

Stop Counting Steps, Start Tracking Glucose

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CONTINUUM



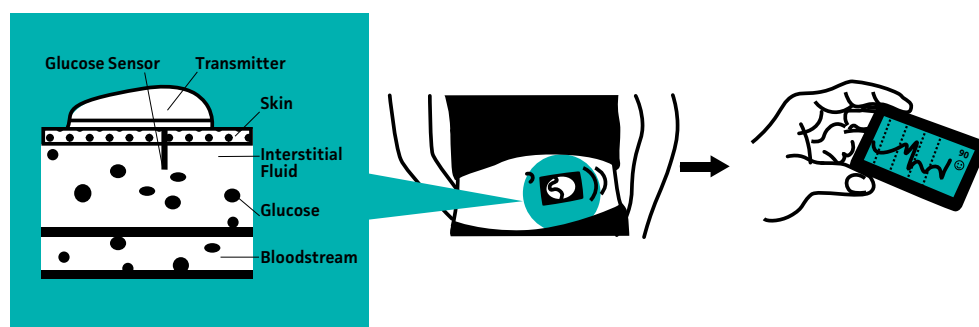
Although continuous glucose monitoring (CGM) is a technology designed and intended for people with diabetes, all of us, whether we have diabetes or not, should be using CGM to track our glucose throughout the day.

Glucose has a meaningful impact on a number of important health risks, including obesity, pre-diabetes, heart disease, and infertility, as well as mood swings.

Instead of putting more and more money towards developing a fancier glorified pedometer, as a healthcare community we should be putting resources behind enabling continuous glucose monitoring to be mainstream.

What is CGM?

A CGM system consists of a small sensor worn on the body that measures glucose in the interstitial fluid in the skin and, via a transmitter, wirelessly sends a reading to a separate display device. While most people with diabetes use a blood glucose meter to test their glucose with a fingerstick once or twice a day, CGM provides frequent readings — typically every 5 minutes, adding up to 288 automatic glucose measurements daily — and a complete picture of how glucose changes throughout the day.





Weight Management

With over **2/3 of adults in the United States classified as overweight**, it's important to understand the biology behind hunger and cravings—two factors that often derail diet and weight loss efforts.¹ Glucose management addresses these challenges in significant ways. When energy is needed, the body will burn its most available source—the glucose in the bloodstream. When one's system is overloaded with glucose, however, the excess will be stored as fat. In addition, glucose spikes can cause the body to overcompensate with an insulin surge. This can lead to subsequent glucose dips, which can leave a person hungry and craving sugar, likely derailing any well-intentioned diet and restarting the glucose roller coaster. For those seeking to maintain or lose weight, keeping glucose levels stable will ensure the body burns available glucose and, as needed, stored fat for additional energy.



Pre-Diabetes

Pre-Diabetes occurs when glucose is higher than normal, but not yet high enough to be classified as type 2 diabetes. **Its impact is huge** – it affects about 79 million people in the US, which is equivalent to the total population of 30 states.² Fortunately, pre-diabetes is a stage that is **ripe for intervention** to prevent or slow the onset of type 2 diabetes, and being aware of how food, exercise, and stress affect glucose levels is crucial for doing so.³ In pre-diabetes, cells stop processing glucose properly (insulin resistance), or the pancreas is not making enough insulin, or both. This causes glucose to build up in the blood stream. Eventually, as insulin resistance grows and the pancreas is less and less able to make enough insulin to maintain normal glucose levels, this can lead to diabetes. While the standard of care recommendations to prevent or slow the onset of diabetes are to lose weight, eat healthy while watching carbohydrate intake, and exercise regularly, understanding the interaction between these things and glucose levels can be a truly eye opening, educational experience that reinforces healthy behaviors and discourages unhealthy ones.



Heart Disease

Glucose also plays a role in maintaining heart health. **Research** has found a causal association between slightly elevated non-fasting glucose levels and an increased risk of ischemic heart disease (blockage or narrowing of the arteries that supply blood to the heart) and myocardial infarction (heart attack) in people without diabetes.⁴ The study, which included 80,522 people, demonstrated that over many years, having glucose values of only 1 mmol/L (18 mg/dL) above normal increases the risk of a heart attack by 69%.



Hormonal Health / Fertility

Another condition impacted by glucose management is **Polycystic Ovarian Syndrome (PCOS)**, which affects as many as 5 million American women and is the leading cause of infertility, due to anovulation.⁵ Though a lot is not yet understood about the mechanisms of PCOS, 50 to 70% of women with PCOS have insulin resistance, which prevents glucose from entering cells and leaves excess glucose and insulin in their blood stream.⁶ This has a twofold effect: 1) excess glucose is stored as fat, a source of estrogen production, which in excess can impair fertility, and 2) excess insulin can cause production of excess androgens, a group of hormones present in differing amounts in males and females that play a role in male traits and reproductive activity. If overproduced in women, they can lead to a host of **unpleasant symptoms**, including acne, excessive body hair, hair thinning or loss, and absence of ovulation.⁵ Thus, for women with PCOS with insulin resistance, keeping glucose levels stable can potentially preserve ovulation and fertility and minimize symptoms.



Mood Swings

Experiencing mood changes when hungry is another legitimate symptom of low blood sugar, in addition to fatigue, headache, dizziness, and shaking. A **study** involving 107 couples found an inverse correlation between blood glucose levels and anger towards one's spouse.⁷ These findings even control for relationship satisfaction and differences between women and men.

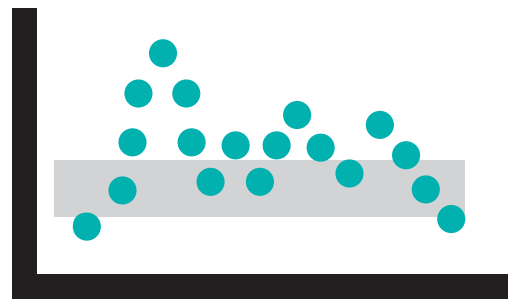
Why CGM Instead of Periodic Blood Glucose Monitoring

Glucose is constantly changing and will fluctuate depending on food intake, exercise, mood, and illness, among other factors. Taking a single reading with a blood glucose meter is only valuable for one thing: knowing what blood glucose is at that very minute. It doesn't give any insight into what happens during the other 23 hours and 59 minutes in the day, and fingersticks are often painful and inconvenient.

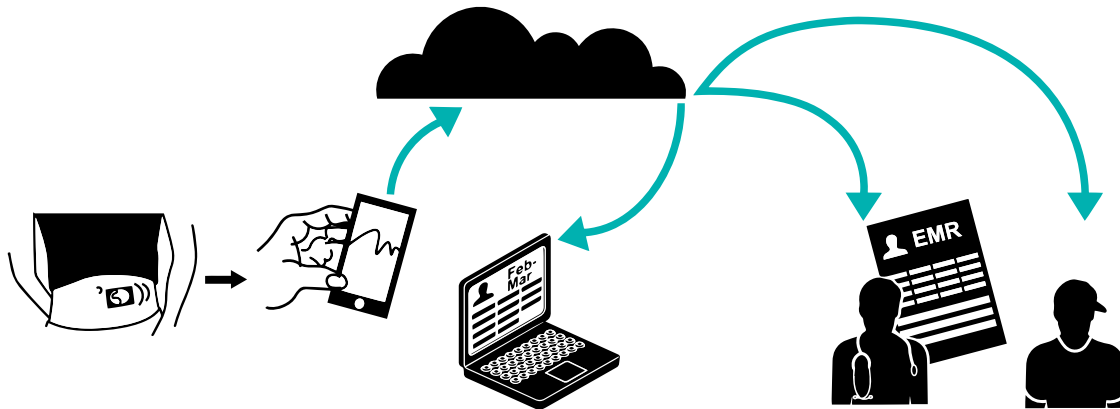
Instead, CGM gives a full glucose picture with an automatic glucose measurement sent wirelessly to a display device typically every 5 minutes, adding up to 288 daily measurements. Armed with this information one can make better choices about when and how to eat and exercise to achieve personal health goals and ward off future complications.



Blood Glucose Monitoring



Continuous Glucose Monitoring



CGM as a Digital Health Ecosystem

When the display device is a smartphone, CGM enables a whole digital health ecosystem, where the data generated can be viewed in real-time for quick adjustments, analyzed retrospectively for habit change, shared with medical professionals for additional clinical insight, and shared with significant others for support. One particularly compelling use case for sharing CGM data centers on children with diabetes, whose parents would find greater peace of mind knowing their child's glucose throughout the day when the child is in school or at night when the child is sleeping in another room or at a sleepover.

Medtronic Diabetes and Dexcom, the two leading CGM companies in the US, have already realized the value of the digital ecosystem for people with diabetes. In September 2014, Medtronic revealed its not-yet-FDA-approved **Guardian Mobile CGM System**, which uses a smartphone app as its sole display.⁸ Dexcom announced FDA approval in January 2015 for its **G4 PLATINUM System with Share**, which connects a patient's Dexcom display device to an app on the patient's iPhone for secondary display.⁹ Dexcom also announced in April 2015 that its system will support the Apple Watch for added discreetness and convenience. Both systems include data sharing via the cloud, and, presumably, both systems will be labeled only for people with diabetes with a prescription.

CGM: A Vision for the Future

CGM would streamline health monitoring by replacing many other things we are already tracking for general health and weight management, bring a bit of peace of mind to those concerned about preventing heart disease and diabetes, and de-stress those facing fertility and anger management concerns based in glucose stabilization.

However, today's CGM technology is far from ideal. Currently CGM technology is only available by prescription and is labeled (and optimized in terms of technology and usability) for people with diabetes. Sensors, which are changed roughly every week depending on the system, require a needle stick to be inserted (though the needle is removed, leaving the sensor behind), they sometimes fall off early, and they must be calibrated regularly with a blood glucose meter reading. They will also run about \$100 each if paying out of pocket, as health insurers don't currently cover CGM for people without diabetes. Furthermore, manufacturing sensors at large volumes is extremely difficult, and much of the process today is done manually. It is likely that innovation would be required in this area to scale up for use by people without diabetes.

Three companies, however, have taken steps towards making CGM technology more accessible for people without diabetes.

In September 2014, Abbott Diabetes Care announced it had received CE Mark for the **FreeStyle Libre Flash Glucose Monitoring System**, which it since launched into several European countries.¹⁰ The Flash is not technically continuous glucose monitoring since it provides on-demand glucose readings via an RFID scanning device. However, it uses a 14-day, calibration-free sensor and is available without a prescription, meaning it's relatively more accessible to people without diabetes (though all of Abbott's marketing materials direct the product to people with diabetes).

Other companies have been more direct about their vision for CGM for people without diabetes.

Founded by former Dexcom scientists and engineers, **Glucovation** is developing their SugarSenz CGM technology for both the consumer and medical markets.¹¹ For the consumer market they are promising the Holy Grail – low cost, calibration-free, prescription-free, and accurate enough to influence fitness, diet, and diabetes prevention.

Echo Therapeutics is also striving to make CGM mainstream.¹² Originally focused on glucose monitoring in the ICU, Echo recently overhauled its management team and pivoted its strategy to concentrate on people without diabetes. The key is Echo's noninvasive technology, which not only enhances the usability of CGM, but also presents lower risk in the eyes of regulators relative to sensors that are inserted in the skin. Furthermore, Echo recently announced its intention for its technology to be classified as a low-risk general wellness product, per the **FDA's recent guidance**, and communicate with Bluetooth-enabled consumer devices, such as a Fitbit or Apple Watch.¹³

For both Glucovation and Echo Therapeutics, it remains to be seen whether they will be able to achieve their ambitious technology and usability goals, especially amidst meaningful distractions like Dexcom's trade secrets lawsuit against Glucovation and Echo's recent management changes, but this is the direction all CGM companies and investors should be going.

With a physiological measurement as impactful as glucose, as a healthcare community we should be focusing more on how to make this technology mainstream.

Funding CGM R&D, expanding the focus on user experience beyond diabetes, and studying the economic and social impact of glucose monitoring on healthcare costs are important steps towards making CGM accessible for everyone.



Citations & Links

- (1) <http://frac.org/initiatives/hunger-and-obesity/obesity-in-the-us/>
- (2) http://articles.chicagotribune.com/2012-10-31/health/sc-health-1031-diabetes-insulin-20121031_1_insulin-blood-sugar-diabetes-educator
- (3) <http://continuuminnovation.com/healthcare-for-the-emerging-middle-class/>
- (4) <http://content.onlinejacc.org/article.aspx?articleid=1208652>
- (5) <http://www.womenshealth.gov/publications/our-publications/fact-sheet/polycystic-ovary-syndrome.html>
- (6) <http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/womens-health/polycystic-ovary-syndrome/Default.htm>
- (7) www.pnas.org/content/111/17/6254.full.pdf+html?sid=103ae41b-fb90-4317-b424-c1336fc9b1f8
- (8) <http://www.health2con.com/tv/medtronic-diabetes-consumer-tech-and-wearables-powering-healthy-lifestyles/>
- (9) <http://www.dexcom.com/dexcom-g4-platinum-share>
- (10) <http://diatribe.org/abbott-freestyle-libre-transforming-glucose-monitoring-through-utter-simplicity-fingersticks>
- (11) <http://www.glucovation.com/>
- (12) <http://www.echotx.com/>
- (13) <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf>



Samantha Katz is the Digital Health Lead and a Senior Strategist at Continuum, a global innovation design consultancy. Continuum partners with clients to discover powerful ideas and realize them as products, services, and brand experiences that improve lives and grow businesses. Sam previously held marketing and product development roles focused on insulin pumps and CGM systems at Medtronic Diabetes. She would use CGM technology regularly if it were covered for people without diabetes.