diaTribe®

research and product news for people with diabetes

in this issue

from the editor

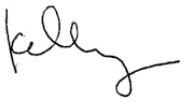
Next month, the residents in San Francisco and Berkeley will vote on ballot measures that, if successful, will create the first soda taxes in our country aimed specifically at improving public health – the proponents' goal is to cut soda consumption and attack a major source of empty calories that is associated with obesity and type 2 diabetes. The proposed taxes in the Bay Area won't ban the sale of any soda but will increase the price tag: in San Francisco, it will cost an extra quarter for a 12-ounce can of soda (not including diet soda), about 40 cents more for a 20-ounce bottle, about $1.35 more for a two-liter bottle, and so on (Berkeley's increases would be a little less than that). But what makes the San Francisco and Berkeley plans unusual is that the tax revenue, estimated to be around $30 million annually, will go toward funding citywide recreation and nutrition programs, paying for new drinking fountains and water bottle filling stations, and helping people get better access to healthy food. If it works as planned, that would be something to celebrate – a two-pronged approach to discourage bad choices and encourage healthy alternatives.

However, at this stage, it's certainly true that soda taxes will not necessarily reduce type 2 diabetes and obesity. While to some extent, there is an analogy here to taxing cigarettes, which produced a marked decrease in smoking rates, it's certainly not exactly the same thing. People can more easily find alternative sources of sugar than they can find alternative sources of nicotine – put differently, a tax on cigarettes leaves people with two options (pay more or stop smoking), while a soda tax could simply shift consumption to other sources of calories.

I dream about those millions of dollars' worth of extra tax revenue that can be used on real, targeted public health initiatives. Maybe charging an extra quarter for a can of soda isn't going to move the needle in a big way with each individual, but raising $30 million to fund nutritional programs, improve public spaces, and provide access to healthy foods might be an important step. Currently, an estimated 32% of children and adolescents in San Francisco are overweight or obese. This is clearly a crisis. And to think of the far-reaching impact our Bay Area could have ...

Clearly, these soda taxes aren't the final word on this issue – the obesity epidemic is far too complex and deep-rooted. But these proposed taxes – if approved -- do represent a bold statement from San Francisco and Berkeley: "Obesity is not okay, and we are doing something about it."

very best,



quotable quotes

"I think we would all agree – A1c by itself is incomplete. If we just take A1c by itself, as a way to look at diabetes, I think we're missing an important message."

–Dr. Irl Hirsch (University of Washington School of Medicine, Seattle) at the EASD 2014 Conference in Vienna.

"People want to drive their own healthcare. This is the idea behind the self-monitoring CGM arena. To what extent can we use that huge resource – their brain – to actually improve care?"

–Professor Philip Home (Newcastle University, UK) at The diaTribe Foundation's Solvable Problems in Diabetes event at the European Association for the Study of Diabetes (EASD) Conference in Vienna, Austria.

"We, the global community affected by T1D, need better treatments and a cure."

– David Panzirer (trustee, Helmsley Charitable Trust) discussing the power of philanthropy in an op-ed piece in Wired.

fingersticks

Illustration by Joesph Shivers

"For my art project, I made you an artificial pancreas!"

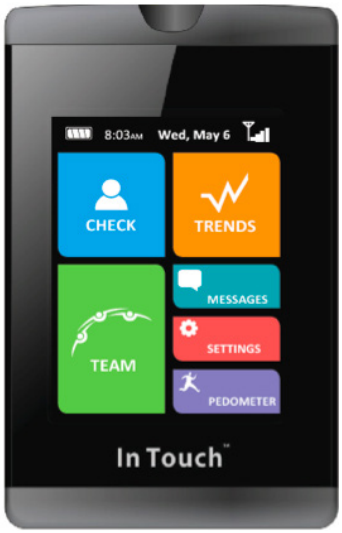
new now next

T1/2 Guardian Mobile: Medtronic's Bluetooth-enabled CGM to send data to a smartphone app

Twitter Summary: @MDT_Diabetes working on Guardian Mobile – new CGM will send readings via Bluetooth straight to a smart phone app!

At the recent Health 2.0 conference, Medtronic demoed its in-development Guardian Mobile system, which will send real-time CGM readings straight from a transmitter to a smartphone app via Bluetooth. Medtronic believes the product will only require a sensor, a Bluetooth enabled transmitter, and a smart phone – no receiver required. The system will operate independently of an insulin pump, which is good news for anyone who injects insulin manually (~70% of people with type 1 diabetes and the vast majority of people with type 2 diabetes). Medtronic plans to start a major trial of the device later this fall, but there are no further details and no official timeline on FDA submission or a potential launch. That said, even in a virtual information vacuum – we are hopeful!

The push to send CGM data to smartphones receives increasing attention by the day, given the convenience and peace-of-mind it can offer patients and caregivers. In diaTribe #69, the great Kerri Sparling wrote about the Nightscout/CGM in the Cloud movement, a grassroots community that has "hacked" the Dexcom G4 Platinum receiver to send the real-time CGM data to the cloud and other devices. Meanwhile, Dexcom is building its own mobile-enabled products: Dexcom Share, a docking station that enables remote monitoring of the G4 Platinum, is in the final stages of FDA review, while an FDA submission of the Gen 5 system and app are expected by early 2015. Lots to look forward to in the coming years for easier ways to access and monitor CGM data – we can't wait to see more on this development. *–AJW/AB/KC*



T1/2 Livongo for Diabetes Enters the Cloud-Connected Blood Glucose Meter Market in the US

Twitter Summary: Livongo for Diabetes cloud-connected meter connects users to virtual care team, has algorithm-based feedback and built-in activity monitor

Livongo Health recently announced the launch of Livongo for Diabetes, a new digital health platform. The system includes a cellular-enabled, color touchscreen meter that immediately sends blood glucose readings to the cloud (similar to the Telcare meter). A software algorithm then uses the data to send immediate feedback to the user (e.g., "You are consistently low in the afternoon") based on rules set by a healthcare provider (and we hope with patients' input). We hear the software "gets smarter and more personalized" over time – it's not clear what this looks like yet but we hope it could learn patients' patterns and tendencies. The user can also elect to send the information to family members, a positive for parents and partners who are involved in care. The Livongo platform provides users with a remote care team, a group of on-call diabetes educators whose role is to provide support to patients and intervene if blood glucose data require attention. This virtual team can reportedly respond to patients within 60 seconds – boy does that sound great!

The entire platform (including the meter, algorithm software, lancing device, access to the remote care team, and unlimited strips) costs $70/month, a good deal

Livongo has partnered with other organizations like the College Diabetes Network to give the system to a subset of college-aged patients free-of-charge.

for patients who test fairly often (4 or more times per day). Currently, Livongo for Diabetes is not available for individual consumers, though a consumer platform is in development – unfortunately, there are scant details on availability. For now, Livongo is working to make the system available to insurers and employers, who would distribute it to patients (it has already made deals with HealthCare Partners and Office Depot, among several others). Livongo has also partnered with other organizations like the College Diabetes Network that will give the system to a subset of college-aged patients free-of-charge.

Unlike the WellDoc BlueStar system, Livongo for Diabetes cannot provide specific insulin-dosing suggestions at this time. Still, the use of immediate feedback is a huge plus, and one that should allow faster therapy changes, assuming patients have healthcare providers willing to work with the system. We look forward to trying the cellular-connected meter and platform in a future test drive. *–AJW/AB*

T1 David Panzirer's Wired Op-Ed Challenges Private Donors to Fund Innovation

Twitter summary: @DpT1D of the #helmsleytrust talks about need 4 philanthropic support in #T1D in inspiring Wired op-ed

David Panzirer, a trustee of the Helmsley Charitable Trust (HCT), wrote a compelling op-ed piece for Wired titled, "When the Biomedical Industry Can't Prioritize Diseases, Private Money Can Save Lives." Mr. Panzirer begins the piece with the story of his daughter, who was diagnosed with type 1 at age six. He says that compared to type 2 diabetes, the small number of type 1 patients discourages companies from investing in new technologies and therapies for that cohort. And when industry does spend resources on type 1, he says that the FDA can make the drug approval process "slow and costly." For these reasons, he calls for private philanthropists to step up and fund innovation for disease that are overlooked by industry.

The HCT's T1D Program has become the largest foundation funder in type 1 diabetes; more than $230 million has gone to various diabetes grants since 2008.

As an example, he discusses the HCT's T1D Program, which has become the largest foundation funder in type 1 diabetes; more than $230 million has gone to various diabetes grants since its founding in 2008. Mr. Panzirer specifically highlights Drs. Ed Damiano and Steve Russell's bionic pancreas, which has been funded largely by HCT and other private donors. We appreciated the visibility of Mr. Panzirer in such a high-profile media outlet, and we salute him for calling on private donors to help accelerate innovation in areas of need. We are curious who he was specifically targeting! He effectively reiterated some of his comments in our five-part interview with him and the T1D Exchange's Mr. Dana Ball – to learn more, see the five part series below:

Part 1. How The Helmsley Charitable Trust became one of the most important players in diabetes, and the funding needs and challenges in type 1

Part 2. The Future of the Type 1 Diabetes Field – what challenges and promises lie ahead?

Part 3. Controversies in Diabetes: Technology, Debates, and the "Cure"

Part 4. The T1D Exchange: A story of David and Dana's drive to accelerate innovative type 1 diabetes research.

Part 5. What can diabetes advocates learn from successes of the HIV/AIDs movement?

-AJW/AB/KC

[Disclosure: diaTribe is supported in part by a grant from the Helmsley Charitable Trust.]

T1/2 Glooko Launches MeterSync Blue – Enables 30+ Meters to Send Data Over Bluetooth to Android and iPhone Apps

Twitter Summary: Glooko launches MeterSync Blue, 30+ meters to send data to iPhone/Android app via Bluetooth using only 1 piece of hardware

This month Glooko announced the launch of MeterSync Blue, a small device that allows users to upload glucose meter data to Android and iPhone apps via Bluetooth. MeterSync Blue is compatible with over 30 meters, including many made by Abbott, Bayer, LifeScan, and Roche – see the list here. To use MeterSync Blue, users plug a small cable into their meter, open the Glooko app, and seamlessly transfer readings via Bluetooth to the Glooko app.

The new model has several other advantages over the original design: it is compatible with more meters and smartphones, no additional adapters are required (the previous model required an adapter for the iPhone 5 and an IR adaptor for Accu Chek meters), and for a few meters (J&J LifeScan's OneTouch Ultra 2 and Ultra Mini, and Walmart's ReliOn meters), the Glooko system can be left plugged in all the time, essentially making them 24/7 Bluetooth-enabled devices.

Glooko hopes to work with insurance companies and healthcare systems to make the system free for patients.

Glooko hopes to work with insurance companies and healthcare systems to make the system free for patients. Current partners include Scripps, Joslin, and Dr. Zachary Bloomgarden (clinical professor, Mount Sinai Medical Center), to name a few. Glooko is also selling limited numbers of the MeterSync Blue direct-to-consumer through its web store - the list price is $59.

We had a chance to try MeterSync Blue ourselves and got it set up and transferring readings from a FreeStyle Lite meter to the Glooko app on an iPhone 5 in less than five minutes. Glooko has done an excellent job of providing a universal and easy solution to the problem of downloading data from the wide array of glucose meters that are available today. Down the road, Glooko has several projects in development to further its efforts beyond meters, such as combining its current product with CGMs, pumps, and other activity trackers. *–AB/AJW*

T1/2 JAMA Publishes First Long-Term Study on National Diabetes Rates – Signs of Leveling Off

Twitter summary: @JAMA_current releases new paper on #diabetes trends in US – the good and bad news

On September 24, JAMA published a paper on long-term trends in the number of people with diabetes in the United States from 1980 to 2012. The results showed a leveling-off in the rates of diabetes between 2008 and 2012 - the number of people with diabetes increased modestly from 7.9% to 8.3% of the population. However, this comes after a very large increase between 1990 and 2008, when

there was a 3.5% to 7.9% jump in number of people affected. The authors explain that there are several reasons for the slower growth rates in cases, likely due to the slower growth in obesity rates and a recent decrease in food consumption and food purchases – though these don't seem to address the broader trends of an aging population and increased risk factors such as unhealthy food environments and inactive lifestyles.

While this trend is moderately good news in the general population, the prevalence of diabetes has still continued to increase in certain at-risk groups such as Hispanics, non-Hispanic blacks, and people with a high school education or less. Unfortunately, this only stands to worsen current racial and socioeconomic disparities and hurts those who need the most help. –*NL*

T1 Stanford team develops a method for easier, more accurate diagnosis for type 1 diabetes

Twitter summary: A new technology from Stanford has potential for easier, more accurate, & cheaper diagnosis for #t1d

This brings potential to accurately diagnose type 1 diabetes much earlier, and by extension, help preserve patients' beta cells.

A team of Stanford University researchers, with the support of JDRF, has developed a potential new tool to diagnose type 1 diabetes. The new chip technology is described in a Nature Medicine paper and is able to detect important markers of type 1 diabetes ("autoantibodies") with a high degree of sensitivity and accuracy in a small blood sample. This brings potential to accurately diagnose type 1 diabetes much earlier, and by extension, help preserve patients' beta cells.

Most impressively, the new chip method is able to detect autoantibodies in an extremely small amount of blood (~2 microliters), which means a potential diagnosis could be conducted with just a fingerstick instead of a blood draw. This would be especially welcome for participants in Diabetes TrialNet, a program that screens siblings of people with type 1 diabetes and other participants at risk for type 1 diabetes.

The inventors are forming a startup called IGIstat to further develop and commercialize the technology, which also has the potential to make tests faster (waiting less than 90 minutes for results) and cheaper (~$5 per test) compared to current options. There is a ways to go before this is commercially available, but it would be welcome for patients and families with type 1 diabetes –*NL*

OMADA

T2 Omada Health Receives Funding to Bring Online Diabetes Prevention Program to Low-Income Communities

Twitter Summary: @omadahealth announces $950K in funding to bring #diabetes prevention program to low-income communities

On September 17, Omada Health announced that it received $950,000 in funding to bring its diabetes prevention program, "Prevent," to low-income communities across the US. CDC data has shown that low-income communities have a higher prevalence of obesity, which increases the risk for type 2 diabetes. This prevention effort will help those who might need it most but who otherwise couldn't afford it. The program for people with prediabetes currently costs $130/month for four months – a big expense for many, though some major insurance companies

such as Kaiser Permanente and Blue Cross do cover it.

We are excited about Prevent, which is an online version of the landmark Diabetes Prevention Program (DPP), which found that people with prediabetes who changed their diet, exercised more, and modified their behavior reduced the risk of progressing to type 2 diabetes by 58%. Participants in Omada Health's 16-week Prevent program receive one-on-one support from a professional health coach via phone and messaging, as well as online courses to guide them through the curriculum. Participants also are placed in support groups with other members of the program, using social networking to improve health outcomes. An original pilot study of 230 people found that Prevent participants lost an average of 14 pounds, or 6.4% of their body weight, and 72% of participants remained in the program for the full 16 weeks. Of course, the big barrier in weight loss programs is usually keeping the weight off – follow-up information from Prevent showed that weight loss was largely maintained after 12 months. For more information about Prevent, please see our past new now next in *diaTribe* #50. *–AJW/ARW*

T1/2 **Lilly's Humalog 200 units/ml KwikPen approved in Europe**

Twitter Summary: @LillyPad receives EU approval for Humalog 200 units/ml Kwikpen – 600 units of insulin in a 3 ml pen, hopeful US resubmission late 2014

Eli Lilly recently announced that its rapid-acting Humalog 200 units/ml KwikPen (insulin lispro) received approval in Europe. Similar to the previous Humalog 100 units/ml KwikPen, this new model holds 3 ml of insulin in the same overall sized pen. The key difference lies in the insulin concentration – the new pen holds 600 total units of insulin in the same sized pen that previously could only hold 300 total units. Humalog 200 units/ml KwikPen is the first 200 units/ml mealtime insulin to reach the market and will be targeted for people who take more than 20 units of rapid-acting mealtime insulin per day (e.g., 7 units per meal, with three meals a day). There is no information yet on pricing for the Humalog 200 units/ml KwikPen. Lilly plans to resubmit it to the FDA by year-end after failing to receive approval in its initial submission earlier this year. *–AJW*

adam's corner

T1/2 What are your "Diabetes Landmines"? The Seven Blood Sugar Mistakes I Always Make and How I'm Working to Avoid Them

by Adam Brown

Twitter summary: *Adam shares seven diabetes landmines – his mistakes that routinely lead to out-of-range blood sugars – and some solutions he's been trying*

Short summary: *In this article, I share my own "diabetes landmines"– seven small mistakes I seem to make again and again that "explode" into out-of-range*

blood glucose values. These include: overcorrecting low blood sugars with too many carbs; overcorrecting a high with too much insulin ("stacking"); snacking directly out of the package; eating when I am not hungry; eating too quickly or overeating; eating too close to bedtime; and not increasing my basal rate following a night of poor sleep or on a day with little exercise. I also identify some solutions I've been using to try to overcome these mistakes.

Even though diabetes is very unpredictable, are there some consistent reasons why my blood glucose falls out of range?

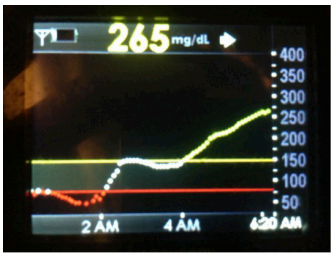
After writing my last column on the 22+ short-term factors that affect blood glucose, I wondered...

"Even though diabetes is very unpredictable, are there some consistent reasons why my blood glucose falls out of range?"

Yes. I call these my "diabetes landmines"– small mistakes I seem to make again and again that seem to "explode" into out-of-range blood glucose values. The list below highlights the seven mistakes I routinely make, and also details some solutions I've been trying out. Writing this list and the potential solutions was highly valuable for me; for the past few weeks, I've been more aware of my own "diabetes landmines" and felt more equipped and motivated to avoid them. Try writing your own list along with some solutions, and email me at adam.brown(at) diaTribe.org or tweet me at @asbrown1 with what you find!

Mistake#1: Overcorrecting low blood sugars with too many carbs, only to go high afterwards. I consider myself someone with a lot of willpower, but with a blood sugar of 55 mg/dl, sometimes I just want to eat everything in sight.

Solution A: Having a single go-to correction for hypoglycemia. Though they're not the greatest tasting treat, I know that one glucose tab (4 grams of carbs) raises my blood glucose by about 20 mg/dl. It's predictable, and I know I won't overeat glucose tabs. Other people I know use mini juice boxes, glucose gels, or packets.



Solution B: Avoiding tempting foods as hypoglycemia treatment options. It's deadly easy to use a low blood sugar as an excuse to over eat a food you would not normally consume. See the picture on the left – that blood sugar nightmare occurred after I stormed the fridge at 2 am and corrected a nighttime low using granola from a friend's work event. The huge bowl was sitting in our fridge, and "I only had a little." Bad idea! When I use low blood sugars as a justification to eat bad food, I always regret it.

Mistake #2: Taking too much insulin ("stacking") when high, and then going low soon after. Rapid-acting insulin can sometimes feel so SLOW, especially if you wear CGM.

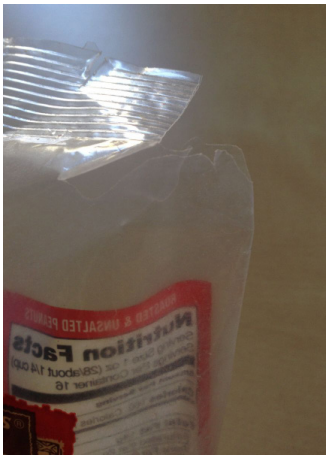
Solution A: Patience. I have to remind myself that in my body, rapid-acting insulin takes about 60-90 minutes to really start dropping my blood glucose and two to three hours to finish working. [Note

these times vary from patient to patient and depending on the size of the bolus.]

Solution B: Use the bolus calculator to account for insulin on board. When I stack insulin, it's because I'm taking too many manual boluses. Using my pump's built-in calculator reminds me that there is still bolus insulin floating around my system. If you take injections, the Time sulin pen cap could be helpful; it is available in Europe and coming very soon to the US.

Solution C: Take walks to correct highs and minimize insulin intake. For a moderately high blood sugar (e.g., 180 mg/dl), I prefer a short walk to drop my glucose – it's more predictable and often suffi cient to bring me back down into range. Even if I only see a modest drop in blood sugar, I'm starting from a lower and safer base to correct from.

Mistake #3: Snacking directly out of the package. It's amazing how quickly I can consume too much of any snack (especially salty options), just because there is a visible package on my pantry shelf and I can mindlessly pour a lot into my hands.



Solution A: Tearing a smaller hole in the package. I've been using scissors to cut a small triangle off the corner of snack packages. This strategy has proven very effective in cutting my consumption – it takes much more shaking, effort, time, and patience to get the same quantity of a snack out of the package.

Solution B: Always pouring snacks into a container instead of directly into my hand. Adopting a blanket, "No-eating-directly-out-of-the-package" policy has been somewhat helpful in curbing this bad habit. In addition to cutting small corners in packages (solution A), I have recently begun trying to force myself to find a bowl or Tupperware container to pour into. If I want more, I have to make the effort to return to the package and put more into the bowl.

Solution C: Stationing myself away from kitchen/snacks. Much of my snacking comes from being in the same room as food. Sitting in my living room or on the back patio, as well as hiding snacks out of sight, has been very helpful.

Mistake #4: Eating when I am not hungry. I do this all the time, particularly when I work from home at my kitchen table.

Solution A: Asking myself, "Am I hungry or just bored/tired/sensing food?" It's almost always that I'm around food, and my brain is telling me to eat it, even though I don't have the sensation of hunger.

Solution B: Drinking water or tea. Often, I can overcome a desire to eat by drinking water or tea. I've become a big fan of loose-leaf hot green tea over the past few years, which fills me up without any calories.

Solution C: Setting a hard-and-fast rule. I've been experimenting with the following black-and-white approach: at least three hours must pass between snacks/meals (unless I am low). This prevents me from snacking indiscriminately just because food is around.

Mistake #5: Eating too quickly or overeating. I'm a flagrant offender of this one, particularly if I'm low and/or haven't eaten in many hours. This is a particularly challenging in type 1 diabetes, since the appetite-suppressing hormone amylin is missing.

Solution A: Eating slower than people I'm eating with. When I'm eating with at least one other person, it's easy to see how relatively fast I'm finishing my food. I've been aiming to eat slower than my meal part ners.

Solution B: Eating with chopsticks. I've been experimenting with this on and off for years and love how much it slows down my eating. The hard part is remembering to grab them out of my kitchen drawer.

Solution C: Adding more vegetables. For a low-calorie, low glyce mic-impact way to fill up, few things beat vegetables. I've bought organic frozen vegetables from Trader Joe's since college – they won't spoil, are fairly inexpensive, and many experts say they are just as nutritious as buying fresh.

Mistake #6: Eating too close to bedtime. Often, I'll eat a low-carb meal close to bedtime, go to sleep with an in-range blood sugar, and wake up in the middle of the night at 190 mg/dl.

I like the old saying, "Breakfast like a king, lunch like a prince, and dinner like a pauper."

Solution A: Eating more calories earlier in the day. When I eat late at night, it's often because I've barely eaten anything all day, or grazed on snacks and not eaten proper meals. I like the old saying, "Breakfast like a king, lunch like a prince, and dinner like a pauper."

Solution B: Avoiding high-fat meals and snacks within three hours of bedtime. I always overeat nuts too close to bedtime, which provokes insulin resistance and a consequent slow and steady rise in blood glucose once I go to bed. See factor #2 here for more detail on why high-fat meals increase blood glucose.

Mistake #7: Not increasing my basal rate following a night of poor sleep or on a day with little activity. My basal rate is set to keep me in range when I've gotten at least seven hours of sleep and I'm fairly active (>10,000 steps in a day or some vigorous exercise). If I fall short of either of these goals – typi-

cally when traveling – I often need to increase my basal rate to stay in my target zone.

Increasing my daytime basal rate - this is a huge advantage of wearing an insulin pump, since it requires just a few button pushes.

Solution A: Increasing my daytime basal rate by 10-30%. This is a huge advantage of wearing an insulin pump, since it requires just a few button pushes.

Solution B: Getting more sleep. Easier said than done, of course, but hugely important for better blood sugars, as I wrote in a previous Adam's Corner. I aim for more than seven hours of sleep and feel most energetic with more than eight hours.

Solution C: Sneaking in activity. I always forget that even a little activity makes a difference. Kelly and I have been known to walk up and down the aisle of an airplane to get steps in while traveling. It's really fun when we're flying together, although passengers have been known to get annoyed. I've found that even 10 minutes on a stationary bike at a base ment hotel gym is better than nothing. When on the road, I also really like the Seven Minute Workout (iPhone and Android), which requires no equipment and can be done in hotel rooms.

I would strongly encourage anyone with diabetes to make a personal list of "diabetes landmines".

I would strongly encourage anyone with diabetes to make a personal list of "diabetes landmines" that seem to lead to out-of-range blood sugars. Just as I did above, try to identify some potential solutions to avoid these scenarios in the future. If nothing specific comes to mind, try this: each time you see an out-of-range blood sugar over the next seven days, try to pinpoint a reason why it occurred. At the end of seven days, can you spot any patterns?

Email me at adam.brown(at)diaTribe.org or tweet me at @asbrown1 #diabeteslandmine with what you find!

[*Editor's Note: Adam is a patient with diabetes and not a health care provider. Please consult with your health care provider before making any changes to your diet, insulin, or medication regimen.]*

Adam is Senior Editor of diaTribe and Chief of Staff/Head, Diabetes Technology at Close Concerns. He is a graduate of the University of Pennsylvania and serves on the board of 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 12 years and a CGM for the past four years. Adam is passionate about exercise, nutrition, and wellness and spends his free time outdoors and staying active. He can be reached at adam.brown(at)diatribe.org or @asbrown1 on twitter.

diaTribe dialogue

T1/2

Our Discussion with Diabetes Experts Professors Philip Home and Jens Sandahl Christiansen: Provocative Thoughts on Patient-Involvement, Potential Game-Changers, and Where to Spend Ten Billion Dollars

Twitter summary: *@kellyclose + Profs Home + Christiansen discuss solvable problems in #diabetes – more patient focus, $10 billion question, and game-changers!*

Short summary: *At the recent EASD conference in Vienna, diaTribe founder Kelly Close moderated a panel discussion with diabetes experts Professors Philip Home and Jens Sandahl Christiansen – the focus was "Solvable Problems in Diabetes." We highlight their thoughts on the need to better empower patients in their diabetes management, future game-changers, and where they'd spend $10 billion.*

Professor Philip Home

As discussed in last issue's Letter from the Editor, The diaTribe Foundation recently hosted an event – "Solvable Problems in Diabetes" – during the European Association for the Study of Diabetes (EASD) Conference in Vienna. The panel discussion, led by diaTribe founder Kelly Close, shared thoughts from two influential diabetes experts: Professor Philip Home, a Professor of Diabetes Medicine at Newcastle University in the UK, and Professor Jens Sandahl Christiansen, a clinical professor in the Department of Endocrinology and Diabetes at Aarhus University in Denmark.

Professor Jens Sandahl Christiansen

Boy, did we learn a lot! In this diaTribe dialogue, find out what these experts had to say about:

- How to empower and support patients to improve management
- Potential game-changers in the future of diabetes
- What they would do with $10 billion to invest in diabetes
- Plus, see how they responded in our bonus lightning round!

HARNESSING PATIENT BRAINPOWER AND THE NEED FOR URGENCY

Ms. Close: Thank you so much for joining us, Professors Home and Christiansen – we're very lucky to be talking with you. First, let's talk about whether we can we do more to involve patients in diabetes care.

Prof. Christiansen: If we don't involve the patient, we're lost. Looking at our

"What is the role of the person with diabetes? People want to drive their own healthcare. To what extent, can we use that huge resource - the brain - to actually improve care?"

systems, we can see that they don't work. Our systems look at adherence to procedures but not outcomes.

Prof. Home: Let me ask something: What is the role of the person with diabetes? We've had initiatives regarding what care to expect in terms of getting hands and feet checked, that if your A1c is above this level, you should be on double therapy. For some reason, it hasn't worked. Do they want to be empowered? People want to drive their own healthcare. This is the idea behind the self-monitoring CGM arena. To what extent, can we use that huge resource – the brain – to actually improve care?

Ms. Close: Some of these things might be starting to change. I think that we need to start increasing the urgency with patients and really pushing on the personal responsibility [Editor's note: She knows that is true for her!]. But until society actually sees this as an urgent problem, I don't know if the patient actually knows. They don't get enough time with their healthcare providers and some don't have access to them at all. Many of them have so much more basic problems associated with socioeconomic status, their shortage of food, and other factors.

Prof. Home: I agree. What can people do with the data that's already available without having access to a health care provider? Some companies are involved, like Abbott and companies involved with CGM, in making CGM more accessible to people with diabetes and professionals. I see this process as a difficult one; after all, we've been working on this since 1987 and we've been relatively unsuccessful for reasons I don't know. But surely, it's the way to go to use that resource.

Ms. Close: Absolutely, I think that many researchers have been ambitious about having to do this. And I think that there's a lot that can be said about the data, to make it more understandable for patients and providers. It's also interesting to see how not only doctors work with this, but also other types of healthcare providers.

FUTURE GAME-CHANGERS IN DIABETES

Ms. Close: Next! What are the next big game-changers in diabetes care?

"Hypoglycemia is the greatest barrier to perfect management."

Prof. Christiansen: Let's bite the bullet. The most effective medications we have carry an implied risk of hypoglycemia. As long as this is the case, and hypoglycemia is the greatest barrier to perfect management, we can do a lot of other things. We need to offer all patients on these agents the opportunity to monitor, maybe not 100 times a day, but certainly when it's needed. The technology is just a finger prick, but innovation makes it easier to report results for more people.

"What is it going to take for foundations like the Bill and Melinda Gates Foundation to be investing in diabetes?"

Ms. Close: It's been really exciting from the patient perspective to see new therapies come on the market. When incretins came on in 2005, we finally had some therapies that didn't cause weight gain and hypoglycemia. I'm really happy that there were the funds to invest in that development all those years ago. I'm not sure if today, we're still in the same environment. You know, we were sad to see Bristol-Myers Squibb and Genentech leave diabetes altogether and it's because they just don't see incentives to stay in the business. I'm glad to see that these therapies exist because they give more options and lead to better access, but I want to make sure that there's an environment out there where there are funds that are being invested to help diabetes. This brings up the question of whether governments are going to invest in these areas or if they are too short-term thinking? Who's going to do this? Sulfonylureas (e.g., glyburide, glipizide, glimepiride) would never be approved today as therapy.

Prof. Home: Perhaps we're thinking about what a government is going to do and why. Governments do things because they are driven in particular directions. It comes back to the diabetes community. The lobbying and parliamentary groups are quite important and effective. Governments are never going to provide the funding for technology development. The research budget is going more toward fundamental science, so the technological developments are going to have to come from a commercial approach. I'm a supporter of that. But we've seen the difficulty with that approach.

Ms. Close: I would love to see more major foundations in the world go in the direction of the Helmsley Charitable Trust. We must show them that the return on investment can be very positive. What is it going to take for foundations like the Bill and Melinda Gates Foundation to be investing in diabetes? I'm really excited to think with stakeholders about what pilots we could take to those foundations.

"I'd go for the two key fundamentals. One is our excess calorie intake. The other is insulin, because it's not insulin that causes hypoglycemia; it's the way we give it."

WHAT WOULD YOU DO WITH TEN BILLION DOLLARS?

Ms. Close: So, what would you do if you had $10 billion to invest in diabetes? The US just spent 20 times that on diabetes in this past year alone.

Prof. Home: I'd go for the two key fundamentals. One is our excess calorie intake. The other is insulin, because it's not insulin itself that causes hypoglycemia; it's the way we give it and the lack of feedback control. If we could develop glucose-sensitive insulin and feedback closed-loop systems, that would be great. Glucose-sensitive insulins would be one of the biggest things to affect hypoglycemia.

Prof. Christiansen: It's still an enigma to me in type 1 and type 2, that there are a number of patients we call non-responders, and there are patients who never get complications despite the fact that they aren't well controlled by all measures. There have been huge studies from industry with new insulins and

other drugs that show a typical response to treatment in one big group, but there are a significant number of so-called non-responders, and we don't understand why. In the future, we need to better understand that it's not only type 1 and type 2, and that it's not only about hypoglycemia and dyslipidemia. There are things there that we don't understand.

LIGHTNING ROUND

Ms. Close: Soda tax: yes or no?

Prof. Home: Yes.

Prof. Christiansen: Well, then I'd say no. [Laughter]

Biggest patient barrier: hypoglycemia or weight gain?

Ms. Close: Biggest patient barrier: hypoglycemia or weight gain?

Prof. Christiansen: Hypoglycemia.

Prof. Home: The answer is not weight, by the way; it's calories. For type 2 patients, it's calories. For type 1 patients, it's hypoglycemia.

Ms. Close: Which diabetes therapy is more likely to reduce the risk of cardiovascular disease – GLP-1 receptor agonists or SGLT-2 inhibitors?

Prof. Christiansen: GLP-1.

Prof. Home: GLP-1.

Ms. Close: Will we look back at cardiovascular outcome trials (CVOTs) as helpful or not?

Prof. Christiansen: No.

Prof. Home: No.

Ms. Close: Which pill formulations of injectable drugs are most promising – oral GLP-1 or oral insulin?

Prof. Christiansen: The combinations?

Prof. Home: The problem is not insulin. It's feedback. So oral GLP-1.

Who should patient advocates focus on: payers or regulatory agencies?

Ms. Close: Who should patient advocates focus on: payers or regulatory agencies?

Prof. Christiansen: I think regulators are authorities that have some kind of common sense. I think you need to work with payers because at the end of the day, they decide in America.

Prof. Home: ...It's two different areas in product development. Payers in one corner; regulators in the other. Regulators are still more important.

What diabetes game-changer do you want to see in the future? Where would you invest 10 billion dollars? Write us your opinion and let us know!

conference pearls

T1/2 Highlights from the Consensus Conference on Glucose Monitoring

Twitter summary: *Meeting underscores inadequate meter surveillance; Novel program to identify subpar BGMs; Medicare coverage of CGM gaining momentum?*

Short summary: *The Consensus Conference on Glucose Monitoring took place in Washington DC to discuss quality and safety of glucose monitoring. Discussion topics included the need for greater post-market surveillance, the DTS Surveillance Program, the FDA, and two CGM Medicare bills currently in Congress.*

On September 28 and 29, we had the opportunity to attend the Consensus Conference on Glucose Monitoring in Washington DC. The meeting brought together some of the brightest minds in industry, government, and academia to discuss the quality and safety of blood glucose monitors and continuous glucose monitors (CGMs).

We heard widespread concern that a significant proportion of meters on today's market (~50%) do not actually meet current accuracy standards.

The discussion largely focused on the need for greater quality surveillance of blood glucose meters after they are approved by the FDA. We heard widespread concern that a significant proportion of meters on today's market (~50%) do not actually meet current accuracy standards – these are usually meters made by obscure manufacturers. Part of the problem is that once manufacturers receive clearance for a device, there are no quality assurance mechanisms in place. The burden is on manufacturers – not the FDA – to make sure strip quality and accuracy remain high. Manufacturers who cut corners are often not identified and, of more concern, their products remain on the market.

We also heard a promising update on the status of the Diabetes Technology Society's (DTS) Surveillance Program for Cleared Blood Glucose Meters. This program has plans to test the accuracy of off-the-shelf, FDA-cleared meters in order to identify inaccurate products. The data would be made publicly available, allowing patients, insurance companies, and healthcare providers know which products are of high or low quality. Though DTS cannot force companies to stop manufacturing low-quality meters, there is hope that identifying them will force a regulatory body, such as the FDA, to take action. The program is still in need of funding, though DTS representative Dr. David Klonoff said that the plan is to begin testing meters by mid-2015.

The FDA's patient-centered spirit was a welcome sign at the meeting. The Agency's Dr. Courtney Lias – who leads the diabetes device division – expressed a clear understanding of the daily challenges patients face, and also shared a strong desire to get devices like the artificial pancreas into patients' hand sooner. On the glucose monitoring front, she emphasized that it is very chal-

It is widely acknowledged that CGM should not be taken away from patients turning 65.

lenging for the FDA to "un-approve" a device, making it difficult for the FDA to remove inaccurate meters from the market. In addition, the agency is pressed for resources and cannot conduct factory inspections abroad as often as it would like. The data from DTS' program could empower the FDA to seek out and investigate those manufacturers with sub-standard products.

Last, we heard increasing momentum for two bills – now in the House and Senate – that seek to establish Medicare coverage of CGM. It was widely acknowledged that this technology should not be taken away from patients turning 65, especially given its ability to significantly reduce hypoglycemia. Our fingers are crossed that we see movement on this front. *–VI/AB*

diaTribe dialogue

T1 Professional Cycling with Type 1 Diabetes – Our Interview with Team Novo Nordisk Founder Phil Southerland

Twitter summary: *@teamnovonordisk cycles w/ #diabetes. dT interviews founder @PhilSoutherland after @USAProChallenge*

Short summary: *Team Novo Nordisk, an all type 1 professional cycling team, rides to prove that diabetes cannot stop it from competing against top athletes in the world's biggest races. diaTribe interviews team founder Phil Southerland after the USA Pro Cycling Challenge, reflecting on the team's progress and discussing his advice for anyone with diabetes who wants to get involved with exercise.*

A highlight for *diaTribe* every year is getting to attend the USA Pro Cycling Challenge in Colorado, where we get to cheer on Team Novo Nordisk alongside team founder Phil Southerland. Team Novo Nordisk is the first professional team in any sport that is made up entirely of people with type 1 diabetes, and this year marked its fourth time competing in the USA Pro Challenge. This seven-day race is considered one of the most intense cycling races in the world and one of the two largest in the US, along with the Tour de California. It covers 525 miles from Aspen to Denver with significant climbing, and the riders maintain a very fast average speed of ~25 mph. Completing this course is a major accomplishment without diabetes – but on top of the high altitudes, dehydration, and extreme fatigue, Team Novo Nordisk must cope with minute-to-minute changes in blood glucose, which have a profound effect on race performance.

diaTribe met up with Phil Southerland to discuss his thoughts on the race, the team at large, and his advice for anyone out there with diabetes interested in exercise and fitness. Phil was diagnosed with type 1 diabetes at just seven months

old, and he has since dedicated his life to inspiring others affected by diabetes and bringing access to insulin globally though the Team Type 1 Foundation.

INTERVIEW WITH PHIL SOUTHERLAND

Q: What was the biggest challenge of riding in this competition, from a cycling perspective?
PHIL: You could say the altitude or you could say the competition, but both of those were same for all teams. We do have a relatively young team and we had to make some last minute changes to the roster due to injuries. It proved to be a difficult race. Lady luck was not on our side, and we hope she will be at the next race.

"There were never any circumstances where diabetes held us back."

Q: What about from a diabetes perspective?
PHIL: There were never any circumstances where diabetes held us back. Our riders and medical staff had to work to make adjustments on the front end to get ready for altitude, but altitude affects every athlete – with or without diabetes.

Q: What would you change if you could ride the race all over again?
PHIL: There is not much else we could change. Colorado is a difficult race to prepare for in that you have to get to altitude well in advance. Bike racing, like diabetes, is not one size fits all. We'll definitely learn from this experience and maybe next year, adapt our racing program a little bit to give our riders the best chance at success.

Q: What is the one diabetes tool the team could not do without?
PHIL: CGM.

"We want these guys to realize they are not just racing bikes for the sake of racing bikes, but they are racking bikes to inspire, educate, and empower."

Q: What advice do you give every rider that joins Team Novo Nordisk?
PHIL: The advice and guidance to all is that they need to work hard because there are millions of fans who look to their success and struggles for inspiration. The riders need to make the sacrifices necessary to be the best they can be. We want these guys to realize they are not just racing bikes for the sake of racing bikes, but they are racing bikes to inspire, educate, and empower. Diabetes is never an excuse for performance.

Q: What has been the biggest surprise or learning as you've ramped up from Team Type 1 to Team Novo Nordisk?
PHIL: I think it's the need for systems and management. Before our partnership with Novo Nordisk, we allowed one or two riders with diabetes to go out there and compete. They were typically experienced riders, both in diabetes and bike racing – they had their own styles and they did it their way. Now, putting eight riders from six different countries on the road, we as an organization needed to make it easier for them to manage their diabetes during exercise. The creation of systems around our diabetes management was one of the most important changes and proved to be one of the most valuable in our evolution.

Q: What has it been like working with Novo Nordisk over the past couple of years? Has anything been different than what you expected?
PHIL: It's been an amazing relationship. We consider ourselves one team and we have one goal. With Novo Nordisk behind us, we feel like we have an additional 40,000 people cheering for us at every race we do. Novo Nordisk is a very involved company, and I feel like I've gotten lessons in business from some of the sharpest people in the diabetes space. It has helped Team Novo Nordisk as a company and allowed us to quickly evolve in a very short period of time.

"It's been an amazing experience. I get the pleasure of seeing the smiles on the faces of these 15, 16, 17, 18, and 19 year old kids who are getting to live their dream because they have diabetes."

Q: We know it's hard to find world-class cyclists with type 1 diabetes, which makes the development team really exciting! What has that experience been like?
PHIL: It's been an amazing experience. I get the pleasure of seeing the smiles on the faces of these 15, 16, 17, 18 and 19 year old kids who are getting to live their dream because they have diabetes. This year, we are going to send two riders from Uzbekistan to the World Championships – which, to our knowledge, there has never been anyone with type 1 diabetes competing in the World Championships at the junior level. We are breaking new ground on a daily basis. The exciting part is, we now have groups of type 1s competing for victories at 17 and 18 years of age. We've had 80 top tens from our juniors this year, all type 1 athletes. That's making the competition for the development team that much tougher, and making the development team that much better. It's going to take a few more years to see the fruit of our labor here, but the foundation has truly been made for a long term and successful all-diabetes professional cycling team.

Q: What advice would 2014 Phil Southerland give to the 2005 Phil Southerland?
PHIL: Tough question. I've learned so much over the years, but what I see now is the importance of being focused – 100% crystal-clear focused.

"Exercise keeps me healthy and more importantly, keeps me happy."

Q: What advice do you have for people with diabetes who find it hard to exercise?
PHIL: I would encourage people to keep trying. And set a goal. Talk you your healthcare professional and figure out what's right for you. Whether it's about running your first 5k or 10k, set a goal and stick with it. It doesn't happen overnight and it's not always fun, but it's absolutely worthwhile. When I come back from a hard ride, my wife will ask me, "How was your ride?" I'll say, "Horrible." And she'll say, "So why do you do it?" I say, "Because it's fun." Exercise keeps me healthy and more importantly, keeps me happy.

Q: What do you see as the biggest unmet need in diabetes care? Would you have answered that question differently in 2005?
PHIL: For me, it's empowerment. People, no matter where they are in the world, need to be motivated. Diabetes doesn't go away. It's not easy. The motivation and empowerment needed to stick with it are so important, in addition to working with healthcare professionals to come up with a treatment plan. The impact of motivation is huge. I've seen what happens once people feel empowered.

trial watch

Welcome to trial watch, where we keep an eye on the latest and greatest trials going on in the field of diabetes. Here, you can learn about new therapies and devices currently under study, and learn more about participating in these trials. Trial participants can get early access to new treatments, receive care at clinical trial centers, and are usually compensated for their time. You can read more about clinical trials at the "Center Watch" volunteer page or the ClinicalTrials.Gov information page.

Can a one-day workshop improve diabetes distress and A1c in adults with type 1 diabetes?

Reducing Distress and Enhancing Effective Management for Adults with Type 1 Diabetes (T1-REDEEM)

ClinicalTrials.gov Identifier: NCT02175732
http://clinicaltrials.gov/ct2/show/record/NCT02175732

As we're sure type 1 readers would agree, many people with type 1 diabetes experience considerable emotional distress about the demands of management, which has been associated with poor glycemic control and outcomes. In the UCSF T1-REDEEM trial, researchers will compare how two different behavioral interventions for diabetes distress reduce both distress and glycemic control.

The interventions consist of one-day workshop programs, with follow-up web meetings and calls. One program, called KnowIt, focuses on new advances in diabetes education and behavioral management to help distressed adults with type 1 improve their self-management. The other program, called OnTrack, addresses the personal stresses and emotional strains of having type 1 that can interfere with self-management. Both KnowIt and OnTrack are behavioral programs, meaning that there are no changes in medications or other drug interventions. Participants must be 19 years or older, have had type 1 diabetes for over a year, have high scores on a screening scale of diabetes distress, and have A1c levels >7.5%. Anyone who has had severe complications within the past 12 months (heart attack, blindness, etc.) is excluded from the trial. Participants will be asked to complete online surveys before the program and at three and nine months. A1C, lipids, blood pressure and BMI also will be collected. Participants will receive gift cards for their time and there will be no costs to participate. The program will be California-based, operating in the San Francisco Bay Area, Sacramento and Los Angeles. If interested in participating, contact the trial team directly at 855-850-3599 or e-mail bowyerV@fcm.ucsf.edu.