working in the medical field, I try to say ‘adherent/non-adherent’ as much as possible, and I notice more professionals saying it too. However, ‘compliance’ in the medical world is very common across several domains, not just diabetes. More education and listening to patients’ feedback are needed.”

“Compliance means following the prescribed order, to the letter,” said Scott Estrin, diagnosed with type 1 in 1981. “Diabetes is about figuring out what the prescribed order is, given the present situation. It may have been an appropriate in “the olden days of diabetes” when we followed a strict regimen and had crude and limited ways to see how we’re doing. Nowadays, when there is so much variability and detail to consider, not just in our choices and our behavior, but in how we measure our current physical and behavioral activity, there is no way to even create a set of rules of which to comply. The term, more than having a positive or negative connotation, is simply outdated.”

Nowadays, when there is so much variability and detail to consider, there is not way to even create a set of rules of which to comply.

Christopher Angell, diagnosed with type 1 diabetes at the age of 30, hit upon the gap between medical advice and disease-in-context: “What I think it illustrates more than anything is the gap between conventional medical care – doctor gives patient instructions/prescriptions, expects predictable results based on those orders - and what’s required for diabetes, like mental health care, peer-support, ability to try different devices/treatment regimens, acknowledgement of the inherent fluctuation of results, etc. I feel like the negative reactions to the word ‘compliance’ or, more accurately ‘non-compliance’ are really reactions to the horribly misguided idea that a doctor, or anyone else, can have specific expectations for an outcome based SOLELY on their medical advice/prescriptions.”

Tricia Moore, a RN with type 1 diabetes, offered her take. “I think if, as healthcare professionals, we were able to get to know our patients better, spend more time with them, and see what’s really going on, the rate of the labeling of ‘non-compliance’ would significantly drop because we would see that the majority of patients are not simply giving up but have other barriers to their successes. We can then also help find different ways to solve the issues that are present and make the end goals more attainable through education, clarification, financial assistance, etc.”

Is the word "compliance" frightfully out-dated? Or misunderstood? As with everything related to diabetes, your mileage may vary.

Is the word "compliance" frightfully out-dated? Or misunderstood? As with everything related to diabetes, your mileage may vary, and the concept of "compliance" is no exception. For me, it can feel like the end-all, be-all assessment of my diabetes, like an A1c result. But even if the word itself stirs up some negative feelings, it does serve to remind me that the to-do list of diabetes is never fully checked-off, and while there are plenty of reasons to feel good about my efforts, there is always something I can do to improve. The quest towards "better" remains constant, and I have to remind myself that a label doesn't matter as much as my actions, and their outcomes.

"People are resistant to change, and the art is finding what it will take for somebody to do what we are 'supposed' to do," said Scott Scolnick, a fellow person with type 1 diabetes said. "Compliance is a journey."

Kerri Morrone Sparling has been living with type 1 diabetes for over 25 years. She writes a much-trafficked diabetes blog, Six Until Me (SUM), and is an active member of the diabetes community. She is known for her tagline, "Diabetes doesn't define me, but it helps explain me." Dexcom is currently a sponsor of SUM, and through that relationship, the company provides her Dexcom sensors free of charge. For Kerri's full disclosure, please visit http://sixuntilme.com/about/2010/03/disclosure.html.

diaTribe dialogue

Teplizumab is an anti-CD3 antibody that may prevent type 1 diabetes by for those at high risk.

T1 An Open Letter to the DOC: How You Can Help Prevent Type 1 Diabetes by Supporting Clinical Trials – Please Help Find More People to Test Teplizumab

by Kelly Close and Alasdair Wilkins

Twitter summary: As a #diabetes community, we can be a part of learning how to prevent type 1 – ask, beg, persuade, & engage your relatives at risk to learn more about teplizumab

This year, it's estimated that more than 15,000 children in the United States will be diagnosed with type 1 diabetes, adding to a number that already includes as many as 3 million people nationwide. What can be difficult for those of us with type 1 diabetes is the knowledge that we are more likely to know the people who comprise those other new diagnoses. Because genetic factors help determine the risk of type 1 diabetes, the odds are that some of the children and young adults who are diagnosed each year will be related to those who already have type 1. They can be our brothers and our sisters, our sons and our daughters, and even our cousins, nieces, and nephews. The Joslin Diabetes Center estimates that a person can be as much as 10 to 20 times more likely than the general population to develop type 1 diabetes if an immediate relative – a parent, a sibling, or a child – already has it, although the specific risk can vary considerably depending on a number of factors.

While the daily goal for people with type 1 is to manage diabetes as effectively as possible, the long-term hope is to ultimately to cure or prevent type 1 diabetes. The idea of prevention has been around a long time, and has been hard to prove. But having

the potential to transform the lives of our relatives, who are at the greatest risk of developing type 1, is very real.

We as patients can make an enormous different by participating in clincial trials and helping out these amazing researchers.

Right now, the best leads that researchers have in the search for a preventative treatment are the anti-CD3 antibodies, teplizumab and otelixizumab. These drugs in development are designed to block the immune cells from destroying the body's insulin-producing beta cells and therefore prevent the onset of type 1 diabetes. In theory, these antibodies could slow down the initial progression of the disease or even, if administered early enough, halt the development of type 1 entirely. These are the long-term goals that we'd say are more than worth striving for. Can you imagine if YOUR diabetes could have been prevented? We know it can be a bit much to think about how to prevent type 1, when we already have it. The teplizumab trial is VERY big and is not going nearly as quickly as hoped - we as patients can make an enormous difference! Lean in, please, and help out these amazing researchers.

The only way to develop these antibodies is through clinical trials. That's why the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is sponsoring a phase 2 trial for teplizumab. Over the next two years, the NIDDK's goal is to enroll around 150 people between the ages of 8 and 45, all of whom should have a close relative with type 1 diabetes and at least two of the autoantibodies associated with the development of type 1. Potential volunteers can find out if they meet these criteria by being screened as part of the Pathway to Prevention Study, which has at least one center in 48 of the 50 states (all except Vermont and Wyoming) as well as the District of Columbia.

So far, only 35 people have enrolled in the teplizumab study, in part because the study requires 14 consecutive days of 30-minute teplizumab infusions, followed by two hours of observation. In today's crazy busy world, we know it's virtually impossible to carve out that kind of time away from school or work. But... think about what you could be achieving for all these people just like us. You could be helping to PREVENT this disease.

What's the other good news? Not only does the study pay for lodging and transportation, but additional compensation for participating.

What's the other good news? Not only does the study pay (of course) for all lodging and transportation costs, it provides an additional $1,500 in compensation for participating in the trial. If you or a relative (your sibling, mom, dad – any first degree relative under age 45) lives in or within commuting distance of study centers in big cities like Denver, Indianapolis, Miami, Minneapolis, Nashville, New York, Pittsburgh, San Francisco, Seattle, and Toronto, please think long and hard about whether they could in fact participate in this vital study. For more information, please check out our recent trial watch. 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 and lrafkin@miami.edu. They would truly be elated.

It is critical that we as a diabetes community do what we can to benefit future generations and others who may be at risk for diabetes. The benefits of participation in trials aren't at all abstract. As someone who has lived with type 1 diabetes for nearly 30 years, I have gained so much strength and resolve from taking part in studies that showed me what remarkable new treatments and devices were possible, and how much better things could be thanks to new research and new thinking. Granted, a therapy like teplizumab isn't exactly around the corner; it's likely still a ways off from realizing its true potential in the fight against type 1. But it's up to us – and, in

this case, our families – to make sure that teplizumab and other innovative therapies don't remain forever out on the horizon, tantalizingly beyond our grasp. If we want to reach the day in which we can prevent and cure diabetes, we need to start walking toward it. I can't guarantee that teplizumab or any other particular treatment represents the path to where we want to go. But I know that we'll never get anywhere if we don't take the first step. Thank you – thank you! – for listening.

trial watch

Will a type 2 drug for type 1s?

T1 **The Efficacy and Safety of Liraglutide as Adjunct Therapy to Insulin in the Treatment of Type 1 Diabetes (ADJUNCT ONE)**
ClinicalTrials.gov Identifier: NCT01836523
http://clinicaltrials.gov/ct2/show/study/NCT01836523

Victoza (liraglutide) is a once-daily GLP-1 agonist made by Novo Nordisk and originally used for the treatment of type 2 diabetes. GLP-1 agonists are delivered by injection, and in type 2 diabetes, these drugs stimulate the pancreas to release insulin Several small studies have shown that GLP-1 agonists for type 1 diabetes can potentially improve A1c and glycemic control, reduce insulin doses, reduce the risk of hypoglycemia, and help with weight loss. Novo Nordisk is conducting a 1,404-patient ADJUNCT ONE trial to further study the potential benefits of using GLP-1 agonists in type 1. This trial will study the efficacy and safety of using Victoza as an add-on therapy to insulin in people with type 1 diabetes. It will run for approximately 58 weeks and participants must have been diagnosed with type 1 diabetes for at least a year, have an A1c between 7.0-10.0%, and be on stable insulin treatment for the last three months prior to screening, among other criteria. The study will be held in 78 locations. If interested in participating, contact clinicaltrials@novonordisk.com. *–NL*

Will a new drug from Lilly help improve A1c?

T2 A **Study of the Safety and Effectiveness of LY3053102 in Participants with Type 2 Diabetes**
ClincialTrials.gov Identifier: NCT02020616
http://clinicaltrials.gov/ct2/show/NCT02020616

Eli Lilly is conducting a trial that will investigate the safety and effectiveness of a new drug called LY3053102 in people with type 2 diabetes. LY3053102 is an injectable drug given once a week that may help with improving A1c. This study is expected to last six months for each participant. The trial is split up into three arms: those using LY3053102, people using Bydureon (exenatide once-weekly), and a placebo group. To be eligible for the trial, participants must have had type 2 diabetes for at least six months, have a body mass index between 23-45 kg/m2, and other criteria. Participants cannot have used insulin for diabetes management for more than six consecutive days within a year of screening, used thiazolidinediones within three months, or use any other drugs for hyperglycemia (besides metformin) within the two months prior to the beginning of the study. If interested in enrolling, please call 1-877-CT-LILLY (1-877-285-4559) or 1-317-615-4559. *–NL*