

# diaTribe®

research and product news for people with diabetes

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## from the editor



November is always a big month for diabetes, though I had no idea what we had in store just a year ago when I met with FDA Commissioner Margaret Hamburg. If I knew then what I know now... well, I would have done a happy jig first to celebrate our progress in having patients heard and then set my sights on helping the FDA upgrade its technology systems (more on that later). But let's rewind. My chance encounter with Commissioner Hamburg in Aspen, Colorado 18 months ago led to this November 3, when The diaTribe Foundation led an unprecedented patient discussion on the unmet needs in diabetes with FDA leaders; we were joined by representatives from the ADA and JDRF as well.

We discussed many of the issues that I've thought a lot about during my work in the diabetes field, and even though I've written about many individual patients, I am still moved by their stories – my gratitude goes out to all those who participated in this meeting! I want to thank the diabetes community for tuning in to the webcast, engaging on social media, spreading the word, sharing your stories, and so much more. Each piece has been critical to the success of the day. So much of the work that we've been doing has fed into this moment when we could finally engage directly with the FDA – I'm so honored to have been part of a monumental day for patient advocates. I'll remember the day as a time where patients from an incredibly diverse and sometimes fractured community finally came together to speak with passion, focus, and urgency on the issues that matter to us the most – better management options and a better quality of life.

My favorite part of the experience was perhaps not even on November 3 at all. The night before our session with the FDA, I had the opportunity to have dinner with all of the patient panelists who traveled to the FDA with us. That night, we went around the table and all shared our personal challenges and experiences living with diabetes. We all chose one word we think connects us with diabetes, and I heard words like Complicated, Frustrating, Stressful, and Rollercoaster – all unfortunately accurate descriptions of diabetes management. But when it got to my end of the table, I was surprised to hear the word Hope springing out from my lips. Hope because this was one of the first times I felt patient voices were being heard in a real way. Hope because once they heard 30 million voices calling out, it was impossible to ignore. And Hope because this could be the start to a meaningful conversation for improving diabetes care for all of the patients out there. Telling the FDA about these pressing issues is only our first step, and the next is in creating solutions for those issues with a dialogue between patients, FDA, clinicians, educators, and industry. Stay tuned!

very best,

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## diaTribe staff

### Editor in Chief

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### Senior Editor

Adam Brown

### Managing Editors

Nancy Liu

Alexander J. Wolf

### Senior Advisor

James S. Hirsch

### Contributors

Varun Iyengar

Hannah Martin

Emily Regier

Ellen Ullman

Manu Venkat

Alasdair R. Wilkins

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## quotable quotes

**“The real point is that we need to move toward a culture that supports health. Really, every sector needs to be involved, whether it’s transportation, agriculture, or the private sector. All of these have a role to play.”**

—Dr. Jim Marks (Robert Wood Johnson Foundation, Princeton, NJ) in our interview with him at the Boston Obesity Week Conference.

**“I think that youth are our best long-term solution to this problem [preventing diabetes]. It is a combination of having youth that are educated in health and that can make positive life choices, perhaps even teaching their parents. That is the real long-term solution.”**

—Mr. Lars Sørensen (CEO, Novo Nordisk) in our interview with him at the Cities Changing Diabetes press conference in Houston, TX.

**“Fighting diabetes is crucial to the well-being of the nation and the American people. It is winnable if everyone does his or her part.”**

—Francisco Estrada (type 2 diabetes, 5 years) at the November 3 patient discussion with the FDA.

## fingersticks



Illustration by Joesph Shivers

**“So, if my diabetes is going to be my job... do I still have to help wash the dishes?”**

## new now next



T1/2

### Dexcom Free Software Update Significantly Improves Accuracy for Dexcom CGM Users

*Twitter summary: Dexcom announces “Software 505” for CGM users – FREE download that improves accuracy to 9% vs. fingersticks, available now!*

In unexpected news, Dexcom recently announced the FDA approval of the G4AP algorithm (called “Software 505”), a new software that improves the accuracy of the Dexcom, strengthening the accuracy vs. fingersticks to 9%. It is now available to Dexcom users as a free download on Dexcom’s website. The previous G4 Platinum software had an accuracy of 13% compared to fingersticks, and this 4% increase in accuracy (lower percentage = better accuracy) makes the Dexcom CGM the first ever CGM to have an accuracy percentage in the single-digits, putting it in the range of standard fingerstick accuracy and representing a significant step forward for CGM accuracy.

Those who already use a Dexcom can run an update tool to add the algorithm onto their existing G4 Platinum receiver, and any newly purchased Dexcoms will come with the new software already included. The download is only available for users 18 years or older; Dexcom will be trying to obtain approval in pediatrics within the following months. The update can only take place on a Windows computer.

The release of this software seems to have gone off without a hitch, even coming out ahead of schedule. Dexcom also has a cool marketing strategy that demonstrates how the G4AP has been used in artificial pancreas research. It is outstanding news for patients to see this come through, as the even-better accuracy and reliability comes without any hassle and no cost. –AB/AJW



T1/2

### Houston Joins Novo Nordisk’s Cities Changing Diabetes Program

*Twitter Summary: Novo Nordisk announces Houston as new member of Cities Changing Diabetes Program – exciting initiative to combat #diabetes in urban life*

Novo Nordisk recently announced (and we were there!) that Houston, Texas will be the first US city to join the Cities Changing Diabetes Program. This makes Houston the third city in the program, following Mexico City and Copenhagen. The program aims to collect data to map diabetes growth and impact in urban areas, identifying the unique challenges that cities present. As context, an estimated 82.8% of people with diabetes live in cities in the US, and globally, people in cities are twice to five times more likely to have diabetes. Armed with that data, the hope is to guide actions and policies to combat the diabetes epidemic.

In Houston, much of the program’s focus will look at differences between individual neighborhoods, as well as differences between socioeconomic and racial/ethnic groups. As the great public health professor Dr. Stephen Linder (University of Texas Health Science Center’s School of Public Health) pointed out at the press conference, the overall diabetes prevalence in Houston is 11%, though in some pockets of the city it’s as high as 20% or as low as 5%. Understanding the differences between these neighborhoods will be crucial in identifying ways to try

Why Houston? To start, it is the fourth largest city in the US and one in nine residents has diabetes.

and prevent diabetes growth in the future. Mr. Stephen Williams, the Director of Houston's Department of Health and Human Services, expressed enthusiasm at the press conference we attended that the data collected through this program could be used to create individualized diabetes prevention plans in different neighborhoods tailored to each neighborhood's unique needs.

Why Houston? To start, it is the fourth largest city in the US and one in nine residents has diabetes. Moreover, one in three adults in Houston is obese, making obesity the most prevalent chronic disease in the city. Novo Nordisk CEO Mr. Lars Sørensen cited three key reasons behind the decision to nominate Houston as a member city in the program:

- Houston city leadership has shown commitment to improving health and wellness, such as with the Go Healthy Houston Initiative launched in 2012
- Houston's socioeconomic and racial diversity provides opportunities to study a wide range of populations and to positively impact the lives of individuals hailing from a variety of different backgrounds
- Medical communities such as the University of Texas Health Sciences Center will provide the research expertise necessary to conduct the mapping phase of the program

With approximately two-thirds of people with diabetes in the world living in urban areas, the Cities Changing Diabetes Program has the potential to make a major impact in addressing this rising epidemic.

Houston Mayor Annise Parker also connected the goals of the Cities Changing Diabetes program with the needs of the Houston community – she obviously has enormous commitment to the city and to addressing this problem. She highlighted the recent period of economic growth in the city, warning that the massive direct and indirect costs of diabetes threaten to stall that progress. She expressed confidence that the partnership between Houston and the program will yield substantive recommendations and real action – this is where there is skepticism and it will be terrific to see the action. With approximately two-thirds of people with diabetes in the world living in urban areas, the Cities Changing Diabetes Program has the potential to make a major impact in addressing this rising epidemic in a unique way. –AJW/MV

### **T1/2** Orexigen and Takeda's Weight Management Drug Contrave Launches in the US

*Twitter summary: Contrave launched in the US w/ weight support program + savings/loyalty programs offer new option for patients*

Two healthcare companies, Orexigen and Takeda, recently announced the launch of Contrave (naltrexone/bupropion combination), a new weight management drug now available by prescription in the USA. After FDA approval on September 10, Contrave is the third weight management drug to recently enter the US market after Arena/Eisai's Belviq (launched in the US in June 2013) and Vivus' Qsymia (launched in September 2013). Contrave is approved for adults with a body mass index (BMI) of 30 or greater or adults with a BMI of 27 or greater who have at least one weight-related condition such as high blood pressure, type 2 diabetes, or high cholesterol. In clinical trials, people taking Contrave lost an extra 5% of their body weight relative to those on placebo (an inactive pill). For more information on Contrave, please see our past new now next coverage in *diaTribe* #69 or the drug's label.

Scale Down will provide users with a wireless body weight scale that triggers personalized texts and tips based on daily weigh-ins.

Certain patients will be able to access Scale Down, a free weight management support program. Notably, Scale Down will provide users with a wireless body weight scale (at no additional cost) that triggers personalized texts and tips based on daily weigh-ins – this sounds very cool. In addition, Orexigen is offering savings programs to help reduce the costs of trying and staying on Contrave. -AJW/MA

## **T2** FDA Approves Once-Daily Xigduo XR – Fixed Dose Combination of Metformin + SGLT-2 Inhibitor

*Twitter Summary: FDA approves Xigduo XR – first once-daily SGLT-2 inhibitor/metformin fixed dose combo in the US*

AstraZeneca recently announced that the FDA approved Xigduo XR, a once-daily fixed-dose combination pill (that means two pills in one) of the SGLT-2 inhibitor Farxiga (dapagliflozin) and metformin extended release. Xigduo XR is approved for adults with type 2 diabetes to be taken in addition to diet and exercise to help improve glycemic control. Xigduo XR is the first once-daily SGLT-2 inhibitor/metformin combination pill available in the US. Janssen's Invokamet, a twice-daily SGLT-2 inhibitor/metformin combination pill, was approved this past September. No pricing or reimbursement information for Xigduo XR is available at this time but we're pretty sure it will be around the same price as what one pill costs that isn't a combination.

As a reminder, SGLT-2 inhibitors are a class of drugs that lower glucose levels by causing the kidney to excrete excess glucose through urine. They reduce A1c, cause very little hypoglycemia (none for most people), and can lead to weight loss and improvement in blood pressure. There are currently three SGLT-2 inhibitors available in the US: Janssen's Invokana, AstraZeneca's Farxiga (dapagliflozin), and Boehringer Ingelheim and Lilly's Jardiance (empagliflozin). Metformin, on the other hand, is a widely used treatment for type 2 diabetes known for its efficacy, safety, low cost, ease of use, and potential anti-cancer properties.

Combination pills have an important convenience advantage for patients, since they reduce the burden of filling multiple prescriptions, taking multiple pills, and could potentially lower co-pays.

Combination pills such as Invokamet and Xigduo have an important convenience advantage for patients, since they reduce the burden of filling multiple prescriptions, taking multiple pills, and could potentially lower co-pays as well. Xigduo is a step forward, particularly given its once-daily dosing. Down the road, SGLT-2 inhibitor/DPP-4 inhibitor combination pills will also be an important innovation in type 2 diabetes drugs – these medications will combine two effective therapies that don't cause hypoglycemia and don't cause weight gain. One such drug, a combination of Jardiance (empagliflozin) and Tradjenta (linagliptin), is currently under FDA review and could receive approval in early/mid 2015 at the soonest – now this combination could be truly exciting, and its (hopeful) approval is really widely awaited. -AJW/KC



T1/2

## Take the Big Blue Test! How Just 20 Minutes of Exercise Can Improve Your Blood Glucose

*Twitter Summary: Take the #BigBlueTest to get active, spread #diabetes awareness, and raise money for non-profits helping #PWD!*

Want an easy and fun way to spread diabetes awareness, exercise, and help raise money for diabetes the same time? Take the Big Blue Test! The Big Blue Test encourages people with and without diabetes to get active and help raise money for diabetes. How does it work? Participants simply have to test their blood sugar (people without diabetes can skip this step), get active for 14-20 minutes, test their blood sugar again, and then share the results through the short Big Blue Test survey. For each survey entry (participants can take the survey more than once!), \$1 is donated to diabetes non-profits providing supplies, services, and education to people with diabetes in need.

For anyone who wants to get even more involved, the amazing folks at the Diabetes Hands Foundation made it simple to share the Big Blue Test at school or the workplace. The Big Blue Test ends November 18, so we're all rushing to get our survey results in soon! And for other ways to keep active, you can help keep track of your physical activity, by entering diaTribe's own #dTGetsFit free giveaway to win a FitBit Flex or Jawbone Up fitness tracker. -AJW

T1/2

## Berkeley's Groundbreaking Vote to Approve Soda Tax, while San Francisco Soda Tax Fails to Pass Despite 55% Majority Vote

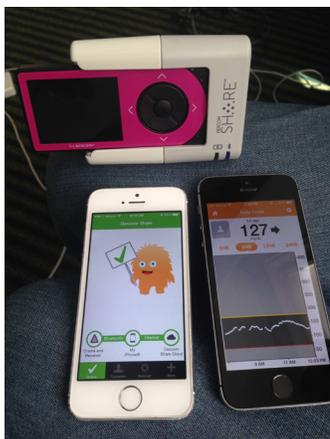
*Twitter summary: Berkeley becomes first US city to pass a tax on soda w/ 75% approval - SF fails to pass its soda tax with 55% approval*

The city of Berkeley voted in overwhelming support of the soda tax, passing it with 75% approval - a groundbreaking decision.

This past election day, two soda taxes went up for the vote in Berkeley and San Francisco. The city of Berkeley voted in overwhelming support of the soda tax, passing it with 75% approval – a groundbreaking decision as the first US city to pass a tax on soda. In San Francisco, the soda tax received 55% of the vote, but needed two-thirds majority to pass. Supporters of the San Francisco Tax still hold the election as a positive sign though, as getting a majority vote is still quite notable.

Berkeley's tax adds one penny per fluid ounce (so 12 cents per typical soda can) on all sugary sodas (not including diet sodas), juices with added sugar, energy drinks, and syrups that go into drinks at cafes (e.g. a Starbucks Frappuccino). The tax is on the distribution companies, and all revenue from the tax goes to Berkeley's general fund. According to the measure, a panel of health and nutrition experts will make recommendations to the Berkeley City Council on how to use that money to fund initiatives for improving children's health. Berkeley is the first city in the US to pass a tax on soda, after 30 cities and states (now 31, with San Francisco) have failed to do so in the past. -AJW

## learning curve



T1/2

### Dexcom Share – Peace of Mind for Loved Ones, Paving the Way for Next-Gen Mobile CGM

by Adam Brown and Kelly Close

**Twitter summary:** *Dexcom Share sends CGM data to iPhone/iPod app, most ideal for nighttime monitoring; paves way for Gen 5!*

On October 22, Dexcom started shipping its long-awaited Share product, an FDA-approved remote monitoring system for the G4 Platinum CGM. Using a receiver docking cradle and the Share app, the system allows CGM data to be sent to up to five designated followers' Apple devices. Share costs \$299 and is available for purchase on the Dexcom website without a prescription.

The system offers the most benefits at night, allowing parents and partners to know their loved one's glucose levels every five minutes from another room, another state, or another country! This test drive discusses how Share works, highlights our experiences from both the patient and caregiver ("follower") perspective, notes who might benefit the most from Share, and addresses what patients can look forward to in more accessible CGM data down the road.

#### How Does Share Work?

- The Dexcom G4 Platinum receiver slides into the Dexcom Share docking cradle
- The Share cradle (plugged into a power outlet) both charges the receiver and transmits CGM data every five minutes to a nearby Apple iPhone or iPod touch via Bluetooth.
- The Dexcom Share app on the nearby smartphone then receives the CGM data and sends it up to a secure Internet server via cellular connection or Wi-Fi.
- Up to five invited followers can log on to a separate app, Dexcom Follow, to view the CGM value, trend arrow, trend graph, and receive notifications and alerts.

#### Share Setup

We found the setup process for Share very easy overall, timing out to less than 20 minutes from beginning to end. After opening the glossy packaging and plugging the Share cradle into a wall power outlet (standard micro-USB cord), we easily found and downloaded the Dexcom Share app from the Apple app store. The app has a terrific quick start guide to carry users through the setup process – as we said at FDA recently, we'd like to be able to start up new products without an

Up to five invited followers can log on to an app to view the CGM value, trend arrow, trend graph, and receive notifications and alerts.

instruction guide (at most, a “quick start” page) and we could certainly do that with this product! (While we know that patients “should” look at instructions, we believe “in real life” most don’t want to.) The most finicky part of setup involves Bluetooth pairing the cradle with the nearby phone, which took us a couple tries. That said, Dexcom put frequently asked questions and troubleshooting information throughout the app. Awesome – we’d love to see more of this!



Once the cradle is Bluetooth-paired, the Share app prompts you to invite “followers” via an email address entry. Then, they receive a simple email inviting them to download the Dexcom Follow app, view the CGM data (number, trend arrow, trend graph), and extensively customize the notifications and alerts they want to receive (e.g., alert me whenever glucose drops below 50 mg/dl, and when glucose is above 180 mg/dl for 30 minutes straight). Overall, we give Dexcom an A+ for the ease of setup.

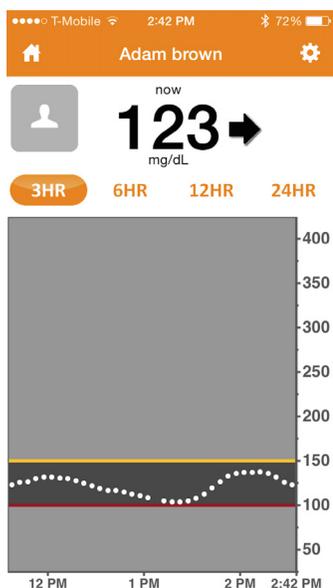
Note that you can use the Share and Follow apps on the same phone at the same time to both Share and Follow your own CGM data – it’s not the intended purpose of the system, but it works amazingly well and allows you to get all the alerts and CGM display on your own smartphone! This is particularly good for those who do not wake up to CGM alarms and wanted the added backup of a phone alert. As well – when the CGM is in the cradle, it’s not in one’s pocket – and some are used to being able to check the CGM at any time. This goes a long way toward making that possible!

### From the Patient Perspective – Sharing CGM Data

#### Pros

- Remote monitoring adds a safety net, especially during nighttime and when traveling.
- Being able to “Follow” our own CGM data on an iPhone or iPod! An excellent way to make alarms louder, especially when sleeping at night when some patients don’t hear even the loudest alarms.
- Simple, intuitive app with a cool, colorful design (the “Glucomonster” character was a nice touch).
- Very easy setup and strong troubleshooting.
- Can eliminate annoying questions (“What’s your number?”) from caregivers and safely foster more independence, especially for younger patients (although now caregivers can see more data, so more annoying questions may well ensue – less “what’s your number” and more “what happened?!”).
- Control over who sees the data and what they can see (e.g., if patients don’t want them to see a trend graph, they don’t see one).
- Good transmission range: Share app on nearby phone can be up to 15 feet away from cradle (within Bluetooth range). CGM sensor/transmitter must be within ~20 feet of receiver cradle.

Remote monitoring adds a safety net, especially during nighttime and when traveling.



### Cons

- Receiver can be a bit hard to slide into Share cradle, potential to break fragile USB port.
- When receiver is plugged into the Share Cradle, it's tethered to a wall outlet and not very portable.
- Can lead to inquiries from a Follower that may be perceived (if not meant) as judgmental – “I saw you spiked to 240 mg/dl. What did you eat?!” (Kelly complained about this a few times about John though she knows he cares about safety and is always trying to help. “But he didn’t have to say it in front of everyone!” she said [admittedly sensitively!])
- Data is only transmitted and not stored online for analysis.
- Only Apple iPhone/iPod compatible (Android is in development).

### From the Follower Perspective

#### Pros

- Peace of mind and relief for loved ones, especially when patients are sleeping at night, traveling alone, or at school.
- Ability to remotely see CGM number, trend, graph from another room, another city, or another country.
- Potential for intervention when patients could be in serious trouble (e.g., 50 mg/dl for an hour straight).
- Highly customizable notifications and alerts.
- Excellent in-app color-coding and display.
- Reliable data transmission.
- Easy email invitation.
- Can follow multiple people (e.g., for a parent with two Dexcom users in the house).



### Cons

- Phone alarms/notifications still might not wake up loved ones at night.
- Potential for alarm fatigue (though customizability is pretty good).
- Only Apple iPhone/iPod compatible (though Android is in development).
- Might lead to increased conflicts (see above) with loved one.

### Should You Buy Dexcom Share?

As noted above, Share costs \$299 and is available for purchase on the Dexcom website without a prescription.

Share seems incredibly well suited for...

- Parents of young children with type 1 diabetes who want to monitor their kids at night, at school, while at sleepovers, and other times.
- Spouses/caregivers involved in diabetes management, especially those who

worry about their loved one's safety due to extra high risk of hypoglycemia.

- Those who do not wake up to CGM alarms at night and want louder alarms.

Share may not be the best option for...

- Independent adults with type 1 diabetes who do not rely on others to manage their diabetes.
- Those who are overwhelmed by data or alarms.

Share is not an option for... Patients not using a Dexcom G4 Platinum CGM

### The Future of More Accessible CGM Data

Share paves the way for Dexcom's exciting Gen 5 mobile system, which will send CGM data straight from an on-body transmitter to a mobile app via Bluetooth.

Notably, Share paves the way for Dexcom's exciting Gen 5 mobile system, which will send CGM data straight from a new on-body transmitter to a mobile app via Bluetooth – no receiver or receiver cradle needed! Gen 5 will use much of the same backend software architecture as Share, meaning the FDA review will ideally go much more smoothly. For context, the FDA review of Share took a lengthy 15 months. Dexcom plans to submit Gen 5 to the FDA in the next two months or early 2015.

Since not everybody will want to look at their phone to access their CGM data, Dexcom does plan to offer a receiver for Gen 5, as well as integration with the Asante Snap and Insulet OmniPod pumps (the Tandem and Animas pumps under FDA review will integrate with the current G4 Platinum). Overall, the future will allow Dexcom patients to access their data wherever it suits them best. Medtronic is also building its own Bluetooth-enabled CGM, called Guardian Mobile. The company plans to begin a major trial soon.

## adam's corner



T1/2

How much activity do you actually get? Why activity tracking is worth it, and perhaps needed more than ever

by Adam Brown

**Twitter summary:** *Why I've found activity tracking valuable, some of the drawbacks, and conversations with others who watch their step count.*

How much activity do you get each week? Do you meet the minimum CDC recommendations?

1. For adults, 30 minutes of moderate activity five days a week (e.g., brisk walking for a total of 150 minutes per week) – note children are advised to get more, along the lines of 60 minutes seven days a week; AND



## 2. Muscle strengthening activities on two or more days per week.

The latest statistics suggest only 50% of adults meet the first guideline, and only 20% of adults meet both guidelines. To make matters worse, the CDC data is all self-reported, and studies show most people overestimate how active they really are.

This points to an unfortunate double whammy: (1) many of us are not as active as we should be; and (2) we often think we are more active than we actually are. The contributing factors are numerous – city design, workplace culture, cars, screen time, a psychological bias to over-report good behavior, to name a few – but to me, there is one factor worth singling out:

Like calories in food and sugar in our blood, there's a certain invisible quality to activity – in other words, it's hard to know how active we actually are unless we measure it.

This article discusses my positive experience logging my own activity, primarily by wearing a Fitbit device that reports the number of “steps” I've taken in a day (among other things). See below for my view of the pros and cons of wearing an activity tracker, as well as a summary of conversations with others that track their activity. You can sign up at [diaTribe.org/dTgetsfit](http://diaTribe.org/dTgetsfit) for our diaTribe giveaway to win your own Jawbone or Fitbit activity tracker.

### The Pros of Activity Tracking

Without question, it changes my behavior and makes me more active.

1. Without question, it changes my behavior and makes me more active. The number of steps on my Fitbit is an indisputable measurement of just how active I am – and as a result, I can quickly change my behavior accordingly when I'm falling short.

- For example, when traveling or visiting the suburbs. I typically have no problem getting more than 10,000 steps a day in San Francisco (walking to work is 2,000 steps alone; we're lucky to have a treadmill desk; and cycling is amazing in the Bay Area), but hitting that goal in other environments can be very challenging. In Phoenix, I must force myself to go for neighborhood walks throughout the day, because so little activity is required to function in a city that revolves around cars (and where the temperature exceeds 110 degrees during the summer). While traveling, I often pace up and down airplane aisles, through airports, and take the stairs up to my hotel room (when they are accessible!).
- According to Fitbit's Amy McDonough, users experience a 43% increase in activity just by putting a Fitbit on. As she noted at the Consumer Electronics Show conference in January, “It's about making it visible.” I couldn't agree more. After handing out numerous activity trackers to friends and co-workers over the past year, it's amazing what often happens. They open the box and seem to immediately change their behavior – they spend more time on the treadmill desk, they go for more walking breaks, and they focus on hitting their step goal for the day.
-

A single actionable goal - I shoot for 10,000 steps every day - it's one number and either hit it or I don't.

2. A single actionable goal. I shoot for 10,000 steps every day – it's one number, and I either hit it or I don't. By contrast, I find that most exercise targets are confusingly worded (e.g., what constitutes “moderate” or “vigorous” activity?) and rely too much on manually tracking time (e.g., 150 minutes per week). When it's 8 pm and I see that I'm at 8,500 steps, more often than not, I'll go for a quick walk or pace around the house to get over 10,000 steps. Does that make me weird? Maybe. But for me, having a clear line in the sand makes all the difference in the world.

3. Activity trackers give immediate feedback – I know in the moment exactly how I'm doing. Like data from CGM, it can be a gamechanger to see the real-time consequences of my behavior. By contrast, I find lots of health data is looked at too far after the fact, when it's hard to remember and difficult to connect specific behaviors to specific outcomes. For instance, in diabetes, we often rely on an A1c measurement that reflects the last three months of diabetes management; then, we take another measurement three months later. It's not frequent enough, and by association, not actionable enough. The ability to see continuous, real-time data is a huge benefit of activity trackers.

Instead of feeling guilty or bad about myself, usually I just feel motivated to be more active. Activity trackers also do a great job of giving encouragement.

4. The feedback feels non-judgmental, and often, very motivating. While blood sugar numbers can often feel like a judgment – “265 mg/dl? What did you eat?!” – activity data feels very objective. “Okay – I've walked 2,500 steps today.” Instead of feeling guilty or bad about myself, usually I just feel motivated to be more active. Activity trackers also do a great job of giving encouragement with badges and achievements for reaching certain milestones (e.g., one million steps walked), as well as progress reports. Overall, the whole experience is much more positive, much more progress-oriented, and thus much more engaging.

5. Friendly encouragement from friends. I'm a huge fan of the social aspects of activity tracking – whereby you can “follow” your friends, give them encouragement, and challenge each other. This might sound like it could be cutthroat or competitive, but I've found it to be the exact opposite. Even the language used (e.g., “Cheer” [Fitbit], “Kudos” [Strava]) speaks to the positive atmosphere that these apps seek to foster. According to Fitbit's McDonough, for each extra friend someone has on the Fitbit system, his or her activity increases by 750 steps per day. Based on my conversations with friends, however, the social features are not for everyone – some don't want followers! Fortunately, you can toggle these on or off as you desire.

6. Passive data collection and seamless sync to my phone. Manually tracking and entering things is the bane of my existence – I refuse to do it. Fortunately, most activity trackers are designed with this in mind. I simply wear the device and charge it periodically; it tracks everything and sends the data to my phone in the background. I get notifications throughout the day to remind me how I'm doing. It's very plug-and-play and very easy – exactly how data downloading should be.

Not every personality responds to activity tracking. If you like setting and achieving goals, activity tracking may be a good fit.

### **The Cons of Activity Tracking**

1. Not every personality responds to activity tracking. I've seen some people become obsessed with their step count, but I've also seen many lose interest over time, or never get into it in the first place. If you like setting and achieving goals, activity tracking may be a good fit – see this Strengthsfinder personality type for what I mean. If you feel like you're already active enough, or don't want to think about more health-related things, or find data like this slightly overwhelming, it may not be for you.

2. Activity tracker devices cost money. Usually, they're around \$100 (depending on the model), but they can run anywhere from \$15 to over \$200 (for example, at \$199.99, the upcoming Basic Peak is on the most expensive side).

- If cost is a concern, use an app like Moves or Strava, or buy an inexpensive pedometer like this one from Omron. You can always upgrade to a more expensive and full-featured device later on. Additionally, many employers offer wellness programs that give out activity trackers for free; you may even get discounts on your insurance premiums by using it.

3. You can lose a device, run it through the washing machine, break it, etc. Many activity trackers are now wristbands, which make them much harder to lose. Some are waterproof, though most won't survive a run through the wash.

4. It's another thing to wear/carry/think about. I generally forget I'm wearing mine, but people with diabetes carry a lot of stuff. You may not want to deal with something else.

### **Concluding Thoughts**

Overall, I've found activity tracking to be a very positive addition to my arsenal of health gadgets.

Overall, I've found activity tracking to be a very positive addition to my arsenal of health gadgets. It motivates me to be more active in a world where physical activity has been largely engineered out of our lives. I love striving toward a single goal and feeling motivated to change my behavior for the better. I encourage anyone out there to try tracking their activity – whether it's through an app, an inexpensive pedometer, or a Fitbit/Jawbone device.

Do you track your activity? Are you considering it? Please email me at adam.brown(at)diaTribe.org and share your thoughts!



## learning curve

T1/2

### The surprising literature on artificial sweeteners and their link with obesity and type 2 diabetes

by *Emily Regier and Nancy Liu*

**Twitter summary:** *Artificial sweeteners with zero calories may not be as 'healthy' as advertised – new study suggests a link with t2 #diabetes/#obesity*

**Short summary:** *New research demonstrates a surprising relationship between artificial sweeteners, the microbes that live in your gut, and obesity and type 2 diabetes. How a series of experiments in mice and humans cleverly showed this relationship and what it means for the public...*

The seemingly harmless artificial sweeteners used in diet drinks and “sugar-free” foods (e.g., Sweet N’ Low, Equal, Splenda) may possibly have a connection with high blood glucose levels and an association with obesity and type 2 diabetes. And it may be through a relationship with gut bacteria (“gut microbiome”) – an exciting, emerging field of diabetes and obesity research.

#### How are artificial sweeteners associated with glucose levels?

In October, the scientific journal *Nature* published a compelling paper with evidence that eating or drinking non-caloric artificial sweeteners (NAS) like Equal (aspartame), Sweet’N Low (saccharin), and Splenda (sucralose), is associated with glucose intolerance – a condition leading to higher-than-normal blood glucose levels. Glucose intolerance is associated with obesity as well as type 2 diabetes. Strangely enough, these artificial sweeteners – though they have no sugar or calories – may disrupt the body’s ability to regulate blood sugar through changes in the gut microbiome, or the population of bacteria that naturally lives in the digestive system. The study’s results challenge the common assumption of non-caloric sweeteners as a healthy alternative to sugar-sweetened foods and beverages, and present some of the most convincing evidence available on the powerful role of gut bacteria.

#### What is the evidence?

In a series of carefully controlled experiments, a team of researchers found that adding reasonable doses of artificial sweeteners to drinking water caused significant glucose intolerance in mice. However, these changes were not seen in mice that drank normal sugar-sweetened water, suggesting that developing glucose intolerance may be specifically caused by artificial sweeteners. Next, the researchers cleared the mice’s gut of all bacteria, which reversed the glucose-intolerance effects in the artificial sweetener group. This step demonstrates the crucial role

Glucose intolerance is associated with obesity as well as type 2 diabetes. Strangely enough, these artificial sweeteners - though they have no sugar or calories - may disrupt the body’s ability to regulate blood sugar.

the microbiome has in glucose regulation.

Notably, the change in bacteria suggested the animal became more efficient at digestion and storage (which may be related to weight gain).

Then, the researchers transplanted feces from the artificial sweetener-fed mice into “germ-free mice” (special mice that have no gut bacteria of their own). The germ-free animals proceeded to develop glucose intolerance from the bacteria transplant, and their new gut microbiome was distinctly different from mice that were fed real sugar instead of artificial sweeteners. Notably, the bacteria involved with carbohydrate digestion and energy storage increased, while bacteria involved with moving glucose decreased, suggesting the animal became more efficient at digestion and storage (which may be related to weight gain).

### **But what about research in humans?**

Many animal studies translate poorly to humans, but a clinical trial of almost 400 people found a significant association between higher artificial sweetener consumption and markers of metabolic dysfunction like higher body weight, A1c, and glucose intolerance. Furthermore, those who consumed higher amounts of artificial sweeteners had a similar microbiome composition as did the mice that consumed artificial sweeteners, showing a consistent pattern between the research in humans and mice.

Finally, in a small trial, the researchers fed artificial sweeteners to people who did not normally consume artificial sweeteners, only to show that those individuals also developed glucose intolerance and a change in their microbiome that mirrored what happened in mice who consumed artificial sweeteners. The researchers conducted several other experiments to eliminate the potential for confounding factors (things that would provide alternative explanations for their results), which made these results particularly compelling.

These findings run counter to popular advice that sugar-free options are a good alternative for people with type 2 diabetes.

### **What does this mean for eating and drinking “sugar free” foods with artificial sweeteners?**

These findings are surprising and run counter to popular advice that sugar-free options are a good alternative for people with type 2 diabetes. These experiments were well conducted, but further work is required to confirm that food and drinks with artificial sweeteners contribute to obesity-related conditions by changing bacteria in the gut. But at this stage, this type of research is definitely cause for concern, especially given the high profile journal (Nature) where it was published.

### **So what foods should I choose?**

Overall, diaTribe believes that the best rules of thumb when it comes to choosing

foods and drinks are to choose options with as few ingredients as possible. Be wary of foods with lots of chemical-sounding ingredients that are hard to pronounce. Avoid fast food and highly processed food, and cook at home as much as possible. Eat more fruits and vegetables, aiming for at least five servings per day – see the CDC calculator for more specifics based on your individual needs. And eat in moderation!

## trial watch

Will a new implantable sleeve improve A1c and weight in type 2 diabetes?

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.

T2

### Safety and Efficacy of EndoBarrier in Subjects With Type 2 Diabetes Who Are Obese (ENDO)

ClinicalTrials.gov Identifier: NCT01728116

<http://clinicaltrials.gov/ct2/show/record/NCT01728116>

In this clinical trial, GI Dynamics is investigating whether the EndoBarrier device improves glycemic control in obese adults with type 2 diabetes. The EndoBarrier implant is a thin, flexible tube that sits inside the intestine (just below the stomach) and creates a physical barrier between food and the intestinal wall. This implant targets weight loss and improves A1c. For a short video explaining how the EndoBarrier system works, please see this link. The procedure does not require surgery and is fully reversible. For this trial, participants will be randomized into one of two groups for a 12-month trial period: the EndoBarrier implant intervention or a “sham” intervention.

The primary endpoint of the study is improvement in A1c during the implant duration. The secondary endpoint is weight loss and improvements in select cardiovascular risk factors, such as cholesterol. To participate in this study, volunteers should be between the ages of 21-65, have a BMI between 30-55, have an A1c between 7.5% and 10%, and be taking oral medications for type 2 diabetes, including metformin, sulfonylureas, DPP -4 inhibitors, and/or thiazolidinediones, but have not achieved adequate glycemic control. People interested in the ENDO Trial should visit <http://www.EndoBarrierTrial.com>, email Kelly Woessner at [kwoessner@gidynamics.com](mailto:kwoessner@gidynamics.com) or call 1-888-978-8399 for more information.

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